The Patent Lawyer

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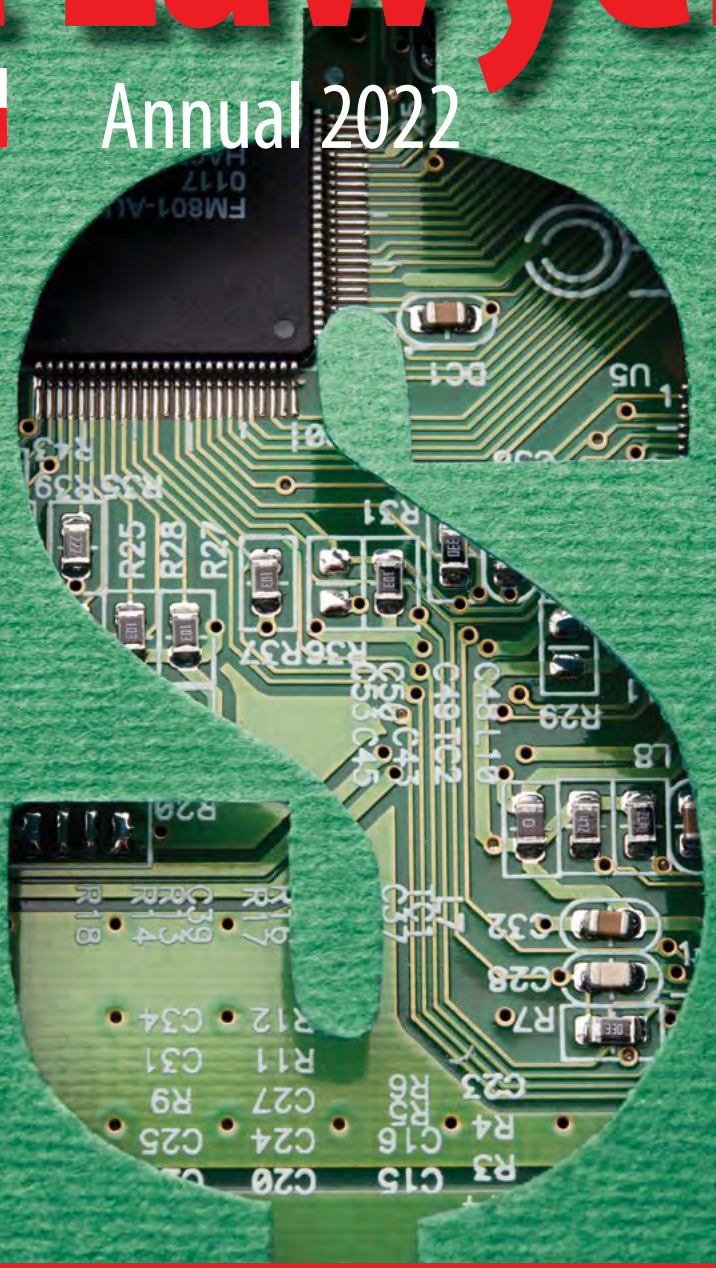
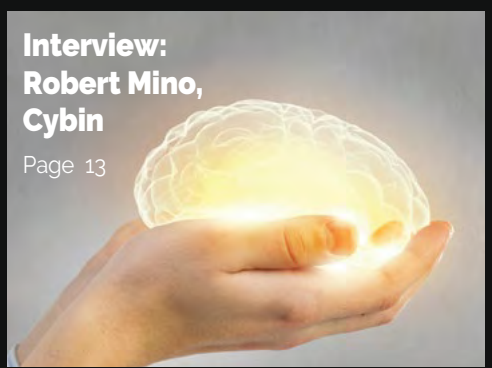
Annual 2022

Keeping up with Fintech: patent filing strategy



Launch interactive document

Hui Li, Partner at Beijing Sanyou IP Agency Ltd., provides an informative update on the developments of Fintech and provides guidance for developing a successful strategy for patenting in this field.



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CTC Legal Media

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Issue 57

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CTC Legal Media

Editor's welcome

Welcome to *The Patent Lawyer Annual 2022*. The past year has seen many developments that effect the field of patent law, with Fintech being one focus point. Our cover story this issue, brought to us by Beijing Sanyou IP Agency Ltd., will bring you up to speed with advice on patent filing strategy for Fintech.

A further hot topic is the developments in patenting AI: this issue includes articles on IP challenges with a proposed way forward, patent protection in India, and a look at whether innovation has outpaced the patent system.

Our guest interview this issue is with GC and IP Counsel Robert Mino of Cybin, a pharmaceutical company with a mental health focus. We discussed strategy, IP protection, clinical trials, and more.

> **"Will bring you up to speed with advice on patent filing strategy for Fintech."**

Also in this issue: an update on SEP's in China; an evaluation of Eurasian industrial designs; Patent Term Adjustment in Mexico; updates from Brazil; intellectual wealth in Russia; an update on the Polish Patent Office; and more!

We would like to thank this issue's *Women in IP Leadership* sponsor Vera Abogados Asociados which facilitates the continuation of this opportunity.

Plus, Chapter 4: DEI in Law – of our Diversity, Equity and Inclusion series.

Contact us now to plan your features for 2022.

We hope you enjoy the issue with best wishes for the new year ahead.

Faye Waterford, Editor

Mission statement

The Patent Lawyer educates and informs professionals working in the industry by disseminating and expanding knowledge globally. It features articles written by people at the top of their fields of expertise, which contain not just the facts but analysis and opinion. Important judgments are examined in case studies and topical issues are reviewed in longer feature articles. All of this and the top news stories are brought to your desk via the printed magazine or the website *www.patentlawyermagazine.com*

November / December 2021

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The Patent Lawyer **would like to thank the Editorial Board for their time and support.**

Keeping up with Fintech: patent filing strategy

Hui Li, Partner at Beijing Sanyou IP Agency Ltd., provides an informative update on the developments of Fintech and provides guidance for developing a successful strategy for patenting in this field.

Patent filing strategy for financial technology, or Fintech, has drawn ever-increasing attention in China. Fintech is a term referring to the application of technology to improve economic activities. It has been used to automate investments, insurance, trading, banking services, and risk management. Relevant innovations involve various technologies, including artificial intelligence, big data, robotic process automation, block chain, etc. Although the Fintech concept has been around for more than 20 years, its patenting strategy has become more critical in recent years due to patent and business policy changes.

Hui Li

For quite a long time, financial companies generally did not attach great importance to patent filing strategy because it was quite tricky for Fintech inventions to overcome the patent eligibility hurdle. In 2002, Citibank had filed around 20 patent applications with the Chinese Patent Office, and it made big news among patent practitioners because financial companies usually filed very few patent applications back then. Even the central bank sent an official notification to all the state-owned banks, urging them to analyze the Citibank patent portfolio and if necessary to follow suit. But at the end of the day, and not surprisingly, just a couple of those Citibank applications ended up patent-granted, reflecting the challenging environment for Fintech applications.

As with other developing industries, patenting regulations have been evolving over time. Given the rapid development of new business forms like e-commerce integrating the internet, AI, and big data, it is undeniable that Fintech innovations made contributions to society comparable to those in the high-tech sectors. Accordingly, the government gradually changed its patentability regulations, which became more amicable to business methods and computer software inventions at large.

In particular, the revised patent examination guideline in 2019 and its proposed revision in 2021 substantially relieve the threshold for patent eligibility. Business method-related inventions, including Fintech, have a much better chance to be patentable, even without a substantial advancement in the traditional technical aspect. Some interesting examples of eligible subjects include an analysis method for coupon usage preference and a dating partner recommendation method. It is surprising to see that a method for recommending a girlfriend/boyfriend is a patent-eligible subject. Nevertheless, that is a patent freshly granted to Tencent just a couple of months ago.

> **Although the Fintech concept has been around for more than 20 years, its patenting strategy has become more critical in recent years due to patent and business policy changes.**

Another notable change concerning Fintech is the overall open-up policy for the financial industry. China has achieved significant progress in opening up the financial sector in recent years. This includes further opening the banking, securities, and insurance industries, easing market access, and improving foreign investment law. Up to now, more than 100 foreign-invested banks and securities, insurance, and payment institutions have been approved.

With all those legal and industrial changes in the financial sector, the patent filing landscape has shown similar progress. For example, we did a patent landscape analysis for Chinese patent applications in the field of AI plus finance filed by Chinese companies. The statistics show that with a total of about 2100 patent applications, there were just dozens of applications before 2016. Then it has grown rapidly. The application number in 2018 was 375 and over seven times that of 2017, and the number in 2020 was 735 and nearly twice that of 2018. The majority of the applications are filed by large domestic financial institutions, such as banks and insurance companies.

In terms of the leading technical fields involved for these patent applications, machine learning and neural network accounted for the largest proportion, mainly used in risk pre-warning, insurance, and claim settlement. What ranked second is computer vision and biometrics mainly used in identity authentication, mobile terminal payment, and fraud identification. Voice recognition and natural language processing mainly used in insurance claim settlement, voice prompt, and telephone banking ranked third. What ranked fourth is knowledge graph mainly used in risk prevention and control, asset management, and product recommendation scenarios, while intelligent robot mainly used in the customer service scenario of intelligent banks has the least applications.

The landscape shows that some companies adopt a quite aggressive patent filing approach for Fintech innovations. Now the question is, how can companies doing business in the financial sector adapt their patent filing strategy to the ever-changing environment?

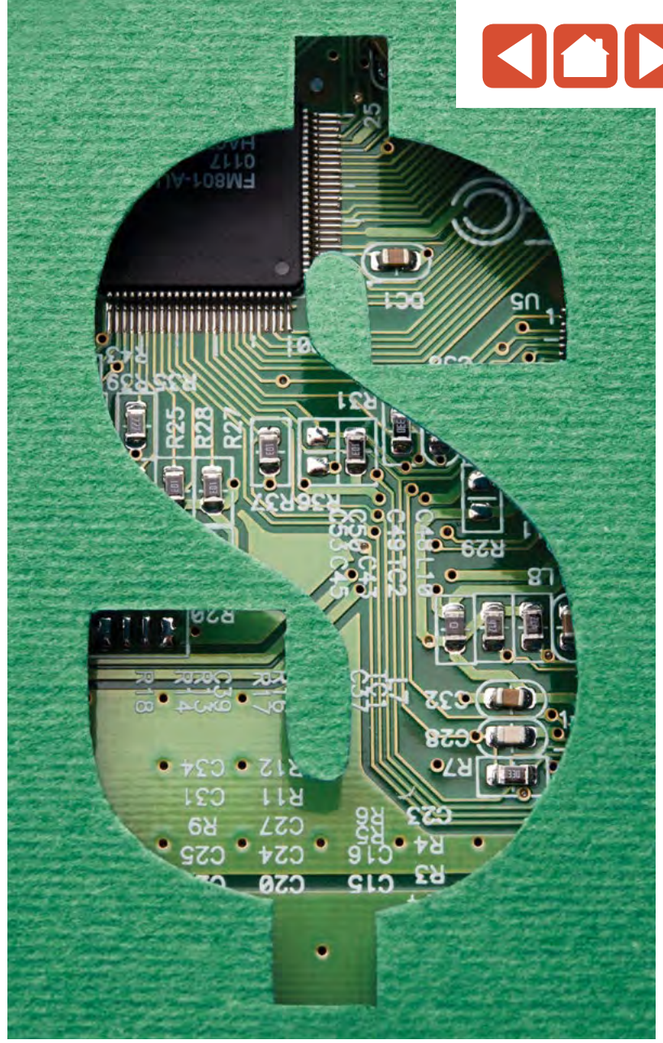
There are many factors to consider when developing a filing strategy, and the outcome will be dependent upon the individual company's requirements and other external factors. Some factors include the patent landscape, the standard-essential patent, the supply chain, and the business value.

In defining a company's patent filing strategy, it is necessary to consider the overall patent landscape to understand the opportunities and risks. A patent landscape can provide an overview of a particular technology area in terms of patent ownership and patent coverage. This can assist companies in determining technology growth and gaps for the direction of further R&D.

As just introduced in the filing statistics, a substantial part of AI related Fintech applications is in the direction of risk pre-warning, insurance, and claim settlement. It may make sense to patent even incremental improvements in this area in case of future cross-licensing situations. In addition, although intelligent robot used in the customer service scenario of intelligent banks has the least applications, it could turn out to be a valuable investment for R&D and patent filing given the transition to a less labor-intensive world.

Standard Essential Patents are vital for the wide adoption of new technologies in the relevant industry. With the development of less restrictive patentability rules and the filing of more patent applications for Fintech innovations, patent standardization should also play an important role in patent strategy. On June 8, 2021, the State Banking Association issued the very first group standard in the financial industry in China for a Fintech patent by the Agriculture Bank of China. The bank also signed a FRAND declaration agreeing to license the patent for free to all the members of the Association.

This very first SEP in the financial sector in China is a reminder for financial companies to



> **The bank also signed a FRAND declaration agreeing to license the patent for free to all the members of the Association.**

Résumé

Hui Li, chairman of board, partner and a senior patent attorney at Beijing Sanyou IP Agency Ltd.

Hui received a master degree in intellectual property from UNH School of Law, Franklin Pierce Law Center and a master degree in thermal engineering from Beijing Institute of Technology.

His practice includes patent prosecution, invalidation, reexamination, administrative and infringement litigation, and patent search in the field of telecommunication, electronics, semi-conductor, and computer systems, etc. With over 20 years' experience in patent drafting and prosecution, he is capable of handling sophisticated patent cases and is skilled in solving difficult problems for clients. He also advised and lectured extensively on patent portfolio management, patent prosecution strategy, and patent validity evaluation.

consider and incorporate SEP practice into their patent strategy. For financial services with high similarity and easily standardization nature, SEP will help to foster a bigger market and gain competitive advantages.

It is also essential to look at the supply chain when deploying a patent filing strategy. By identifying your customers, suppliers, and competitors, patent deployment will be more business-oriented and efficient. Nowadays, the financial industry has many new players from other sectors. To name just a few, we have Alibaba from e-commerce, Tencent from social media and personal entertainment, Meituan from on-demand food delivery, Didi from mobility service, and Xiaomi from mobile communication. All of them have set foot into financial services, including investment, credit loan, insurance, and others. For traditional financial entities like banks and insurance companies, these newcomers usually have a mixed role of a customer, a supplier, a partner, and a competitor.

In such a cross-industry business environment, financial companies need to closely evaluate the cooperation with these newcomers, properly invest resources, and deploy patent filings in both traditional and extended areas.

For example, in cooperation with an e-commerce company, a bank provides settlement support to online shopping and, in return, has easy access to a massive pool of potential customers. The bank may try to design and patent the settlement solution, which the bank may leverage to have a better position in cooperation with the e-commerce company and also restrict the company's collaboration with other banks.

Another important factor in patent strategy is determining where patenting innovations will bring great value to the company. For instance, innovations have the greatest value when the business models are platform-based and data-intensive, because such business models have easily extendable service scale and lower marginal cost. In doing so, financial companies will need to choose where they will specialize and where they will rely on external partners.

In particular, for the insurance industry, an online insurance platform as the primary sales channel will add tremendous value to the company. With such a platform plus other advanced technologies such as AI, IoT, and 5G, it is possible to achieve substantially faster, more accurate, more transparent, and more cost-effective insurance service, partly because IoT devices will enable insurers to easily collect data and personalize insurance. Accordingly, it is advisable for financial companies to partner with AI algorithm providers, wireless operators, data providers, and wearable device manufacturers to make innovations and file patents.

All of the above examples of diversified factors are necessary for consideration in patent filing strategy. Companies doing business in the financial industry have to adapt to the fast-changing IP, technological, and business environment and do comprehensive patent planning. Otherwise, they may get left behind in the Fintech patenting world.

> **"Otherwise, they may get left behind in the Fintech patenting world."**

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An interview with Cybin's General Counsel and IP Counsel, Robert Mino

Robert Mino sits down with *The Patent Lawyer* to discuss the rapidly growing pharmaceutical company that is Cybin, and the work that they are doing in the mental health space that they hope will profoundly better the human condition.

Tell us about Cybin and your role in the company?

I serve as Cybin's general counsel and IP counsel. Cybin is an excellent, early-stage, rapidly growing pharmaceutical company focused on mental health.

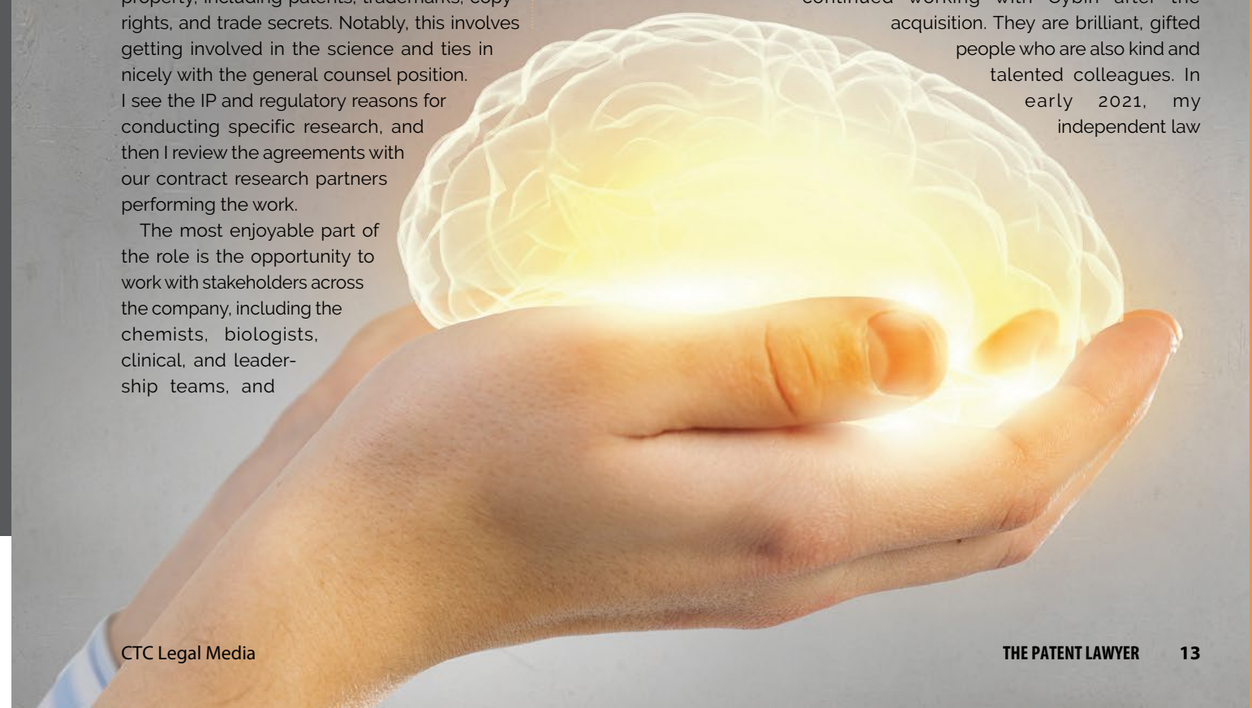
As general counsel, I work across a range of legal matters for the company, from contracts, employment agreements, MSAs, SOWs, press releases, and provide legal guidance on corporate, human resources, pharmaceutical regulatory, and other areas of law. As IP counsel, I additionally manage the company's intellectual property, including patents, trademarks, copyrights, and trade secrets. Notably, this involves getting involved in the science and ties in nicely with the general counsel position. I see the IP and regulatory reasons for conducting specific research, and then I review the agreements with our contract research partners performing the work.

The most enjoyable part of the role is the opportunity to work with stakeholders across the company, including the chemists, biologists, clinical, and leadership teams, and learning from these very talented individuals.

There are many ways to describe Cybin because we're an innovative decade-defining pharmaceutical company in the mental health sector. Cybin is an innovation engine.

How long have you been working at Cybin, and what attracted you to the role?

Startup Adelia Therapeutics became my client in November of 2020, and Adelia joined the Cybin family in December of 2020. I enjoy working with the Adelia founders, who all continued working with Cybin after the acquisition. They are brilliant, gifted people who are also kind and talented colleagues. In early 2021, my independent law



CYBIN'S GENERAL COUNSEL: ROBERT MINO

> One of the challenges in psychedelics is that these compounds can have a delayed onset of action.

Robert Mino

practice was bustling. Although I was not seeking to join a company, I received several unsolicited offers simultaneously, Cybin included.

In March 2021, I was driving home from a job interview for a general counsel and COO position with a gene therapy company, with a verbal offer in hand, when I pulled off the road to speak with Cybin's Chief Legal Officer about an opportunity with Cybin. Considering I already worked with Adelia and Cybin for a few months, I already knew that the leadership team are great people to work with, including the CLO to whom I would report. Having had the rare opportunity as outside counsel to truly see Cybin's distinctive company culture first-hand, the chance the company presented quickly moved to the top of my list. I joined full-time in April as Deputy General Counsel and IP Counsel before being promoted to General Counsel in October.

What is Cybin's Three pillars strategy?

Cybin focuses on the three pillars strategy of:

1. Our novel drug development platform,
2. Our proprietary delivery formulation approaches, and
3. Our novel treatment regimen is improving patient outcomes.

Cybin creates active pharmaceutical ingredients and new chemical entities by modifying them to become more commercially viable. One of the challenges in psychedelics is that these compounds can have a delayed onset of action. This delay can make pairing a therapy session with bioavailability challenging. For example, a therapist works with a patient through a clinical counseling session to reach the window of time when the drug therapy is most effective. However, each patient varies on how quickly they will respond to therapy. The time in which a drug is administered may not be uniform from the time therapy begins. Some psychedelic compounds take up to an hour and a half to reach efficacious bioavailability and require clinical supervision for several hours after administration. Timing those compounds with a therapy session in real-time can be tricky.

Cybin leverages our three-pillar strategy to address the variability in the process. As a result, the company hopes to create therapeutics with a faster onset of action, decreased side effects through more targeted dosing windows, and condense the in-clinic time to something that can be accomplished within a standard workday. Those factors are important because they're making psychedelics more usable and more likely to be viable therapies for those in need.

How do you capture and protect IP at Cybin?

As an in-house attorney, I participate in our research, development, pre-clinical, and clinical team meetings to understand how our programs are progressing. I also draft or review the agreements emanating from these teams, so I have a front-row seat to our goals and data generation supporting those goals. From this vantage point, I collect innovative new ideas, additional new data, and creative works to bolster our IP position. As an innovation-focused company, we schedule our research to support the development of sustainable intellectual property. I spend as much of my time thinking about copyrights and trade secrets as I do patents, maybe even more time, as these forms of IP pervade every contract, discussion, or disclosure we have as an organization.

How do you think patents affect clinical trials? Does Cybin have any relatable experiences?

The interplay of patents and clinical trials is a tricky balance. In many jurisdictions, previous public use of an invention is a bar to patentability. Clinical trials are conducted under confidentiality to decrease the likelihood of the public disclosure of the data, but that doesn't always happen, and sometimes data leaks out.

Companies usually file patents before starting clinical trials to capture the inventive concept of what they believe will happen in a trial. Still, science is science, so we often don't know the clinical trial outcome until we've done this study! Completion of the study is generally needed to generate an entire picture of the trial data. However, patent challengers often argue that the reduction of practice occurred earlier than the completion of the clinical trial; the trial was a public use and, therefore, bar its patentability. Consequently, it is a delicate balance that is often litigated.

There are a few areas where the in-house attorney can decrease risk. Firstly, Academic clinical sites always want the right to publish data. Ensuring they don't have the right to publish before the company is ready or has completed the entire study is one of the most critical yet over-looked issues in a clinical trial site agreement.

Secondly, regulatory affairs consultants often push a narrative that certain aspects of a trial are not novel to provide comfort to the regulatory agency to allow the trial, which makes perfect sense. Still, the in-house attorney needs to ensure that the discussions harmonize with the assertions made in the patent filings.

Finally, the in-house attorney needs to keep on top of any opening of the study data and evaluate if the data has patentably probative value, either in support of current thinking or unexpected results.

Can you tell us about Cybin's Research Phase programs?

We have four active drug programs targeting major depressive disorder, alcohol use disorder, anxiety disorders, and therapy-resistant psychiatric disorders. They are CYB001, CYB003, CYB0004, and CYB005.

Cybin psychedelic molecules are the foundation for our active drug programs. The use of psychedelic drugs to treat major depressive disorders is under research and development. We aim to collect clinical trial data supporting our lead drug candidates in the United States, Canada, and Europe. We have developed more than 50 proprietary psychedelic molecules in-house designed to meet critical criteria: efficacy, safety, scalability, stability, appropriate duration, and other clinically relevant features. We have an amazingly talented group internally; I work closely with our CSO, CRDO, CIO, CCO, COO, and their teams and have a ton of respect for them. I will be the first to admit that our scientific leadership has forgotten more about this space than I'll ever even learn, which has made it a true blessing to work with, and learn from, these brilliant individuals.

You've recently filed for your 15th patent and two additional international patents. Can you tell us about these filings? Why International?

We've filed more than 15 and two at this point but allow me to describe our portfolio. Cybin focuses on creating helpful psychedelic therapeutics by altering their structures to optimize duration, efficacy, and getting them into patients to take effect. One way we've sought to accomplish this is through a process called deuteration, meaning our scientists replace a hydrogen molecule located on the psychedelic with a heavier version of the hydrogen. Deuterium forms a stronger bond with carbon. Subsequently, the bond is slightly more problematic for an enzyme to break down, which benefits non-deuterated molecules.

We file internationally because mental health disorders do not have any geographical borders.

As a young company, what challenges has Cybin faced?

Rapid growth, which is challenging but promising! Cybin has raised more than $120 million Canadian dollars. The company uses these resources to + development, and make essential acquisitions, like Adelia Therapeutics.

We started with about 12 employees at the beginning of the year across the two companies, and now we have approximately 60 employees in multiple countries. Rapid expansion can be stressful, primarily from operating virtually. During the pandemic, we managed to add very talented individuals to our team, which has enabled us to build a solid foundation.

Speaking of challenges, Cybin recognizes the enormous ones in the mental health sector and the families affected by them. There are millions of people affected by these terrible disorders – according to the WHO, nine billion people worldwide – and we hope to help them.

What do you think is Cybin's most outstanding achievement to date?

In my opinion, Cybin's most outstanding achievement is putting together such a fantastic company culture during such a trying time. We truly have the most positively uplifting company culture I've ever encountered. People are collaborative and always assume our teammates have the best intentions. We have such a polite, cooperative environment. Being a drafter of employment agreements, I've witnessed the very talented new hires we are bringing into our family. Adding amazing people to a wonderful culture is a recipe for enormous potential. The sky's the limit.

What are Cybin's hopes for the future?

Cybin's hope for the future is to bring therapeutics to the market that will positively impact the global mental health space. We hope to profoundly better the human condition.

> The interplay of patents and clinical trials is a tricky balance.

Résumé

Mr. Robert Mino is a registered US patent attorney licensed to practice law in Florida, the District of Columbia, and Massachusetts. He holds JD, MBA, and MS (pharmacology and genetics) degrees from the University of Florida, a BS in Genetics from the University of Georgia, a Certificate in regulatory affairs for pharmaceutical and medical devices from RAPS , and a Certificate in Copyright Law from Harvard Law.

Robert is ideally suited as a general counsel at a growing pharmaceutical company. An admitted generalist, Robert has served in roles beyond legal, including business development, general manager, sales, marketing, and entrepreneur. As a patent attorney, Mino is a rarity. He has won a president's club sales award at a Fortune 1000 company, created a bench-level cGMP quality system, responded to FDA inspections, given hundreds of presentations, and held responsibility for a $500M international product line. As a leadership team member, Robert finds his diverse experience invaluable working with stakeholders across the organization.

[1] https://www.raps.org/

Artificial intelligence: IP challenges and proposed way forward

Marta Duque Lizarralde, LL.M, TUM, and Dr Claudia Tapia, LL.M, 4iP Council, examine the recent developments in AI and their impact on the industry.

I. Introduction

From the technical point of view, it is nowadays possible to produce 'patentable inventions' with AI. For example, by exploring and mixing large and complex bodies of data of technical compounds, AI can create new technical compounds which treat a certain disease. On the downside, these AI 'tools' focus on a very specific field and still demand significant human intervention. In other words, we are far from the so-called "artificial general intelligence", where the AI system is so independent that it requires very little to no human supervision to create inventions in several different technical fields. From the legal perspective, AI faces several unsolved issues, some of which will be analysed in the following section.

Marta Duque Lizarralde

Dr Claudia Tapia

II. Legal challenges related to AI

a. Inventorship claims

Some believe AI systems complete the entire inventive and patenting process autonomously, thus deserving to be acknowledged as the inventor. They support this view with the fact that the most sophisticated AI systems are generating inventions and that AI is already being used to draft patent applications.[1] Others strongly disagree with that position.[2]

The heated debate became even more popular when, in 2019, Dr Thaler filed two patent applications designating an AI system named DABUS as the inventor in several offices worldwide, which were rejected by several of them (the UKIPO, the EPO, and the USPTO). Their main argument (later on affirmed by the UK High Court[3], the UK Court of Appeals,[4] and the US District Court for the Eastern District of Virginia[5]) was that, in the respective patent statutes, the inventor is addressed with pronouns that are only used for natural persons, such as "him" and "her". Therefore, interpreting the term inventor so broadly as to include an AI system would go against the principle of plain reading. In addition, the offices pointed out, DABUS lacks legal personality and, consequently, the capacity to own IP rights and to transfer them to Dr Thaler.

In contrast, the South Africa patent office issued in July 2021 a patent listing DABUS as the inventor, and the Federal Court of Australia ruled that AI systems can be recognised as inventors under the Australian Patent Act.[6] Thus, the debate is far from being over.

A common mistake within the inventorship discussion is to confuse automation with autonomy. The use of AI in the inventive process allows to automate the performance of different tasks. However, the conception of "invention" remains attributable to the natural persons employing it.[7] Yet, identifying the inventor of "AI-assisted works", which WIPO defines as works "generated with material human intervention and/or direction",[8] can on some occasions be challenging. This is because the degree and number of contributions from different actors vary depending on the project and the application of the AI technology for that particular case.

b. Authorship

For a work to be eligible for copyright protection, it must be original. A work is considered original if it is "the author's own intellectual creation" manifested by their "free and creative choices".[9] On the other hand, even if not explicitly stated, it could follow from the provisions of the Berne Convention and the EU copyright directives that the author must be a natural person.[10]

A distinction must be made here between the above-mentioned "AI-assisted works" that would be protectable if they met the originality requirement, and "AI-generated works", defined by WIPO as those created by "AI without human intervention".[11]

Many of the results that are referred to as "AI-generated", including "the next Rembrandt", are actually AI-assisted, because human involvement in the different phases that predetermine the outcome is still decisive. Since AI systems are not capable yet of generating results autonomously, the definitions adopted by WIPO do not reflect the state of the current debate. A more accurate term for this type of existing creations is that of "Authorless AI-assisted work ", adopted in the 'Trends and Developments' in the AI report.[12] Examples of this type of works would be the initial translations performed by DeepL, some reports generated in the field of automated journalism, or texts created with sophisticated language models, such as GPT-3. These results, created using advanced training methods, are still tied to pre-existing data and parameters provided by the AI developers. Thus, the space for the creative freedom needed to meet the originality requirement is too limited.

It is also debatable whether authorless creations could be protected by certain related rights, such as the rights of phonogram and film producers, broadcasting organisations, publishers of press publications, and non-original photographs, since they do not require originality or human authorship; or whether a legislative reform would be needed, since their ownership is still conceived only for humans. There has furthermore been some discussion on the desirability of creating a new sui generis right.[13]

Résumés

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> **A common mistake within the inventorship discussion is to confuse automation with autonomy.**

1 The World Economic Forum (WEF), 'Artificial Intelligence Collides with Patent Law' (2018) <http://www3.weforum.org/docs/WEF_48540_WP_End_of_Innovation_Protecting_Patent_Law.pdf>

2 Daria Kim 'AI-Generated Inventions': Time to Get the Record Straight?', *GRUR International 69 (5)* 443,456.

3 *Thaler v Comptroller General of Patents Trade Marks and Designs* [2020] EWHC 2412 (Pat).

4 *Thaler v Comptroller General of Patents Trade Marks and Designs* [2021] EWCA Civ 1374.

5 *Stephen Thaler v. Andrew Hirshfeld, Performing the Functions & Duties of the Under Sec'y of Com. for Intell. Prop. & Dir. of the United States Pat. & Trademark Off., et al.,* No. 1:20-cv-903 (LMB/TCB), 2021 WL 3934803 (E.D. Va. Sept. 2, 2021).

6 *Thaler v Commissioner of Patents* [2021] FCA 879 (30 Jul 2021).

7 Noam Shemtov, 'A Study on Inventorship in Inventions Involving AI Activity' (2019) <http://documents.epo.org/projects/babylon/eponet.nsf/0/3918F57B010A3540C125841900280653/$File/Concept_of_Inventorship_in_Inventions_involving_AI_Activity_en.pdf>:

8 WIPO, 'Revised Issues Paper on Intellectual Property Policy and Artificial Intelligence' (21 May 2020) <https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_ai_2_ge_20/wipo_ip_ai_2_ge_20_1_rev.pdf>

9 Among others, C-145/10, *Painer v. Standard VerlagsGmBH and Others (2011) ECLI:EU:C:2011:798, para 119,120; C-604/10, Football Dataco Ltd and Others v. Yahoo! UK Ltd and Others (2012) ECLI:EU:C:2012:115, para 37,39; C-403/08 and C-429/08, Football Association Premier League v. QC Leisure* and *Karen Murphy v. Media Protection Services* (2011) ECLI:EU:C:2011:631, para 97; C-310/17, Levola Hengelo (2018) ECLI: EU: C: 2018:899, para 35,36.

10 For example, Art. 7.1 Berne Convention states that *"The term of protection granted by this Convention shall be the life of the author and fifty years after his death"*. In the Community framework, Art. 1 Directive 2009/24/EC89, Art.6 Directive 2006/11690, and Art.3 Directive 2006/1169/EC state that for a creation to be protectable by copyright, it must be original in the sense of constituting *"the author's own intellectual creations"*.

11 WIPO (n.9)

12 Bernt Hugenholtz et al. 'Trends and Developments in Artificial Intelligence, Challenges to the Intellectual Property Rights Framework, Final Report' (2020) <https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=71915>

13 For instance, Ana Ramalho, 'Will robots rule the (artistic) world? A proposed model for the legal status of creations by artificial intelligence systems' (2017) *21 Journal of Internet Law*, 12,25; proposes "a disseminator's right, bearing a similar regime to the publisher's right in the publication of previously unpublished works as prescribed by the EU Term of Protection Directive.

The latter is supported by part of the academic community, which rejects the idea of any kind of AI-generated works falling into the public domain. Some argue, however, that it may not even be necessary considering the available tools, such as trade secrets, factual control, and unfair competition, to protect the results of creative AI systems.[14]

c. Liability

Another question that is keeping stakeholders busy is the one of liability, in particular considering scenarios where the AI engineer will have limited to no influence on the behaviour of the AI system. In particular it might be problematic if an AI engineer generates a method and different companies apply it for different use cases. The AI engineer cannot know where it will be applied and what the use case may imply. Moreover, with global interconnectivity, it will become increasingly difficult to identify who among the many actors had caused certain damage and, if several of them were responsible, to which degree each of them.

d. IP protection of AI features: Copyright, patents, and trade secrets

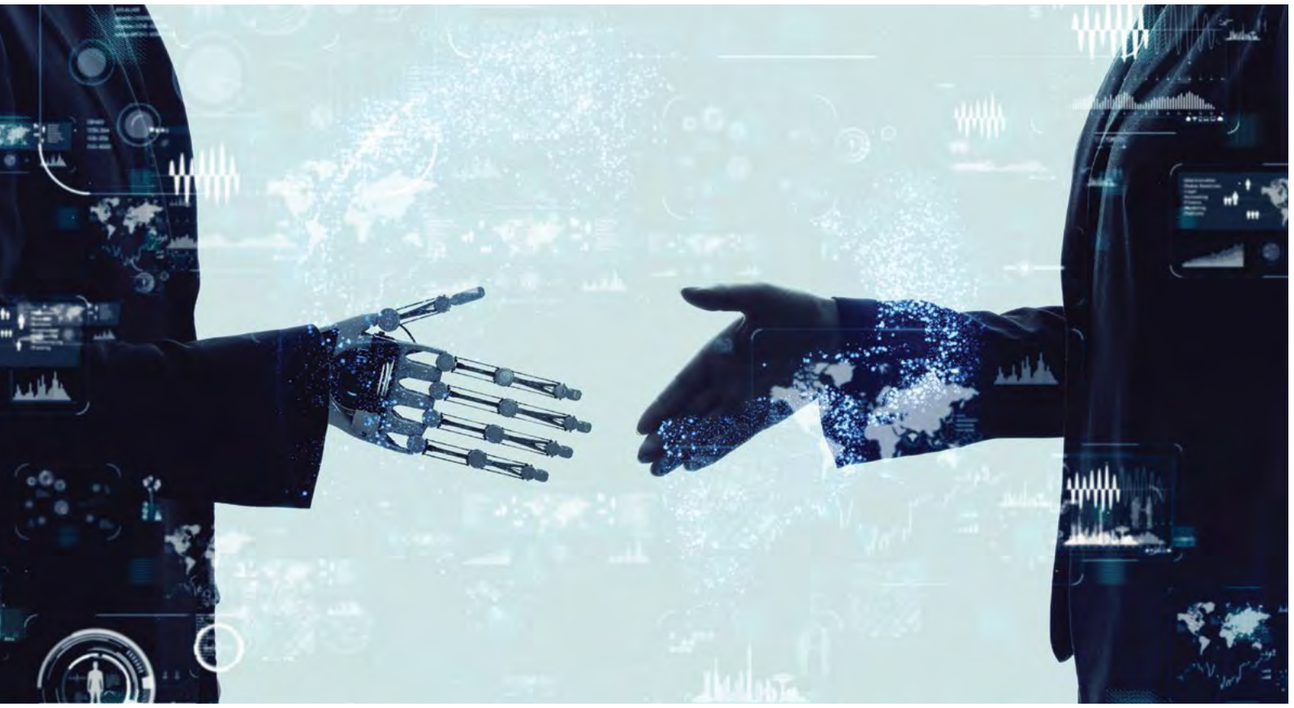
Companies wishing to benefit from their own investments in AI are wise to adopt an efficient IP strategy to protect the different elements of AI systems. A starting point of such strategy should consist in identifying the AI features that are protectable by IP rights.

> **The definitions adopted by WIPO do not reflect the state of the current debate.**

AI systems are formed by algorithms, which by themselves are not copyrightable. Nevertheless, they are encoded in a programming language and incorporated into software that is protectable by copyright. However, copyright does not protect the program's underlying ideas and principles but rather the way in which they are expressed. Consequently, the functional aspects of the software are not covered by copyright.s[15] Against this background, there is an active debate on whether Machine Learning models can qualify as learning algorithms, AI software or super-software. Some argue that they do not meet the originality requirement[16]; others that complex, dynamic Machine Learning models might be protected by the *sui generis* database right.[17] Further research is needed on this issue.

The algorithms, weights, models, and evaluation mechanisms that compose an AI system are of an abstract mathematical nature. Therefore the European Patent Office typically excludes them from patentability when claimed as such. Nevertheless, these features applied in an invention with a technical character can be protected as elements of the invention.

Finally, there are other elements that, when not protectable by copyright and patents, or holders are not willing to disclosed them, are protectable by trade secrets. But are trade secrets the best option considering our need for maximal diffusion and further collaboration to develop AI?



e. IP rights embedded in the training datasets

One important legal barrier for data sharing is the uncertainty about which IP rights are embedded in the training datasets. Training datasets often include data that is publicly accessible and freely available on websites. While raw data is not protected by IP rights, other data, such as images or sounds, can be protected by copyright or related rights. Consequently, if the latter data are not covered under the Text and Data Mining exceptions of the Directive on copyright and related rights in the Digital Single Market,[18] a license will be needed for their use. It is also unclear whether the training datasets can be protected by copyright and the sui generis database right. Thus, there is a risk that companies choose to restrict access to raw data and datasets by means of factual control.[19]

In practice, triggering business-to-business (B2B) data sharing is resulting in a very challenging process, among other reported reasons, because of the lack of confidence among economic operators that the data will be used in accordance with the contractual agreements, or the fear of losing a competitive advantage.[20]

f. Competition law

In this situation, it must be evaluated if competition law could be used to correct imbalances. Yet, companies cannot be forced to license their datasets merely because they have a competitive advantage and have refused to license them. Access to data under competition law can only be granted in the circumstances set out in the essential facilities doctrine. The application of such doctrine to this case is problematic because in most cases datasets are not 'essential' since it would be feasible to find a substitute of the same.[21] Notwithstanding this, the EC has stated that compulsory access to data on fair, reasonable and non-discriminatory terms (FRAND) *"will be needed where specific circumstances so require"*.[22] It will therefore be necessary to bring some clarity and identify those "specific circumstances" and how FRAND is to be interpreted in this context. Also, it may be recalled that competition law only operates ex-post, and that ex-ante regulation seems more appropriate to address B2B data-sharing concerns.

> **A starting point of such strategy should consist in identifying the AI features that are protectable by IP rights.**

g. Soft law

In 2018, the EC issued non-binding guidance setting some principles to which the parties might adhere for promoting the voluntary B2B data sharing based on fair contractual arrangements.[23] However, they have proven to be insufficient. As a result, the EC has recently stated that it *"will continue to assess whether amended principles and possible codes of conduct are sufficient to maintain fair and open markets, will address the situation"*, and if needed, [it] *"take appropriate actions"*.[24]

h. Data protection

AI development is dependent on the availability of large quality datasets for its training, at least for most AI systems. In general, for many AI systems to work properly, specific data must be collected, organised and prepared in a very particular way with the know-how of the AI engineer. In other words, as the algorithm will not work if the AI system is provided with a random selection of data, one needs to filter or 'clean' the 'lake' of data. This means removing any inconsistencies, duplicates or incorrect entries, and verifying that the data is accurate, complete, reliable, and up to date. Companies can easily spend around 80% of the resources on collecting and preparing the data. To pre-process the data to be used in the AI system

14 Bernt Hugenholtz *et al.* (n.13)

15 Peter R Slowinski ´Rethinking Software Protection, ´ Draft Chapter, in J.-A. Lee, K.-C. Liu, R. M. Hilty *(eds.), Artificial Intelligence & Intellectual Property, Oxford, Oxford University Press,* 2020 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3708110>

16 Begoña Gonzalez Otero, 'Machine Learning Models under the copyright microscope: is EU Copyright fit for purpose?' (2021) GRUR International 70(11), 1043,1055.

17 Josef Drexl, Reto M. Hilty, Luc Desaunettes-Barbero, Jure Globocnik, Begoña Gonzalez Otero, Jörg Hoffmann, Daria Kim, Shraddha Kulhari, Heiko Richter, Stefan Scheuerer, Peter R. Slowinski, Klaus Wiedemann, ´Artificial Intelligence and Intellectual Property Law Position Statement of the Max Planck Institute for Innovation and Competition of 9 April 2021 on the Current Debate´ (2021) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3822924>

18 Arts. 3 and 4 Directive (EU) 2019/790.

19 Josef Drexl, 'Designing Competitive Markets for Industrial Data – Between Propertisation and Access' (2017) *8 JIPITEC*, para 6,12.

20 Communication from The Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee of The Regions 'Building A European Data Economy', COM/2017/09 final [2017].

21 Giuseppe Colangelo and Mariateresa Maggiolino, 'Big Data as Misleading Facilities'(2017), *13 European Competition Journal 13(2),* 272,274.

22 Communication from The Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee of The Regions 'A European Strategy for Data', COM (2020) 66 final [2020] 13

23 Commission Staff Working Document Guidance on Sharing Private Sector Data In The European Data Economy, SWD(2018) 125 final [2018].

24 Communication from The Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee of The Regions, 'Towards A Common European Data Space', COM (2018) 232 final [2018].

there are two options. Either humans process the data, or they use automation tools or even human-created AI system to do so. Having taken into consideration the significant work and research behind the filtering of data, companies generally wish to protect 'data cleaning' systems with patents. However, some patent offices are reticent to recognise the technical purpose of that invention because they perceive the system as 'only' manipulating and reorganising data. Unfortunately, to date there is no harmonisation amongst patent offices on this topic.

Moreover, some questions arise regarding ownership and transfer of data. What can data holders do with the data and how do they maintain the ownership? If data is generated, for example, by the operators running through a network, who has the ownership rights? If the algorithm uses data from another data holder and changes it, who is the owner of the transformed data? How can companies protect personal data in compliance with GDPR and data protection regulations when transferring data between different countries? International companies or institutions may require that their employees exchange data in order to create and make AI systems work. Data holders may wish to allow others to use the data in some cases, but does this mean we need an open database?

> **In this situation, it must be evaluated if competition law could be used to correct imbalances.**

i. Natural language processing

Some patent offices employ a system for the prior art search that uses so-called 'natural language processing'. This system enables the use of algorithms to 'match best' the text of patent applications to a big database of text. As patent examiners still need to filter, verify and sometimes correct the results, this processing is only an 'assisting tool' for patent examinations. Patent offices also use the system for their classifications and statistics, which they later on publish in several reports. Let's say "Top 10 companies with patents in AI Machine Learning". This has led to companies including some particular keywords in their patent claims (in this example 'AI Machine Learning'). Should they choose not to do so, they may risk being perceived as not innovative in that area.

In any case, there is a great deal of potential in those AI tools. Google and IBM have developed a very elaborated natural language processing system using algorithms that enable, for example, to generate human speech or human text that is so realistic that it is very hard for the individual to distinguish it from that produced by humans. On the downside, let us imagine AI generates thousands of articles on a certain field (impacting the state of art). It would then be very challenging for inventors to obtain a patent because of lack of novelty. Another concern would be if someone with sufficient financial resources decides to pollute the patent environment. That person/association/government could overload patent offices by generating, with AI, thousands of automated patent applications.

j. Enforcement

Let us now imagine one obtains a patent for an AI invention and needs to enforce it. It would not work as it does nowadays with, for example, patents essential to a standard. For essential patents companies can show a claim chart, mapping the patent with the standard. But with some AI systems, it may be difficult to show infringement. Infringement may be in the internal workings of the algorithm, or in the filtering of data. The way some other AI systems work is often not well understood by their own designers. How can you enforce it if the patent office or the court requests to reproduce it? Can we give the data of the operator incorporated in the network for which the AI patent is granted?

k. Functional and geographical distribution

Another challenge regards the functional and geographical distributions of the AI system. Let's imagine that, in the architecture, part of the algorithm is performed at the edge, e.g., in collecting or filtering the data in the mobile phone, and the other part is performed in a node, in the network. Also, how can you enforce your right to an algorithm that is in a device in Germany but the node is in Spain and the execution is in the US? In these scenarios it is usually decisive the territory where the technical result occurs.

III. Proposed way forward

As we are preparing for making the unimaginable possible,[25] it is indispensable that we start addressing the above-mentioned challenges.

Definitions of AI-generated results, such as the one given by WIPO, do not appear to reflect the current state of the debate and may lead to confusion. Therefore, a first step in advancing this debate is for (legal) practitioners to better understand how AI technology works and its actual capabilities, and to make decisions in line with reality.

> **A first step in advancing this debate is for (legal) practitioners to better understand how AI technology works and its actual capabilities, and to make decisions in line with reality.**

While the volume of data production is increasing, its potential is still underused, so greater data availability and interoperability should be fostered, especially in the B2B context. The EC should create a framework for B2B data sharing, taking into consideration the interests of the various players involved and the rapid changes in the data and AI sector, which requires flexibility. However, it remains open what the appropriate legal instruments for this purpose are.

We also need a B2B data-sharing framework, given the importance of data in AI development. But there are still some open questions. For example, would the recommendation of standard licensing rules help to create a common framework? What is the role of the OSS community? Would it be desirable to apply a method of controlling unfair terms?

Regarding liability aspects, one could consider whether to create an insurance tailored to AI driven products.

A final remark is dedicated to courts and patent offices. We need harmonisation by courts and patent offices in getting protection for AI systems and in the enforcement. Equally important is for them to keep up to date with the fast development of AI. Finally, creative solutions may be required to prove infringement. For example, one could present to the patent office the feeding of specific data to the AI system and observe the outcome. If one gets the output expected, then the patent office (or the court) could conclude there is a high likelihood that there is an infringement. Another possibility would be to use 'comparable tests' (with data X one is able to get the claimed result, but with other data that result is not achieved) or to exploit techniques currently developed in the growing field of Explainable Artificial Intelligence (XAI).

The views expressed herein are those of the authors and do not necessarily reflect the opinions of former, present or future employers, or of associations or organisations they are active in. The authors would like to thank Piotr March and Margarethe Zmuda, both at Ericsson, for their valuable contribution.

[25] Machine Learning and other AI technologies will lead to innovation we cannot even imagine today. See more at https://www.ericsson.com/en/careers/better-brighter-tomorrow

Has innovation outpaced the patent system?

Dr. Robert Fichter, Managing Director of the IP law firm Dennemeyer & Associates, evaluates the efficiency of the patent system in the ever-evolving world we find ourselves in today.

1909, a year in which most people still traveled in horse-drawn carriages, probably marked the first time humans set foot at the North Pole[1]. By 1969, we were sending people to the surface of the moon[2]. It is not hyperbolic to say that more innovation took place in the 60 years between these milestones than in the preceding 600.

To think that we went from horses to space rockets in a single lifetime is utterly mind-boggling. Moreover, that breakneck pace of innovation showed no sign of slacking over the decades that followed the Apollo 11 expedition. Today, the internet grants us unparalleled connectivity, telephones have become near-supercomputers that fit in our pockets and artificial intelligence (AI) is being integrated into a growing number of industries. One could go on, but we would be here a long time if we did.

By contrast, consider the patent system, through which the innovations mentioned above (and many others) are codified as Intellectual Property (IP) protected under the law. Some of the specific patenting steps have changed slightly to be better aligned with the realities of modern technology. Take the Swiss Patent Office as an example. For every Boolean search, they also use various advanced AI-based solutions, including Octimine[3], to ensure the degree of accuracy one would expect from the country's famous watches. On the whole, however, it is reasonable to say that patent regulations[4] in many countries are not entirely in sync with the nature of modern innovation. Amendments and additions to the current system will be necessary, especially given the quickening rate of innovation and our increasingly tech-centric society.

Dr. Robert Fichter

> **They say necessity is the mother of invention.**

A timeline of innovation

As we understand it, human innovation started around 5,000 years ago when the first alloy, bronze[5], was discovered. At first, change was slow-paced: The plow, for instance, came thousands of years after humans invented the wheel and started working with metals. However, with time, technology gained momentum. Fast-forward to the 18th century, and the Industrial Revolution introduced steam engines into the mix. These machines quickly became popular as effective ways to generate mechanical power for transportation and manufacturing. The result was an explosion of industrial output and technological development. The modern capitalist system also started during this period, as entrepreneurs quickly learned how to raise investment capital by trading shares in growing businesses.

As the revolution progressed, many people in the United States and Europe moved to the cities to find jobs in factories powered by machines. New inventions and processes that increased efficiency – such as mechanized looms and improved engines – were patented because their owners hoped to exploit them unimpeded and prevent rivals from copying their ideas without permission. By the late 1880s, the mastering of electricity[6] had opened up an entirely new world of possibilities – and patents.

They say necessity is the mother of invention, and so it comes as no surprise that nuclear power, computers, helicopters and radar are all examples of technologies developed during, or in direct response to, the Second World War.

Résumé

Dr. Robert Fichter, Managing Director of the IP law firm Dennemeyer & Associates

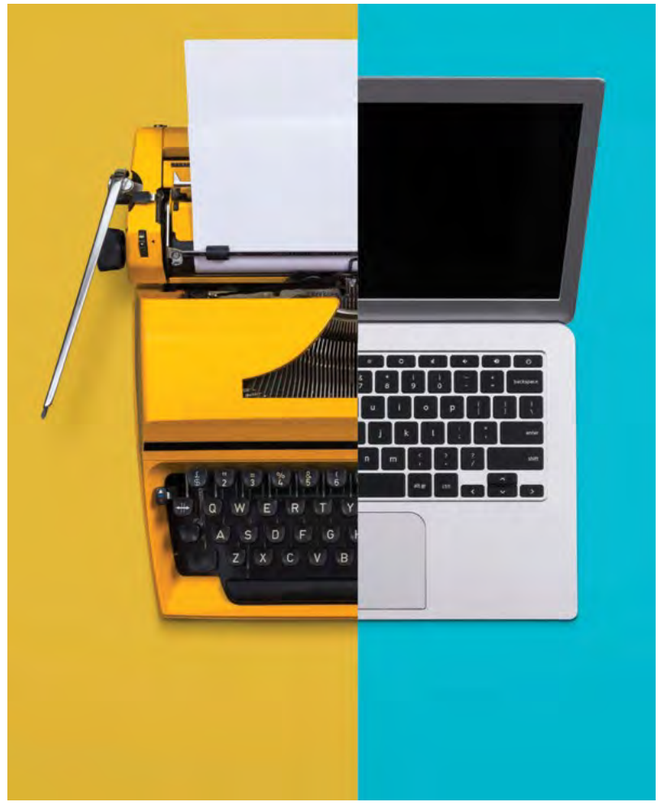
Dr. Robert Fichter is responsible for the strategic direction and management of all international branch offices of Dennemeyer & Associates and manages day-to-day operations. Before joining Dennemeyer, Dr. Fichter was a partner at a German patent law firm handling patent, trademark and design matters for local and international clients, including Fortune 500 companies. This position was preceded by employment as unit head for IP software in a Finnish company and as an IP specialist at 3M Espe. Dr. Fichter frequently lectures at universities, law schools and conferences about IP and business strategies and IP-related outsourcing matters.

Yet, even in the aftermath of the devastating global conflict, innovation proceeded with startling vigor. No doubt, the antagonism of the Cold War and the ever-looming threat of a nuclear conflict were behind the frenzied activity at the very vanguard of technology. After all, from the United States government's ballistic missile research of the 1950s[7] grew NASA's space program of the 1960s. Though the specter of nuclear war has, for the most part, liftedß, the developments of the mid-20th century succeeded in laying down the groundwork of the digital age we now live in.

By the last quarter of the 20th century, we had entered what could reliably be called the "Golden Age of Innovation." Computers developed at breath-taking speed, as researchers succeeded in doubling transistor counts[8] every two years from the late 1960s onward. With modern computers came wireless communication, and now, the internet and smartphones help people share ideas across the entire planet[9]. In under two decades, we went from cell phones that could barely hold a handful of text messages to devices capable of storing millions of pieces of information and processing complex tasks in fractions of a second.

These days, almost every modern appliance can connect to the internet: Washing machines can be accessed through smartphones, lights have their own apps and refrigerators can tell people when they are out of milk. Technological progress has helped foster connectivity throughout society as the number of users, and devices, has mushroomed.

Despite the obvious trend of innovation witnessed over the past century, patent regulations have struggled to keep up with the blinding pace of change. Companies spend hundreds – if not thousands – of hours each year filling out forms, keeping inventories and filing patent applications in tedious manual processes. In an increasingly technology-focused world, this way of going about business feels uncannily antiquated. How can it be that our system of cataloging new devices and processes lags behind those very inventions? To answer this properly, we must look at the history of patents in more detail.



> **These days, almost every modern appliance can connect to the internet.**

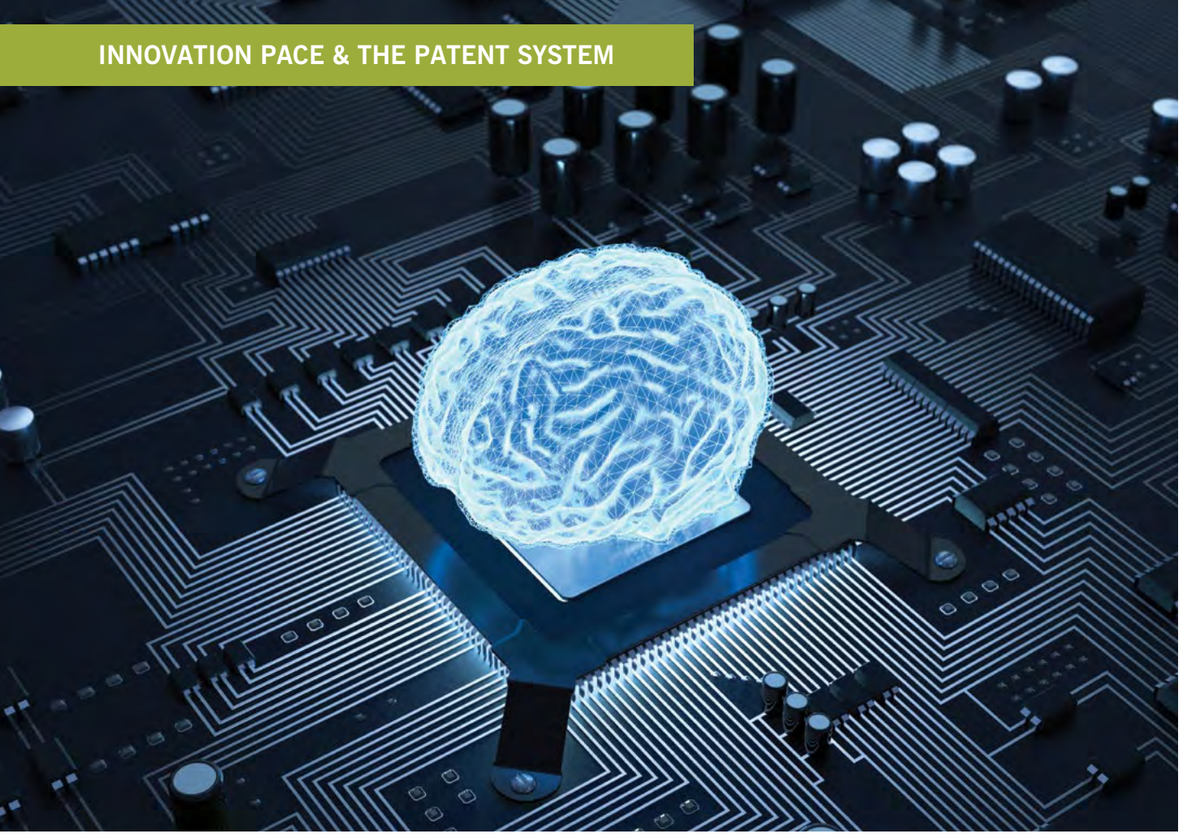
The industrial basis of patent law

The first written patent law came from Venice in 1474[10] to regulate the lucrative glass-blowing industry, though it was quite basic by modern standards.

Much of the patent system as we currently understand it stems from concepts that emerged incrementally from the early Industrial Revolution, eventually culminating in formal codification over the course of the 19th and 20th centuries. Consider:

- The United Kingdom's Patent Law Amendment Act of 1852[11] established a system that was not significantly changed until 1977.
- As codified in Title 35[12], U.S. patent law is mainly based on the Patent Act of 1952.
- Japan's patent regulations are based on the Patent Act of 1959[13].

1 https://www.cbp.gov/about/history/did-you-know/first-man
2 https://www.nasa.gov/mission_pages/apollo/missions/apollo11.html
3 https://www.octimine.com/
4 https://www.dennemeyer.com/services/?asset=patents&cHash=e9a5663b54695ffcef4527ca46f6de70
5 https://www.history.com/topics/pre-history/bronze-age
6 https://www.energy.gov/articles/war-currents-ac-vs-dc-power
7 https://www.nps.gov/articles/mimiarmsrace-03.htm
8 https://www.investopedia.com/terms/m/mooreslaw.asp
9 https://world101.cfr.org/global-era-issues/globalization/two-hundred-years-global-communications
10 https://www.wired.com/2012/03/march-19-1474-venice-enacts-a-patently-original-idea/
11 https://web.archive.org/web/20131031094427/http://www.ipo.gov.uk/types/patent/p-about/p-whatis/p-history/p-history-19century.htm
12 https://www.law.cornell.edu/uscode/text/35
13 http://www.japaneselawtranslation.go.jp/law/detail/?id=42&vm=04&re=02



Even countries that updated their patent laws later, including India (1970[14]), China (1984[15]) and France (1992[16]), did so before the proliferation of personal computers and the internet. As such, although most of these laws have been amended in some way since their implementation, the systems they created and currently uphold were not conceived with an eye toward a world dominated by digital technologies.

It stands to reason that if patents are a relatively new concept, then so is rapid technological advancement on a societal scale. Technology, as we know it today, did not come about without an exceptionally long incubation period. One could argue that before the 20th century, significant changes only occurred over spans of hundreds of years, and infrequently at that. To put it simply: The pace of innovation we now take for granted is unprecedented in all of human history, and the legal system is struggling to match it.

Patentability issues for software and AI

Nowhere is this shortcoming more plainly demonstrated than in the debate over the patentability of software. In many major jurisdictions, the answer to whether software is considered directly patentable can be incredibly difficult for inventors to track and often comes with caveats attached.

For example, in the United States, patents can and have been issued for software-related inventions. However, the Supreme Court's 2014 decision in *Alice Corp. v. CLS Bank*[17] has muddied the waters by stating that the plaintiff (Alice Corp.) could not patent its escrow system because it was an "abstract idea." On the other hand, jurisdictions like the European Union, Russia and the United Kingdom argue that programs for computers are unpatentable yet are still willing to consider software-related inventions that "solve a technical problem." In all of these jurisdictions, standards that appear straightforward on the surface are actually quite confusing.

> **But critics argue that such actions are effectively gaming the patent system to drive up pricing.**

AI has been an even thornier, though less-encountered, issue in terms of patentability. We see this in the case of DABUS, an AI platform created by Dr. Stephen Thaler at Imagination Engines. Dr. Thaler's AI invented, among other things, a novel beverage container and a signal lamp[18]. However, when he filed patent applications with the offices of Europe and the United States, citing DABUS as the inventor, all were rejected. In this context, it is noteworthy to mention that the German Federal Patent Court determined on November 11, 2021, that the German Patent and Trade Mark Office's (DPMA) decision to reject a patent application naming DABUS as an inventor was wrong[19]. The Court ruled that the DPMA's refusal of the application on the grounds that the invention was AI-generated was too far-reaching. Computer- generated creations are not *per se* excluded from patent protection in Germany. Rather, a human being must be identified as the inventor, while the AI may be mentioned as an involved party.

Thus far, and according to our research, the only IP regulator to accept an application naming a computer as a direct inventor is South Africa's Companies and Intellectual Property Commission (CIPC), which granted a patent to DABUS in August 2021[20].

Though the CIPC does not conduct substantive examinations of patent applications, it is worth noting that Thaler won an appeal to the Federal Court of Australia[21] after that nation's Deputy Commissioner of Patents ruled that DABUS could not be named an inventor.

The general question with regard to AI-generated patents remains whether the original purpose of our patent systems is fulfilled in acknowledging an AI as an inventor. Our patent systems were established to foster innovation, inspire creativity and circumvent existing monopolies by creating new and non-obvious inventions. In many of these frameworks, inventors receive credit and remuneration for their work. As things stand, AI does not care to be compensated or credited and is only generative when instructed and directed by a human.

Pharmaceutical controversies

Existing patent systems may also be ill-equipped to meet the challenges presented by the modern pharmaceutical industry. The way that some companies in the sector use their patents has come under fire, exemplified by the case of Gilead and its hepatitis C treatment, Sovaldi. Gilead did not develop the drug but bought the company that did[22] and then filed for extensive patent protections. This is, of course, permissible by the letter of the law in many jurisdictions, but critics argue[23] that such actions are effectively gaming the patent system to drive up pricing.

More recently, there has been considerable debate over the IP rights to the various COVID-19 vaccines. Some groups argue that companies should waive their patent protections[24] to allow these drugs to be more readily produced worldwide. Opponents of the waivers state that this would actually drive up costs[25] and hinder a global rollout. Considering all technological aspects, there are not only a few patents involved in COVID-19 vaccines but dozens, if not hundreds. It is not for us to say which side is right or wrong, but the patent systems as they stand, specifically the imposure of compulsory licenses, might not be optimized for complex technologies.

> **We live in a time in which innovation occurs at a breathtaking speed, but, thus far, patent law has been slow to adapt.**

Considering the future

We live in a time in which innovation occurs at a breathtaking speed, but, thus far, patent law has been slow to adapt. Since the complications we have touched upon will only become more relevant in the years ahead, patent examiners and lawmakers will inevitably have to establish firm standards to satisfy current and future demands.

Putting aside whether or not we should turn to open-source methods of invention, one thing is for sure: We need to ensure that our patent systems enable progress rather than encumber it. So many of our IP principles were designed for the industrial period, not necessarily the post-industrial one, yet the law is notoriously reluctant to deviate from the "tried and true" ways of doing things. When it comes to implementing change, perhaps it is time for the legislator to take a leaf from the inventor's book – without infringing on their copyrights, of course.

At Dennemeyer, we keep closely abreast of the most critical IP trends and regulations[26] to protect our customers' patent rights best while ensuring compliance. With our global network of company offices and trusted partners, we can serve all of your patent management needs — whatever or wherever they may be.

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Artificial Intelligence and Patent Protection in India: the current scenario

Rachna Bakhru and Suvarna Pandey, Partner and Associate Partner at RNA, Technology and IP Attorneys, review the current developments and IPR policies in India in relation to AI and AI-assisted innovations.

Artificial intelligence is the ability of a computer or a robot to perform tasks commonly associated with intelligent beings or humans. This includes the ability to reason, make decisions and generalize based on data processing using algorithms. The pre-programmed computer can analyze data by studying the repeat patterns of human behavior and do intuitive thinking, also called machine learning. AI-powered by Apple's Siri, Amazon's Alexa, IBM Watson, Music, and video streaming services recommend songs and playlists. Speech recognition, chatbots, virtual assistants in messaging applications, Self-driving cars, automated stock trading are practical examples of machine learning. AI and machine learning are no longer new to India and have penetrated almost every industry. It is impossible to think of technology in any area, e.g., health sector, communication, food sector, electronics, software, environment, education, and transportation, without being equipped with Artificial Intelligence (AI). As per AI and Analytics start-up investment study for 2020-2021, the Indian AI market is valued at $7.8B as of July – August 2021. This represents a 22% increase in the size of the market over 2020.

Given the significance of AI globally and in India, it would be prudent to understand the legal framework of AI and machine learning. The article analyzes current trends in artificial intelligence inventions, their patentability, and laws surrounding the protection of AI inventions in India.

AI ecosystem in India – current trends

According to the latest Government AI Readiness Index (Oxford Insights and IDRC, 2020), India has the fourth-highest number of technology unicorns after the USA, China, and the UK, and the third-

Rachna Bakhru

Suvarna Pandey

Résumé

Rachna Bakhru, Partner

Rachna qualified as an Electronics graduate from Delhi University, followed by diploma in Business Administration and a degree in Law. She is a registered Patent Agent and a member of The Bar council of India. Rachna currently heads the Dispute Resolution team of the firm, dealing with IP enforcement and advisory. She has over 25 years of extensive experience in managing non-contentious and contentious IP matters, IT and technology issues. Her expertise includes risk assessment, IP clearance, regulatory issues, litigation, and alternate dispute resolution. She has worked on portfolios of large international companies and her industry expertise includes pharmaceuticals and information technology. She advises her clients on issues related to IP infringement, information technology, trade secrets, data protection, and geographical indications.

Suvarna Pandey, Associate Partner

Suvarna is a registered patent agent and a law graduate. Having been in the practice for around 13 years, her specialties include patent searches, patent drafting, and providing patentability and infringement opinions. She is also involved in patent prosecution proceedings at the patent office, opposition and other invalidity proceedings. She is specialized in the development and strategic management of patent portfolios in areas that include biotechnology, chemical, and pharmaceutical inventions. She has been advising clients on global patent strategy including PCT applications and national phases in designated countries. Suvarna has also authored various articles and delivered training sessions in the domain of Indian patent practice.

highest market value for technology companies in the Forbes Global 2000, demonstrating India's strong interest in the adoption of AI. The Government of India has taken various initiatives to promote the implementation of AI by releasing the national policy on Artificial Intelligence. One of those is the "National Strategy on AI," which was announced by the National Institute of Transforming India (NITI) Aayog (an apex think-tank of the government) in 2018. The Ministry of Finance sanctioned a budget of INR 7,000 Cr (USD 945M) by for the period (2019- 20 to 2024-25)7 to NITI Aayog for the creation of a cloud computing platform called AIRAWAT (AI Research, Analytics, and knowledge Assimilation) and research institutes and set up a high-level task force to oversee the rollout and implementation of AI in the country. According to Worldwide Artificial Intelligence Spending Guide Forecast, India's AI spending will grow to USD 880.5M in 2023 at a compound annual growth rate (CAGR) of 30.85% (IDC, 2020).

The Data from Stanford AI Index 2021, published by arXiv discloses a steep increase in the publications from Indian Researchers on AI-related topics from 2015 to 2020.

The statistics indicate the Indian government's commitment and efforts in promoting AI in the country. However, as per the UK-based consultancy Oxford highlights survey, India still ranks at number 40 in the AI readiness index compared with its global counterparts due to certain factors, including privacy and transparency.

Unifying the AI ecosystem

The Indian government has set up a central knowledge hub/portal on artificial intelligence to create a unified AI ecosystem. The INDIAai portal driven by the Ministry of Electronics and

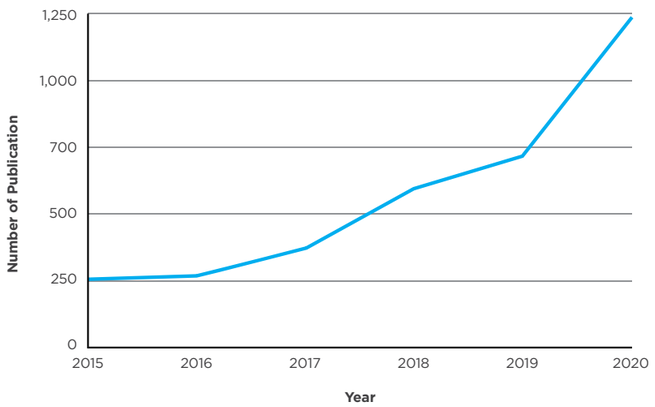


Fig. 5: AI-related publications on arXiv from India 2015- 2020

> **The laws need to keep pace with the fast-changing technologies.**

Information Technology (MEITY), National e-Governance Division (NEGD), and National Association of Software and Service Companies (NASSCOM) has released their report highlighting that:

- More than 70% of the technology patents filed in India relate to one or more emerging technology domains. At an international level, the patent filing grew by 4% in the year 2020. Interestingly, AI accounts for 6% of all emerging tech patents in India.
- India is emerging as a key destination for AI innovation: innovation in AI has gained significant traction over the last decade as India is ranked 8th in terms of AI patent filing and 4th in terms of AI research papers.
- Over 5,000 AI patents filed over the last decade in India - 94% of them filed in the previous five years.
- 60%+ of patents filed originated in India.
- Consumer electronics/ personal computing devices and healthcare were leading vertical focus areas.
- With a 93% share, Machine Learning was the most popular AI technique; Computer Vision, with a share of 36%, was the leading functional area.
- Among assignees, the technology sector leads AI patents with a share of 47%.
- AI patent filings in India will maintain an upward trajectory, driven mainly by the growing importance of patent filing and protecting intellectual property. However, the filing will continue across diverse application areas.
- India's AI success story can face challenges if adequate financial support, effective policies, and mentorship are not laid out for start-ups.

Overall, the policy-level initiatives by (MeitY) and programs around AI by NASSCOM and the Defence Research & Development Organization (DRDO) have laid the groundwork for future disruption and created a roadmap for AI in India.

> **AI patent filings in India will maintain an upward trajectory, driven mainly by the growing importance of patent filing and protecting intellectual property.**

Intellectual Property Rights in technologies based on AI

The inventions/technologies based on Artificial Intelligence are examined similarly to that of computer-related inventions (CRI) in India. The inventions should qualify the requirements of Section 3(k) of the Indian Patent Act, which restricts computer program patentability *per se.* There have been concerns over the correct interpretation of Section 3(k) not to extend the same to all computer-related inventions. In today's digital world, most inventions are based on computer programs; therefore, denying protection to them would discourage innovation. In a writ petition filed at the Delhi High Court (DHC) challenging the IPAB's decision refusing patent to Ferid Allani on a "method and device for accessing information sources and services on the web", the DHC has laid down the following criterion patentability of Computer related inventions: (WP (C) 7/2014 & CM APPL. 40736/2019):

"Section 3(k) has a long legislative history and various judicial decisions have also interpreted this provision. The bar on patenting is in respect of `computer programs per se*...' and not all inventions based on computer programs. In today's digital world, when most inventions are based on computer programs, it would be retrograde to argue that all such inventions would not be patentable. Innovation in the field of artificial intelligence, blockchain technologies*

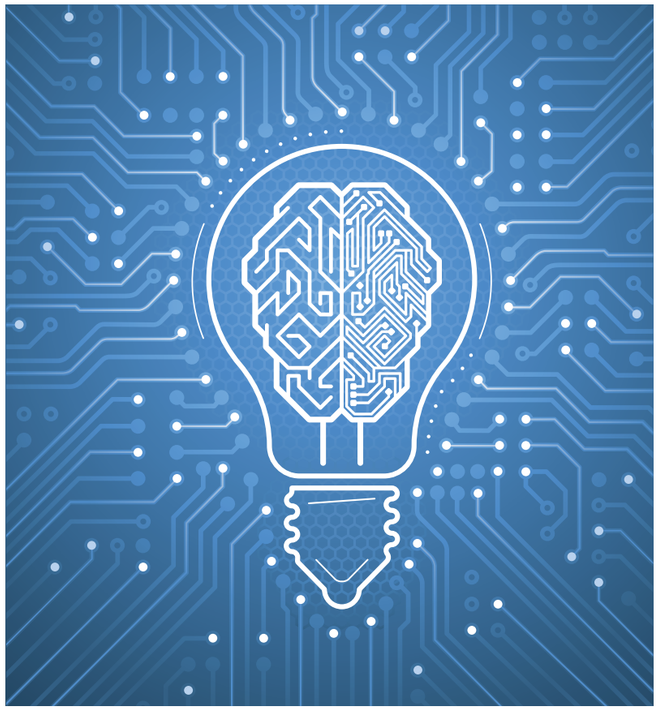
and other digital products would be based on computer programs, however the same would not become nonpatentable inventions – simply for that reason. It is rare to see a product which is not based on a computer program. Whether they are cars and other automobiles, microwave ovens, washing machines, refrigerators, they all have some sort of computer programs in-built in them. Thus, the effect that such programs produce including in digital and electronic products is crucial in determining the test of patentability."

The above decision concluded that the innovation in Artificial Intelligence would be judged based on "technical effect" and "technical contribution". Therefore, if the technologies can solve a technical problem through technical means, it will be eligible to be considered for grant of a patent.

Ownership of AI inventions/ intellectual property

Under the Indian Patent Act, a person or assignee of that person or legal representative of any deceased person is entitled to apply for patents under section 6. The definition of "person" as defined in the Indian Patent Act includes "Government". Thus, either the natural person or government can file the patent. However, there is no reference to the machine being named as an Inventor of a patent. Therefore, it is unclear who owns the intellectual property rights in an invention or creation originating from the AI. Until the law is amended to include machines as inventors, the parties will need to rely upon robust contracts with clear clauses on ownership. In case of disputes, the courts will decide conflicts based on the circumstances of the case and agreement between the parties. Currently, there are no decisions from the courts related to ownership of IP rights in AI inventions.

> **Therefore, if the technologies can solve a technical problem through technical means, it will be eligible to be considered for grant of a patent.**



However, the Indian Copyright Office has accepted and registered a copyright application for a painting titled "Suryast" created by an AI painting app (RAGHAV) and a person. As per the published facts, the painting was created by the AI painting application (RAGHAV) based on Vincent van Gogh's painting "Starry Night" and a picture captured by Mr. Ankit Sahni, who was the owner of the AI painting application (RAGHAV).

Liabilities for the act of AI

The legal liabilities in the case of resulting IP based on AI remain unclear, considering that the AI invention is the result of the combination of inputs/instructions from the programmer and the decision taken by the AI-based on the user's inputs. At this time, the subject is being highly debated across the world on who owns the liability in case of any wrongful acts of the AI. As AI does not have a legal personality, thus, the question remains valid that how can it be imposed for any infringement or how would the damages be assessed, e.g., accidents caused by driverless cars. The UK Department for Transport has proposed new two-way insurance policies that cover autonomous vehicle insurance. If the car is in driverless mode, the insurance companies can recover claims from the party responsible for the crash, vehicle manufacturer, or technology/ software company. Few other countries are implementing similar changes to their current regulations keeping the AI-driven businesses in mind.

Challenges to AI

1. Data is one of the primary drivers of AI solutions, and thus appropriate handling of data, ensuring privacy and security, is of prime importance. There are challenges in the implantation of AI-equipped technologies related to Data privacy, including concerns relating to data usage without consent, risk of identifying individuals through data, etc. India currently does not have a specific privacy law to safeguard personal data. There are provisions under the Information Technology Act of India that cover some of the issues related to data collection, usage, retaining, and disclosing of the personal data of individuals and require them to have a privacy policy. However, such regulations are not comprehensive, and there is a dire need for a special law. The Personal Data Protection Bill (PDPB) modeled on the General Data Protection Regulation (GDPR) protects personal data. However, the law is yet to see the light of the day. In the absence of a dedicated law governing personal data, the contracting parties would look at the terms and conditions of the contract and privacy policies in case of any disputes.
2. **Expertise and skill development:** Other factors need to be addressed for comprehensive and better implementation of AI technologies like lack of enabling data ecosystems, inadequate availability of AI expertise, human resources, and skilling opportunities, high resource cost, and low awareness for adopting AI in business processes. The public and private sectors need to train the workforce with multidisciplinary skills to make them AI-ready. While there are concerns that AI will take away jobs, AI can generate new employment opportunities where humans and artificial intelligence can work together to make human lives more comfortable with appropriate skill development.
3. **Ethical issues:** With the advent of AI products and algorithms and their increasing role in daily lives, ethics and morality have emerged as significant challenges for AI solution providers. The ethical considerations for every industry can be different, e.g., the safety and security of confidential information is an essential requirement in the Healthcare and Finance industry. Clear regulations must be in place to address ethical standards for broader cultural acceptance and trust in AI solutions.

What next?

While India is noticeably investing in implementing AI in every industry, the laws need to keep pace with the fast-changing technologies. The Department-related Parliamentary standing committee on commerce reviewed the Intellectual Property Rights Regime in India and presented their report to both the parliament houses on July 2021, laying the significance of AI. The Committee recommended that a separate category of rights for AI and AI related inventions and solutions should be created for their protection as IPRs. It further suggests that the Department review the existing legislation of The Patents Act, 1970 and Copyright Act, 1957 to incorporate the emerging technologies of AI and AI-related inventions in their ambit. It further suggested following the *approach linking the mathematical methods or algorithms to a tangible technical device or a practical application for facilitating their patents as being done in the EU and US.*

> **This represents a 22% increase in the size of the market over 2020.**

Summary

Artificial intelligence continues to evolve globally and is expected to revolutionize the existing process and technologies. At this time, when India needs to revitalize productivity and growth to fulfil aspirations of its growing population, AI promises to fill the gap. To fully seize the opportunities provided by the AI revolution, foster economic growth, and improve lives through it, multiple stakeholders need to work together to develop a responsible AI ecosystem. Further, a reliable legal and regulatory framework, skilled AI-ready workforce, strong research & development will help attract people's confidence and investment into this promising area. With the right strategy, policies, and regulations in place, India's AI journey has the potential to lead to a brighter future.

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The Supreme Court applied the most-significant-relationship test to justify Chinese courts' jurisdiction over SEP global licensing in *Oppo v Sharp*

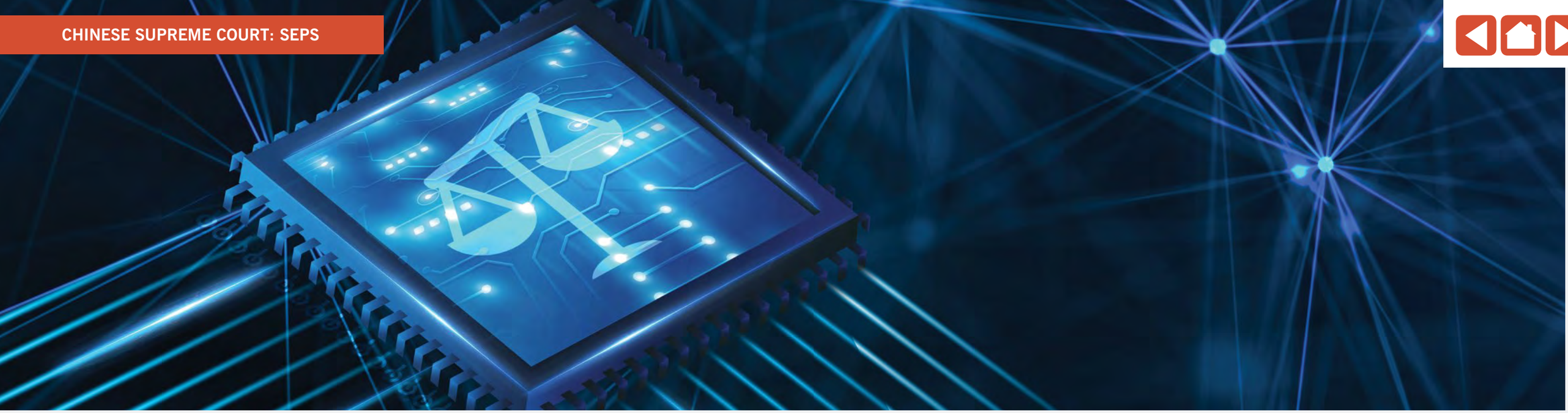
Xiaojun GUO, Attorney at CCPIT Patent and Trademark Law Office, analyzes the SEP ruling in light of the *Oppo v Sharp* case and what it means for FRAND in the jurisdiction of China.

Résumé

Xiaojun GUO is a patent attorney with trademark attorney qualification and lawyer qualification at CCPIT Patent and Trademark Law Office. He has extensive experience in prosecuting patent applications for inventions, utility models and designs, and in patent litigation as well. He can be contacted at: **guoxj@ccpit-patent.com.cn**

Xiaojun GUO

On August 19, 2021, the Intellectual Property Tribunal of the Supreme Court of China handed down its decision in connection with the jurisdictional dispute over the global licensing of the standard-essential patents (SEPs) in *Oppo v Sharp*, rejecting the appeal instituted by Sharp and upholding the first-instance ruling ((2020) Yue 03 Min Chu No. 689 made by the Shenzhen Intermediate Court on October 16, 2020). The Supreme Court decision ((2020) Zui Gao Fa Zhi Min Xia Zhong No. 517) affirms Chinese courts' jurisdiction to set global FRAND rates and terms and clarifies the applicable tests in deciding Chinese courts' jurisdiction over such type of cases.



1 Brief

On July 10, 2018, Sharp Corporation and its wholly-owned subsidiary ScienBizip Japan (hereinafter collectively referred to as Sharp) sent a licensing letter to Guangdong OPPO Mobile Telecommunications Co., Ltd. and Shenzhen Branch of Guangdong OPPO Mobile Telecommunications Co., Ltd. (hereinafter collectively referred to as OPPO), listing their SEPs for 3G, 4G, WiFi, and HEVC by jurisdiction and seeking for a global license. The Chinese patents represent a significant ratio within the SEP portfolio.

As one of the largest mobile phone manufacturers, OPPO's share of sales in China exceeded 70%, while its share of sales in Europe was approximately 0.20% and in Japan was less than 0.1%, as of December 31, 2019.

On February 19, 2019, OPPO and Sharp held licensing talks at OPPO's Shenzhen office. Sharp proposed a preferred overall structure of license: a five-year period, covering the 3G, 4G, WiFi, and HEVC SEPs owned during the term, a global non-exclusive license with no sub-licensing rights, limited to implementation and use of the licensed standards.

In the course of the negotiation, Sharp began to file a series of patent infringement lawsuits against OPPO or its business partners in Japan, Germany, and Taiwan province of China from January 2020 onwards.

On March 25, 2020, OPPO filed a lawsuit with the Shenzhen Intermediate Court, asking the Court to: (1) rule that Sharp violated its FRAND obligations or the principle of good faith during the licensing negotiation; (2) set global licensing rates and terms for Sharp owned SEPs of 3G, 4G and WiFi and (3) order Sharp to compensate OPPO RMB 3 million for economic losses caused by violating the FRAND obligations. Sharp challenged the court's jurisdiction by filing a jurisdictional objection to the case.

> **As long as one of the afore-mentioned places is within the territory of China, the case shall be deemed to have proper connection with China and Chinese courts shall have jurisdiction over it.**

In October 2020, the Shenzhen Intermediate Court ruled in favor of OPPO, confirming its jurisdiction to set global licensing rates and terms over the SEPs by taking a wide range of factors into consideration.

Sharp appealed to the Supreme Court requesting: the case be dismissed; and if the above request is not satisfied in full, that the infringement dispute in the case be dismissed, and that the dispute concerning the licensing conditions of the SEPs for 3G and 4G in China be transferred to the Guangzhou IP court, and that the Global licensing conditions of the SEPs for WiFi and the licensing conditions of the SEPs for 3G and 4G in other countries or regions than China be dismissed. The appeal requests are substantially the same as those submitted in the jurisdictional objection.

2 The decision of the Supreme Court

The case is a dispute of jurisdiction over SEP licensing. The issues in dispute during the second trial of the case included: whether Chinese courts had jurisdiction over the case; if Chinese courts had jurisdiction over the case, whether it was appropriate for the first-instance court to exercise jurisdiction over the case; if the first-instance court had jurisdiction, whether it was appropriate for it to rule on global licensing rates and terms of the SEPs in question.

(1) Jurisdiction of Chinese courts over the case

The essence of an SEP licensing dispute is to ask the court to determine the specific licensing rates and terms to urge both parties to conclude a license agreement or to perform the license agreement. Therefore, the Supreme Court considered that such a dispute was relatively more contractual than patent infringement in nature.

Sharp is a foreign enterprise without a domicile and a representative office in China. The jurisdiction of Chinese courts over such a foreigner-related dispute depends on whether the dispute has proper connection with China. To determine whether an SEP licensing dispute is properly connected with China, the following factors may be taken into consideration: the place where the patents in question were granted, the place where the patents are implemented, the place where the patent license agreement was signed or where the patent license agreement was negotiated, the place where the patent license agreement is performed, or the place where the property available for seizure or enforcement is located, etc. As long as one of the afore-mentioned places is within the territory of China, the case shall be deemed to have proper connection with China and Chinese courts shall have jurisdiction over it.

In this case, the SEP portfolio involves a great number of Chinese patents, the manufacturing activities of OPPO to implement the SEPs in question took place in China, and the parties had conducted negotiations on the licensing of the SEPs in question in Shenzhen, China. Therefore, Chinese courts have jurisdiction over this case, whether as the court where the patents were granted, the court where the SEPs in question were implemented, or the court where the licensing of the SEPs in question was negotiated.

(2) Jurisdiction of the Shenzhen Intermediate Court over the case

The jurisdiction of a Chinese court over the SEP licensing dispute may also be based on the above-mentioned jurisdictional connections.

> **The parties in this case had the intent to agree on global licensing rates and terms over the SEPs in question and had negotiated the license therefor.**

OPPO Shenzhen, as a wholly-owned subsidiary of OPPO and one of the subjects implementing the SEPs in question, is located in Shenzhen and implemented the SEPs in Shenzhen too. The Shenzhen Intermediate Court, as the court in the place where the SEPs in question are implemented, could exercise its jurisdiction over the case. Meanwhile, the Shenzhen Intermediate Court, as the court where the SEP license was negotiated, could also exercise its jurisdiction over the case in this connection.

(3) Jurisdiction of the Shenzhen Intermediate Court to rule on SEP global licensing rates and terms

Whether it is appropriate for the Shenzhen Intermediate Court to rule on global licensing rates and terms over the SEPs in question should be considered comprehensively based on the facts of the jurisdictional dispute and in combination with the special nature of SEP licensing disputes. In particular, the Supreme Court considered multiple factors to find the jurisdiction of the Shenzhen Intermediate Court over the case: the scope of the parties' willingness when negotiating the SEP license (Sharp proposed a five-year global non-exclusive license for its SEP portfolio with no sub-license rights); the countries granting the SEPs and the distribution ratio of the SEPs (most of which are Chinese patents); the main place of implementation, main place of business or source of revenue for the SEPs in question (The main place of business of OPPO, the manufacturing site and the main sales area of its smart terminals involved in the case are all in China, its share of sales in China was 71.08% as of December 31, 2019); the place of negotiation for the SEP licensing between the parties (which is in Shenzhen), and the location of the property

available for seizure or enforcement (which is also in Shenzhen).

In view of the above, the parties in this case had the intent to agree on global licensing rates and terms over the SEPs in question and had negotiated the license therefor. The scope of the parties' willingness to negotiate constitutes the factual basis for ruling on global licensing rates and terms. Second, the SEP licensing dispute in this case is obviously more closely linked to China. Most of the SEPs involved in the licensing negotiation are Chinese patents; China is the main place of implementation, the main place of business and the main source of revenue of the implementer of the SEPs in question; China is the place where the licensing negotiations took place; and China is also the place where the property of the patent licensee is available for seizure or enforcement. It would be more convenient not only to find out the facts of OPPO's implementation of the SEPs in question, but also to enforce a court decision, for Shenzhen Intermediate Court to rule on the global licensing rates and terms over the SEPs in question.

The Supreme Court therefore rejected the appeal of Sharp and affirmed the first-instance ruling.

3 Conclusion

(1) The most-significant-relationship test

The Supreme Court's decision can find its legal basis from Article 265 of the Civil Procedure Law of the People's Republic of China, which provides for six types of connections for exercising jurisdiction over extraterritorial defendants: "Where an action is instituted against a defendant which has no domicile within the territory of the People's Republic of China for a contract dispute or any other property right or interest dispute, if the contract is signed or performed within the territory of the People's Republic of China, the subject matter of the action is located within the territory of the People's Republic of China, the defendant has any seizable property within the territory of the People's Republic of China, or the defendant has an representative office within the territory of the People's Republic of China, the people's court at the place where the contract is signed or performed, where the subject matter of action is located, where the seizable property is located, where the tort occurs or where the domicile of the representative office is located may have jurisdiction over the action."

So, in spite of different expressions such as "proper connection", "more closely linked to", the Supreme Court found the jurisdiction of the Shenzhen Intermediate Court basically by application of the most-significant-relationship test. This should further attribute to the contractual nature of the SEP global licensing. Applying the most-significant-relationship test, it becomes very clear that Chinese courts have jurisdiction over the dispute and are more suitable to adjudicate the case.

> **OPPO made an extremely strong case and met almost all of the applicable connections under the most-significant-relationship test.**

Although the most-significant-relationship test should be deemed the basic test for the Supreme Court to make the decision, the willingness of both parties to enter into a global license over the SEPs and the subsequent negotiations therefor, and the application of so called forum convenience doctrine are also intensively considered by the Supreme Court.

(2) The consent of the parties to jurisdiction is not a premise

The Supreme Court has also made it clear in the decision that the consent of the parties to jurisdiction is not a premise for a particular court to excise its jurisdiction and address the rates and terms of an SEP global license. Where the parties have the willingness to enter into a global license and the case has a closer connection to Chinese courts, it is appropriate for Chinese courts to rule on the rates and terms of the global license of the SEPs in question.

In general, OPPO made an extremely strong case and met almost all of the applicable connections under the most-significant-relationship test, though from the opinions of the Supreme Court, Chinese courts might excise jurisdiction over such dispute when only some of the connections are met in China.

Whatever, the Supreme Court clearly rejected the viewpoint that the court of any country even having a very loose connection with the SEP licensing dispute may adjudicate such a case. This is consistent with the practice of settling international commercial disputes, and is also beneficial to avoid judicial competition to some extent and inhibit forum shopping by an SEP owner or an implementor, which may leverage a case by suing in a country with little interests to the patent portfolio. As the highest court of the second biggest market in the world, the standpoint of the Supreme Court of China on such disputes can't be ignored.

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> **A court action for a declaration of invalidity provides the challenger a fuller opportunity to advocate against the patent.**

Noel Courage

Résumé

Noel Courage, Partner

Noel is a member of the Life Sciences practice group. He is co-leader of the COVID-19 practice group.

Noel's practice focuses on the patenting and licensing of biotechnological, chemical and mechanical inventions.

Post-grant patent challenges in Canada

Noel Courage, Partner at Bereskin & Parr LLP, evaluates the success of re-examination in a post-grant patent challenge case, *Cusitar v Canada* 2019 FC 1641.

There is no patent opposition or *inter partes* re-examination system to kill Canadian patents. The main basis to challenge patents is re-examination or a court impeachment proceeding. The re-examination process is of very limited use because it is *ex parte*, meaning that the challenger makes initial assertions of a substantial new issue of patentabilty. If the allegations meet the threshold to trigger a re-examination proceeding, the challenger is out of the process. The patentee will correspond directly with the patent office and attempt to recharacterize the prior art. The challenger is at a significant disadvantage since it has no right to respond. In view of the limited participation rights, Canadian re-examination is not a recommended strategy unless the prior art that triggers re-examination is strong, ideally destroying novelty. At the very least, the prior art should make a clear case of obviousness.

The Federal Court of Canada recently provided a good example of a successful post-grant challenge in *Cusitar v Canada* 2019 FC 1641. The patent was invalidated as obvious during re-examination at the Canadian Patent Office. The decision was upheld on appeal to the Federal Court.

The case began with the inventor filing a patent application on January 5, 2015 for a process for an improved oil sand mining and haulage method. This patent no. 2,876,770 ("**the Patent**") issued on November 8, 2016. A key prior art document during prosecution was patent no. 2,567,644 (issued long before, in 2007) which was referred to as reference "**D1**". Reference D1 described an oil sands mining and haulage method using conveyor belts. The Examiner took the position that the Patent overlapped with D1 with the primary exception of conveyor belts being substituted for haulage trucks. The Examiner did not consider a mere substitution of a fleet of haulage trucks for the conveyor belt element of D1 as inventive. The inventor responded arguing that due to the nature of the industry, prior patents, such as D1, would not be used with trucks instead of conveyors for certain steps. He also argued there were more changes than just the use of trucks. The Examiner was satisfied by these comments and eventually allowed the Patent to proceed to grant.

Filing of prior art against pending patent application

Shortly before the Patent issued, a challenger submitted four prior art documents, along with a statement of pertinency of the prior art. The submission argued that the Patent was obvious because it "has long been well known in the oil sands mining industry (and other mining industries) that conveyors and haul trucks can be used interchangeably to transport mined ore". The Examiner did not respond to these comments, and allowed the Patent to proceed to grant uninterrupted.

Re-examination threshold – substantial new question of patentability

A couple of months after grant, the same challenger requested re-examination of the Patent. This request provided eight documents, four that were previously submitted to the Examiner, and four new ones. The Re-examination Board combined reference D1 and several others to find that the re-examination threshold was met, because there was a substantial new issue of patentability (obviousness). Re-examination requires a new question of patentability, not entirely new prior art documents.

The substantive re-examination

The inventor argued during re-examination that his invention was not just about equipment, but rather it was a process flowsheet to increase reliability, availability, productivity, and costs. The inventor had an option to amend his claims, but it does not appear that he did so.

The Board went through the inventor's written submissions and provided a preliminary opinion which found that each of the steps was either already in the prior art, or would have been obvious to a person of skill in the art. This preliminary opinion also indicated that there had been no evidence of inventiveness based on an industry bias against his oil sands methods (i.e., no evidence that the prior art effectively taught away from his invention). The inventor filed further written arguments and appeared before the Board in person to make a presentation with further oral arguments.

The re-examination decision ultimately concluded with a certificate that cancelled all 15 claims of the Patent based on obviousness over D1, as well as another prior art reference, and the common general knowledge in the art.

This case provides a good illustration of the Canadian re-examination process. Re-examination is best used to challenge patents only where there is a very strong prior art basis. Although this case did not appear to be straightforward, it worked out for the challenger. The challenger does take a risk by filing a re-examination application rather than proceeding with invalidity litigation, because the challenger is not permitted to participate in the proceeding after filing the re-examination application (i.e., the inventor gets to make arguments to CIPO without counter-arguments from the third party). If budget permits, a court action for a declaration of invalidity provides the challenger a fuller opportunity to advocate against the patent and bring more types of evidence forward.

> **“At the very least, the prior art should make a clear case of obviousness.”**

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The 10 main steps to depicting industrial design protection in Brazil: what to expect and how to proceed?

Marina Castro, Head of the Patent and Innovation Department at Vaz e Dias Advogados & Associados, delivers a step-by-step guide to understanding the 2019 Design Manual for successful grant of industrial design protection.

Industrial design protection in Brazil has been an increasing tool to foster technological developments expressed in ornamental form of an object or arrangement of lines and colors applied to a product. Areas related to decoration articles, clothing, furniture and graphical user interface (GUI) of electronic products and mobiles have been leading the way to evidence the importance of such form of protection. Firstly, these products are very much dependent and vulnerable to the visual perception of consumers when disposed for sales. Secondly, decoration articles, clothing and furniture are indeed leading export products of Brazil whose creative new arrangements and forms conquered international consumers. Thirdly, Brazil holds a very large population mobile consumers and internet users. As an example, 160 million internet users in 2020 have been identified,[1] and 159.1 million social media users in 2021[2] and 205 million mobile connections in January 2021 equaled to 96.3% of the total population.[3] These figures demand higher GUI sensitive display production. Fifthly,

> **“How long can an industrial design registration last?”**

[1] Available at https://www.statista.com/topics/2045/internet-usage-in-brazil/
[2] Idem.
[3] Available at https://datareportal.com/reports/digital-2021-brazil

> **Deadlines for prosecution are usually calculated in days not in months.**

Brazil holds an Innovation Law since 2004 (Federal Law 10,973/2004) that foster the development of indigenous technology and creative products.

There is therefore a clear understanding that strengthening industrial design rights matches with the technological development interest and investments. Following up this belief, the Brazilian Patent and Trademark Office (BRPTO) issued the Manual of Industrial Design under Resolution INPI/PR no. 232/2019 on January 7, 2019. This Manual consolidated harmonized procedures to the prosecution of industrial design applications. Further, it promoted changes that recognize the protection of designs related to parts of object insofar as the claimed part relates to the whole object, among others.

Notwithstanding the changes, Brazil is not a member of the Hague Convention, yet which evidences the existence of peculiar rules to the prosecution of design in Brazil. This article aims to depict the key elements of the examination procedure adopted by the 2019 Manual and the legal framework for industrial design protection by means of 10 steps or information that an applicant should consider when seeking design protection.

1 No substantial examination procedure. How far shall my protection go?

Brazil is within the countries where no substantive examination is conducted to identify possible prior rights violation as a condition for the grant of registration. For the filing, there is a first exam related to the formal examination of the documents and then a second phase applied to quality, views of the presented design and aspects of the industrial design application, but not in relation the state of the art. Therefore, registration may take place in Brazil without examination procedure. Nevertheless, registration without substantial examination limits the property rights as the holder will be prevented from asserting its rights in court over third parties' infringement. To make third parties cease violation of industrial design registration, prior substantial procedure will be required. On the other hand, substantial examination is not demanded for a licensor to obtain royalties from a local licensee for the use of a registered industrial design. Therefore, substantive examination needs to be analyzed under a practical viewpoint and it is therefore recommended to avoid vulnerability to invalidation and protection against third parties. Applicant may request a substantial examination regarding a state of art search at any time during prosecution and the registration validity period.

2 How long can an industrial design registration last?

According to Article 107 of the IP Law (Law 9,279/96), registration will be valid for a period of 10 years from the date of filing, extendable for three successive periods of five years each. The extension request must always be made during the last year of registration validity, accompanied by proof of the official fees' payment. If the extension request has not been made by the end of the registration period, the registrant may do so within 180 subsequent days, upon payment of an additional fee. Neither proof of use is required for the renewal nor forfeiture procedure is stipulated by the IP Law on industrial design.

3 What are the deadlines and conditions for filing a design in Brazil under priority?

The deadline to claim priority for an industrial design registration in Brazil is six months from the filing in another Paris Convention signatory country following up Article 4 of the Paris Convention. The deadline for submitting the certified priority document is 90 days. Deadlines for prosecution are usually calculated in days not in months. This is important information since timeframes are calculated in other jurisdictions in months, thereby leading applicants to confusion. Despite being obvious, it is important to emphasize that normally 90 days is a period shorter than three months, since the filing date of priority document is a clear hindrance to protecting an industrial design, since the BRPTO takes these rules stringently and with no exception. Furthermore, a scanned copy of the certified industrial design application suffices for the purpose of complying with the certified copy of the design application. This means, in other words, that notarization nor legalization of the priority copy are not required. It is important to note that the local application must be identical to the priority document, otherwise the BRPTO can publish an office action and, in extreme cases, the BRPTO may reject the priority claim. It is recommended, for the latter case, that the same shapes and patterns presented in the priority document be used in the application for a Brazilian industrial design.

There is however a controversy in a second Manual complementing the 2019 Manual that specifies rules and requirements for the electronic filing entitled "BRPTO's Electronic Application Industrial Design Module User's Manual". The controversy relates to a statement informing that the deadline for claiming priority is 180 days, instead of the six months set by the Paris Convention. Further to that, Articles 16 and 99 of the IP Law reinforces the Paris Convention rules but it does make explicit the six months deadline for claiming priority that increases the existing error in the BRPTO Electronic Application. This confusion demands immediate amendment of the Second Manual so that such mistake cannot interfere in the request of design application. By any means, the time frame for claiming priority of industrial design in Brazil is six months from an earlier filed foreign application.

4 How does the grace period for industrial design work in Brazil? What are the requirements?

Novelty is an indispensable requirement for registering an industrial design. Therefore, the grace period situations are important as they are accepted exceptions to novelty. According to the IP Law, an industrial design where disclosure occurred within the 180 days preceding the date of filing the application or where the priority claimed will not be considered as included in the state of the art, provided such disclosure is made by the author of the industrial design, the BRPTO (official publication of a patent application filed without the consent of the author and based on information obtained from them or as a result of the author's acts). Thus, Brazil has a grace period in conditions above 180 days. Again, 180 days is shorter than six months. This difference between the deadline in months and days often gives a point of confusion and loss of the novelty requirement.

5 How should the 3D object or design be presented in the application?

It is possible to protect 3D objects applied in objects or surfaces with new and original visual result in its external configuration and that can serve as a type of industrial manufacture. Concerning the 3D object, industrial design protection in Brazil must be represented in solid lines by their seven main views (front, back, top, bottom, left, right, and perspective), in other words, the main views for a clear understanding of the design as a whole. Exceptions are only in the case of a mirror image or in the case of ornamental pattern protection. In this latter possibility a plan view is also possible. If the applicant does not provide the seven main views, the BRPTO will publish an office action and demand the amendment of it.

6 When can an applicant use dashed lines in the industrial design application?

Dashed lines are allowed when the applicant is filing an ornamental pattern. Thus, to evidence the ornamental pattern applied to a product, the product must be represented in dashed lines to illustrate that the applicant does not intend to protect the object, but only the ornamental pattern. This is an important rule, since it affects particularly GUI protection if the applicant also represents the screen where the GUI is viewed, in which case the screen needs to be in dashed lines. When the applicant wishes to present additional images in addition to the main views of the application as illustrative images, it is

> **The BRPTO does not accept partial protection of an industrial design.**

Résumé

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Marina Castro

The controversy relates to a statement informing that the deadline for claiming priority is 180 days, instead of the six months set by the Paris Convention

possible in these illustrative images to represent auxiliary objects or possibilities related to the main object in dashed lines. The BRPTO will never accept a 3D object configuration in one of the main views with dashed lines.

7 What are the type and quality of the images accepted for the filing?

The accepted images for an industrial design application are those formed by solid line drawings or photographs. Images must be on neutral background without any kind of shine, shadow, mask, or light effect. The images also must be with a minimum of 300 dpi. If the applicant does not provide the images with the quality described above, an office action will be published for compliance. The industrial design will only be granted or published with the images if the requirements are fulfilled, otherwise the application will be denied. In addition, the application my lose the priority rights if the priority document is different from the images filed in Brazil, for example, figures with less than 300dpi or image effects such as glow, shadow, mask, or light effect they can make it difficult to compare the priority document with the document deposited with the INPI.

8 Is partial design protection granted in Brazil?

The BRPTO does not accept partial protection of an industrial design. However, it is possible to protect the plastic form of an object which may refer to parts of objects when these parts are dissociable from the complex form to which they are integrated. Therefore, elements and fragments manufactured independently and having a completely defined physical form are subject to registration. Industrial design is not registrable if it refers to object parts that are not fully claimed in the drawings or photographs. In these cases, the configuration does not constitute either the plastic form of an object nor the ornamental set of lines and colors that can be applied to a product. If the applicant insists in a partial protection, an office action will be published for compliance and the presentation of the complete shape of the object, replacing the dashed lines by continuous lines. Failure to comply with the requirement will give rise to the granting of registration under art. 106 of the LPI.

9 How many designs can be filed together?

It is possible to file up to 20 variations per industrial design application. If the application has more than 20 variations, the BRPTO will publish an office action to request the applicant to divide the application into two or more applications based on Article 104 of the IP Law. It is important to highlight that the variations must have the same purpose and they must share the same preponderant distinguishing feature.

10 What is not possible to protect considering the aspects of the industrial design object?

The IP Law does not allow protection to representation of brands and logos on the surface of the 3D object or in the pattern of the ornamental pattern, nor designs contrary to moral or standards of respectability or that violates the honor or image of persons or ordinary shapes of the object, among other events set in Article 100 of the IP Law. Furthermore, exploded view representations should not be included in the registration application, as they do not constitute the assembled form of the object nor reveal its external configuration. If the applicant insists and files the exploded view, an office action to demand correction will be published.

Concluding comments

The objective is to guide better investors on how to smoothly navigate possible rough seas and obtain an industrial design registration. The 2019 Design Manual is indeed an adequate document that evidences the improvements to examination standards of industrial design applications. Besides disclosing mandatory demands for the acceptance of the application, the Manual accepted complementary shapes of the products, including those amplified ones that allow the examiner to comprehend where the protection of the product will take place. Further to that, rules related to priority claims are better set as the applicant may understand how the examiners will analyze the priority claims.

Nevertheless, there are errors in the Manual that leads to confusion about the timeframe for priority in Brazil under the Paris Convention. Further, the BRPTO applies stringently rules and deadlines linked to prosecution. The 10 highlighted steps towards industrial design application attempt to make investors understand concisely the framework for industrial design and how to adopt the procedure of the 2019 Design Manual.

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Eurasian industrial designs versus Russian industrial designs

Elena L. Davydova, Chief of Ineureka LLC IP Protection Department, evaluates the benefits of the recently introduced Eurasian industrial design patent system in comparison to the Russian industrial designs patent system.

The event all of us have been looking forward to for many years at last happened on June 1, 2021. The Eurasian Patent Office (hereinafter the EAPO) has started to process applications for industrial designs within the framework of the Protocol to the Eurasian Patent Convention on the Protection of Industrial Designs (hereinafter the Protocol).

The Protocol is made as special agreement in accordance with the Article 19 of the Paris Convention. The Protocol has been signed by eight contracting states: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tadzhikistan and Turkmenistan; but at the moment just six participants of the Protocol have ratified it. They are Armenia, Azerbaijan, Kazakhstan, Kyrgyzstan, Russia and Tadzhikistan. Therefore, so far a Eurasian patent for an industrial design will be valid just for territories of these six states, and selection of states for validation of the patent is not provided.The aim of this overview is to show the main points of the Eurasian legislation in respect to industrial designs and to compare the applications prosecution procedures in the EAPO and in the Russian PTO.

As it is in the Russian Federation, the Eurasian industrial design patents protect the solutions of factory-made or home-made articles. The scope of legal protection for an industrial design which is provided by the Eurasian design patent is determined by the set of essential attributes of the industrial design that are reflected in images of an article.

Similar to the Russian industrial designs the Eurasian industrial designs are patentable when they are novel and original (the Rule 78(1-3) of the EAPO's Patent Instruction). The criteria of patentability "novelty" and "originality" are defined in the same way as they are defined in the Civil Code of the Russian Federation:

Elena L. Davydova

The event all of us have been looking forward to for many years at last happened on June 1, 2021.

- An industrial design shall be deemed novel if the aggregate of its significant features reflected on images of the article's appearance is not known from the information that was made available to the public worldwide before the priority date of the industrial design.
- An industrial design shall be deemed original, if its significant features are stipulated by the creative nature of the article's features, in particular if it is not known from the data that has become generally available worldwide before the priority date of an industrial design that is the solution of the appearance of an article of similar purpose making upon an informed consumer the same general impression as the industrial design shown on images of the article's appearance.

Résumé

Elena L. Davydova, Russian and Eurasian Patent Attorney, Chief of Ineureka LLC IP Protection Department. Elena graduated from Moscow Auto-Construction Institute (Honors Diploma) with a Master's Degree in Data Science. Elena has more than 15 years of experience in the field of Intellectual property protection and is a Member of Russian Chamber of Patent Attorneys. Elena is also and active Member of AIPPI, INTA, ECTA, AIPLA, IPO.

One application is allowed to contain up to 100 industrial designs which can be considered as variants.

The absolute and relative grounds for refusal of registration of Eurasian industrial designs are also similar to the ones in the Russian legislation. They are listed in the Rule 78(6) of the EAPO's Patent Instruction.

The right of priority with respect to an industrial design shall be recognized in accordance with the Paris Convention.

The prosecution processes are carried out only in Russian language.

As for particularities of the prosecution of Eurasian designs applications, one application is allowed to contain up to 100 industrial designs which can be considered as variants. The requirements to the unity of an industrial design are not very strict: all the variants contained in one application just should be classified within the same class of the Locarno International Classification (even not by a subclass!). In this view the Eurasian requirements stand in contrast to the Russian PTO's requirements to the unity of an industrial design which are very strict (in our practice just a group of industrial designs is allowed to be filed with the Russian PTO as variants of an article within one application only when they have the same shape but different colors).

The number of designs within one Eurasian application defines the amount of official fees not only at the filing stage but also at the stage of registration and issue of a patent, and during the maintenance period. In the table below (where "N" is the number of designs within one application) we provide the way of calculation of the official fees in rubles depending on the number of designs within one application (see table below).

Thus, in spite of the fact that Eurasian official fees are much higher than the official fees of the Russian PTO, the practice shows, that beginning from four industrial designs within one Eurasian application, filing an application will already cost the applicant less than filing four separate design applications with the Russian PTO, even if your agent proposes you a discount of 50% for agent fees. Needless to say that maintenance of one Eurasian patent containing some industrial designs seems perfectly competitive in comparison with the maintenance of the same number of Russian designs patents. There is no official fee for the first five-years period of maintenance in EAPO at all, and, for example, the official fee for maintenance of a Eurasian patent containing two industrial designs for the second five-years period (i.e. for 6-10 years) will be 14000 RUB (7000 x 2) while the official fees for maintenance of two Russian patents for industrial designs for the same five-years period will be 37800 RUB (18900 x 2), and that is disregarding the agent fees.

The procedure of application prosecution in the EAPO can be considered as registration system. While examination of an application at the EAPO does not carry out the kind of all-encompassing searches that the Russian PTO does, in order to prevent granting Eurasian patents to unfair applicants or to faithful applicants who are not aware of the existing

	Official fees (RUB)		
N ***(the number of designs within one application)***	**Filing an application**	**Registration and issue of a patent**	**Maintenance**
1	20000	15000	0 (for 1-5 years)
From 2 to 10	20000 + 10000 x (**N** - 1)	15000 + 7500 x (**N** - 1)	7000 x **N** (for 6-10 years) 9500 x **N** (for 11-15 years)
From 10 to 100	20000 + 10000 x 9 + 5000 x (**N** - 10)	15000 + 7500 x 9 + 3750 x (**N**-10)	12000 x **N** (for 16-20 years) 14500 x **N** (for 21-25 years)

solutions of the articles' appearance, that might lead to increasing conflict situations and overloading courts, the EAPO provides an opportunity to file a statement of opposition against a grant of a patent. There two timeframes for filing statements of opposition:

- two months after publication of an application;
- six months after publication of a patent (so-called 'administrative cancellation of a patent').

A Eurasian industrial design application is published within one month after preliminary (formal) examination of the application is completed. After publication any person who considers the claimed industrial design not to be novel and original or considers that protection of the claimed industrial design cannot be provided on the grounds listed in the Rule 78(6) of the EAPO's Instruction, can file a statement of opposition against the grant of a patent. Filing the statement of opposition should be accompanied by payment of the official fee in the amount of 20000 RUB. Within seven days the EAPO notifies the applicant about received statements of opposition and publishes the information about them. After that the applicant's opinion in regard to the statements of opposition can be presented to the EAPO within one month, and then the substantive examination of the application begins.

In order to maximize protection of the rights of persons who are not interested in granting a Eurasian industrial design patent the EAPO provides the procedure of administrative cancellation of a patent, according to which a patent can be invalidated based on a statement of opposition filed by any person within six months after patent publication. The grounds for opposition can be the same as above and some more. The official fee in this case is 30000 RUB.

In addition, the EAPO normative documents provide a mediation procedure. During the mediation procedure the opposite parties may reach an agreement which will be taken into account by the EAPO. In case of mediation the examination of an application is suspended for six months. If the opposite parties have not made any agreement and one of them is not satisfied with the EAPO's decision on the matter, there is still a possibility of appellation to the President of the EAPO within four months after issue of the decision.

Even when all the above terms for opposition have been missed, a Eurasian industrial design patent still can be invalidated by the Courts or other relevant authorities of the contracting states.

As for the timeframes of examination duration in the EAPO, they are not specifically defined by the Eurasian normative documents, but by the time of writing this article two Eurasian patents have already been granted and published. The applications for both of them were filed in June 2021 and granted in October 2021. So, we can see that when there have been no oppositions to a Eurasian design application, the duration of examination took just five months from the filing date to the granting date. Here it should be noted that some additional time, which passed from issue of a decision on allowance to payment the official fee for granting a patent, is included in these five months as well. That is another advantage of Eurasian design applications in comparison with the Russian design applications which, on average, are considered at the examination stage for eight-nine months.

The initial term of validity of a Eurasian industrial design patent is a five-year period and as it was mentioned above this term does not claim any official fees. During the last year of the validity term the patent validity can be prolonged for the next five-year period. A validity of the Eurasian patent can be prolonged four times, so the total period of validity can reach 25 years. If the deadline for payment of the official fee for patent validity prolongation is missed, there is a grace period of six months within which the official fee should be paid with the 50% penalty.

In conclusion, in order to sum up all the above I would like to note that it is obvious that patenting industrial designs in the EAPO looks quite attractive, has certain advantages comparing with patenting industrial designs in the Russian PTO, and in my opinion, the Eurasian industrial designs could eventually become very serious competitors to the Russian ones.

The Eurasian industrial designs could eventually become very serious competitors to the Russian ones.

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Effects of *Measures for the Implementation of Early Resolution Mechanism for Drug Patent Disputes* on R&D and marketing of generic drugs in China

Dr. Yongqiang Qi, Partner and Patent Attorney at Corner Stone, reviews the benefits offered to the development of generic drugs in China as a result of the patent linkage system to lawfully deliver good, cheap, and effective substances into the market.

On July 4, 2021, the National Medical Products Administration (NMPA) of China and China National Intellectual Property Administration (CNIPA) jointly released *The Measures for the Implementation of Early Resolution Mechanism for Drug Patent Disputes* pursuant to Article 76 of The Patent Law of the PRC which entered into force on June 1, 2021. This marks the establishment of a frame of a drug patent linkage system in China and the formation of a "China Program" for the early resolution of drug patent disputes. The drug patent linkage system links the procedure for marketing approval of relevant drugs with the procedure for resolution of patent disputes over relevant drugs, protecting the interests of innovative drug manufacturers to stimulate their continuing research, and development of innovative drugs and showing a way for manufacturing and marketing of lawful generic drugs.

The contents of the Measures include: (1) the drug regulatory and administrative department under the State Council will establish a patent information registration platform for marketed drugs in China; (2) the scope of patent information to be registered does not include the patents on intermediates, metabolites, crystal forms, preparation methods, or test methods; (3) an applicant for a generic drug shall make a declaration on each drug patent related to the generic drug; (4) the time frame for a patentee or any interested party to raise objections, if any, is 45 days; (5) the drug regulatory and administrative department under the State Council will set a nine-month period for awaiting the approval for marketing of chemical generic drugs; (6) the drug regulatory and administrative department under the State Council will perform examinations and approvals by categories on the basis of the category of declaration on drug patents made by the chemical generic drug applicants; (7) a market exclusivity period will be granted to the first chemical generic drug that has successfully challenged the drug patent and obtained marketing approval; within 12 months of approval for the drug, other applications for the same drug will not be approved.

The design of this drug patent linkage system reflects, to a great extent, a balance between innovation and imitation. On the one hand, the generic drug applicants' notifications enable the innovative drug patentees to exercise their right to file patent lawsuits and know the applications for marketing of generic drugs so as to make infringement disputes resolved wherever possible before the generic drugs come on the market and thus avoid the detrimental effect on their market produced by the generic drugs' coming on the market; on the other hand, the right granted to generic drug applicants to make declarations on non-infringement or patent invalidation and the market exclusivity period granted to the first generic drug after it has won the lawsuit against innovative drug over patent challenge encourage generic drug applicants to challenge innovative drug patents so as to facilitate generic drugs' coming on the market as quickly as possible and improve access to the drugs. Only in this way can innovative drugs and generic ones be developed together and, in turn, can the development of the whole pharmaceutical industry be achieved.

> **"The drug patent linkage system links the procedure for marketing approval of relevant drugs with the procedure for resolution of patent disputes over relevant drugs."**

Dr. Yongqiang Qi

In other words, drugs are necessary for sustaining human life and keeping personal dignity. Improving access to drugs needs to consider both the boost to R&D of new drugs and the reduction in drug price. On the one hand, measures must be taken to boost R&D of new drugs, fully protect R&D achievements in new drugs, and provide an institutional guarantee for making huge gains from new drugs, so as to stimulate the sustainable R&D of drugs and provide a basis for the manufacturing of generic ones; on the other hand, the reduction in drug price is based on the improvement in the ability of generic drug manufacturers so that generic drugs they produce can really be good, cheap, and effective substitutes for innovative ones.

The patent linkage system specified in Article 76 of The Patent Law of the PRC becomes

Résumé

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Focused on patent matters, including drafting applications, replying to OAs, invalidations, prosecution, etc., Yongqiang engaged in research in the Chinese Academy of Sciences for seven years before going to Japan to study and work for eight years. He has practiced as a patent attorney for 15 years and handled a large number of cases for domestic and foreign companies. He studied European patent system in the UK in 2012, and studied Japanese patent system in Japan in 2016. He joined CORNER STONE in 2018 and is responsible for the Japanese Department. His rich experience and outstanding skills to look after clients from Japan and other parts of the world have made him one of the core members of our patent team.

operational after the Measures came into force. In our opinion, most of the measures are designed to favor generic drug manufacturers obviously for the reason that generic drugs dominate the pharmaceutical industry in China in the present.

As we see it, the sections (2), (5) and (7) of the aforementioned seven contents of the Measures are designed to favor generic drug manufacturers, obviously. Firstly, under Section (2) of the Measures, which says that the scope of patent information to be registered on the registration platform does not include the patents on intermediates, metabolites, crystal forms, preparation methods, or test methods, generic drug manufacturers may, on the basis of patent analysis, develop generic drugs extensively and apply for patents for their R&D achievements to protect their generic drug technologies. It should be noted that the Measures specifies registration of only the patents on pharmaceutical active ingredient compounds, patents on pharmaceutical composition containing active ingredient(s), and patents on pharmaceutical uses, not including the patents on intermediates, crystal forms, preparation methods. Therefore, generic drug applicants cannot make decisions depending on the information registered on that platform alone, but take into account other relevant patents, including derivative patents, filed by the patentees. Secondly, Section (5) of the Measures suggests a dual mechanism (via courts or via CNIPA) for settling patent disputes. Generic drug applicants may choose either of them. As for the nine-month waiting period, in particular, it is usually difficult for a court to come to a judgment within such a short period, and therefore it would be better for generic drug applicants to seek resolutions via CNIPA. This is actually an encouragement to generic drug manufacturers' actively making investments. The investment in consistency evaluation of generic drugs is huge, and the litigation over drug patent disputes is more time-consuming and more complex than that over ordinary patent infringement. This system provides an early resolution mechanism via CNIPA, mitigating litigation fatigue of generic drug applicants. Thirdly, per Section (7) of the Measures, the first generic drug that has successfully challenged the drug patent and obtained marketing approval will enjoy a 12-month market exclusivity period. This presents an enormous challenge to generic drug manufacturers. They will have to increase their R&D capability and R&D speed on the one hand, and watch their competitors' speed and achievements on the other. This will greatly stimulate or encourage generic drug applicants to take the initiative in challenging drug patents and filing applications for patent invalidation. There will be some more fierce competition for the qualification for the first generic drug manufacturer among generic drug manufacturers, thus accelerating R&D of generic drugs and facilitating technological innovation in this field in China. Besides, we expect that the provision for the 12-month exclusivity period, although the period is not long, will lead generic drug manufacturers to mount a challenge to more drug patents and that lawsuits over patent invalidation will considerably increase in number. This will, in turn, further promote an improvement in the preparation of drug patent documents, which would be favorable to the professionals in the patent agency field.

> **"The design of this drug patent linkage system reflects, to a great extent, a balance between innovation and imitation."**

Meanwhile, these provisions have the disadvantage that foreign innovative drug manufacturers would be reluctant to adopt this early resolution mechanism for drug patent infringement to resolve disputes. Even worse, their relevant drugs would not come on the market in China so that there would be no drugs to be imitated in China. The advantage is, however, that the drug patent linkage system encourages generic drug manufacturers to lawfully launch good, cheap, and effective substitutes for innovative drugs earlier through patent challenge and patent avoidance so as to improve access to drugs.

After the early resolution mechanism for drug patent disputes is put into operation, the procedure for invalidating patents will no doubt be increasingly important. The CNIPA's decision on patent re-examination and patent invalidation will be favorable to applications for generic drug marketing approval. Therefore, one aspect to which generic drug manufacturers must attach importance is that they should take advantage of the mechanism to mount an effective challenge to drug patents.

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Federal Circuit rejects constitutional challenge to PTAB's structure

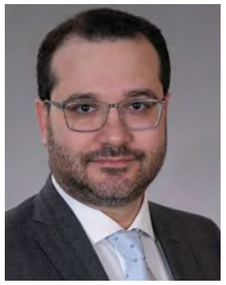
David McCombs, Eugene Goryunov, and Jonathan Bowser of Haynes & Boone evaluate the rejections made by the Federal Circuit in the *Mobility Workx, LLC v. Unified Patents, LLC case.*

Third parties may challenge the validity of an issued patent before the Patent Trial and Appeal Board (PTAB). Under the America Invents Act (AIA), a third-party initiates review of the patent by filing a petition for *inter partes* review (IPR) or post-grant review (PGR). IPR petitions are often filed by parties accused of infringing a patent.

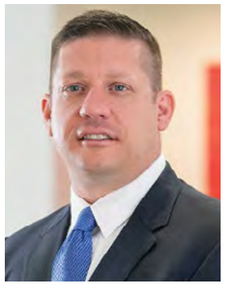
A three-member panel of administrative patent judges (APJs) of the PTAB reviews a petition and any preliminary response filed by the patent owner, and then may institute an IPR or PGR trial if the petitioner's patentability challenge has merit. 35 U.S.C. §§ 314(a), 324(a). At the conclusion of a trial, the PTAB issues a final written decision indicating whether the petitioner has shown that the challenged claims are unpatentable. When filing a petition, the petitioner pays a request fee and a post-institution fee. If the Board denies institution, the petitioner may request a refund of the post-institution fee.

In *Mobility Workx, LLC v. Unified Patents, LLC,* the patent owner appealed the PTAB's final written decision finding that its claims were unpatentable. On appeal, the patent owner raised a constitutional challenge to the structure of the PTAB, arguing that "the structure and funding of the Board violates due process." 15 F.4th 1146, 1152 (Fed. Cir. 2021). The patent owner argued that APJs "have an impermissible financial interest in instituting AIA proceedings," and "have an interest in instituting AIA proceedings to generate fees to fund the agency and ensure future job stability." Id. at 1150. In *Mobility Workx*, the patent owner tried to liken AIA trial proceedings to previous U.S. Supreme Court cases finding due process violations when a mayor presiding over criminal proceedings either received compensation if the defendant was convicted, or levied fines that were used to fund community finances for which the mayor had executive responsibilities. Id. at 1152-53 (citing *Tumey v. Ohio*, 273 U.S. 510 (1927), and *Ward v. Monroeville*, 409 U.S. 57 (1972)).

David McCombs



Eugene Goryunov



Jonathan Bowser

The U.S. Court of Appeals for the Federal Circuit rejected the patent owner's constitutional arguments, finding that the structure of the PTAB did not create a due process violation.

No temptation to institute

First, the Federal Circuit held that the fee-generating structure of AIA trial proceedings does not create an impermissible "temptation to institute…in order to collect post-institution fees [] for the merits stage" of an instituted trial "and fund the agency." *Id.* at 1153. Patent Owner calculated that "24% of the PTAB's collections are dependent on instituting AIA trial proceedings," and senior judges of the PTAB "oversee fiscal planning and expenditures" of the PTAB. *Id.* at 1154. The Federal Circuit was not persuaded by this argument, finding that the Director of the USPTO, not the PTAB's senior judges, has responsibility for the entire USPTO's budget, including the PTAB. The Federal Circuit found that the role of senior leadership of the PTAB in budgeting is "too remote to constitute a due process violation," unlike *Tumey* and *Ward*. Further, the Federal Circuit found that the USPTO is a fee-funded agency for which Congress annually sets the budget, such that "the agency's fees do not automatically become available to the agency." *Id.*

No individual interest in instituting

The Federal Circuit also rejected Mobility Workx's argument that "individual APJs have an unconstitutional interest in instituting AIA proceedings because their own compensation in the form of performance bonuses is favorably

affected." *Id.* at 1155. The Federal Circuit noted that APJs receive payment under a fixed rate of basic pay set by the Director (35 U.S.C. § 3(b)(6)) and by a performance bonus. The performance bonus is determined through an annual review where the individual APJ must "generally earn at least 84 decisional units per year." *Id.* at 1155. Mobility Workx argued that APJs have a financial incentive to institute review because APJs can then author final written decisions after review is instituted, since the number of decisions authored is one factor in allocating performance bonuses or salary increases to APJs. *Id.* at 1155-56. The Federal Circuit disagreed with this argument, finding that, unlike *Tumey* and *Ward* where fees were collected only upon the allocation of a fine, an APJs' number of "decisional units" is based on the number of decisions authored and not on the outcome of those decisions. The Federal Circuit reasoned that "[e]ven though an APJ will earn decisional units for a follow-on merits decision if he or she issues a decision instituting an AIA proceeding," there was no evidence "showing that APJs institute AIA proceedings to earn sufficient decisional units to qualify for a bonus." *Id.* at 1156. Further, the Federal Circuit found that APJs

> **If the Board denies institution, the petitioner may request a refund of the post-institution fee.**

Résumé

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David is primary counsel for many leading corporations in *inter partes* review before the US Patent Office's Patent Trial and Appeal Board and in appeals before the Federal Circuit. His practice includes appellate argument, patent litigation, licensing, and dispute resolution.

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Eugene is a partner at Haynes and Boone with nearly 15 years of experience representing clients in complex patent litigation matters involving diverse technologies, from consumer goods to high tech, medical devices, and therapeutics.

Jonathan Bowser
Jonathan focuses his practice on patent litigation disputes before the PTAB and federal district courts, and related appeals before the Federal Circuit.

CONSTITUTIONAL CHALLENGE TO PTAB'S STRUCTURE

"The Federal Circuit found that the USPTO is a fee-funded agency for which Congress annually sets the budget."

can author other opinions in other cases before the PTAB (e.g., appeals of examiner rejections), such that "even if there were an incentive to institute AIA proceedings to earn decisional units, any interest APJs have in instituting AIA proceedings to earn decisional units would be too remote to constitute a due process violation." *Id.*

While the Federal Circuit rejected Mobility Workx's constitutional challenge to the structure and funding of AIA trial proceedings, Judge Newman's partial dissent in Mobility Workx may give rise to another constitutional challenge to AIA trial proceedings following the Supreme Court's decision in *United States v. Arthrex*, 141 S.Ct. 1970 (2021). In *Arthrex*, the Court held that APJs, as inferior officers, may not issue "final" decisions on behalf of the USPTO without discretionary Director review. Judge Newman argued that the issuance of institution decisions by APJs "appears likely to violate the Appointments Clause" because decisions to institute are "final and non-appealable" under 35 U.S.C. §§ 314(d), 324(e). *Mobility Workx*, 15 F.4th at 1159. Litigants before the PTAB should pay careful attention to see if this line of argument gains traction at the Federal Circuit.

This article reflects only the present personal considerations, opinions, and/or views of the authors, which should not be attributed to any of the authors' current or prior law firm(s) or former or present clients.

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Women in IP Leadership

Celebrating achievements and continuing the empowerment of women

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We give special thanks to Vera Abogados Asociados for their dedication and support in continuing the empowerment of women in IP by facilitating this opportunity.

This segment is dedicated to women working in the IP industry, providing a platform to share real accounts from rising women around the globe. In these interviews we will be discussing experiences, celebrating milestones and achievements, and putting forward ideas for advancing equality and diversity.

By providing a platform to share personal experiences we aim to continue the empowerment of women in the world of IP.

This segment is sponsored by Vera Abogados Asociados, from Colombia, who, like *The Patent Lawyer*, are passionate to continue the empowerment of women. Vera Abogados Asociados' sponsorship enables us to remove the boundaries and offer this opportunity to all women in the sector. We give special thanks to Vera Abogados Asociados for supporting this project and creating the opportunity for women to share their experiences, allowing us to learn from each other, to take inspiration, and for continuing the liberation of women in IP.

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"Intellectual property has a dual function: on the one hand, to stimulate creativity and on the other, to foment access to culture and knowledge. In this dual dimension, the participation of all social actors is crucial and even more so, with those who possess such a creative capacity to produce works and inventions susceptible to protection by this specific area of law.

Nevertheless, in accordance with WIPO figures, in the case of international patents, the participation of women and other groups described as diverse is scarce, largely because in many countries only the men have access to and receive sufficient education to prepare them for it, as well as them being the ones who are most easily able to raise capital, as for chauvinist reasons, they are perceived to generate more credibility.

It is therefore the duty of all concerned to bridge the gap and generate equal opportunity for men, women and diverse groups so that IP can rightly comply with its dual function."

Natalia Vera Matiz, Partner at Vera Abogados Asociados

If you would like the opportunity to share your experiences with *Women in IP Leadership*, would like to nominate an individual to be involved, or would like to learn more about sponsorship, please contact our Editor.

Chantal Hoffelner: Patent Attorney, Smit & Van Wyk

An interview: inspirations, experiences, and ideas for equality.

"I studied hard, worked hard, and tried to learn as much as possible from my colleagues."

Chantal is a director and admitted patent attorney at Smit & Van Wyk, specializing in biotechnology, medical, pharmaceutical and life sciences. Before joining Smit & Van Wyk in 2009, she worked as a researcher in the Microbial, Biochemical and Food Biotechnology Department at the University of the Free State.

Qualifications: B.Sc Biochemistry and Microbiology; B.Sc (Hons) Microbiology (Cum Laude) M.Sc Microbiology (Cum Laude); LLB; SAIIPL (Qualified Patent Practitioner).

Areas of expertise:

- Drafting and prosecution of patent applications with a focus on life sciences.
- Conducting patent subject matter and novelty searches.
- Vetting and amending foreign patent applications to ensure compliance with South African law.
- Registered design filing, prosecution and enforcement.
- Plant breeder's right applications, prosecution and litigation.

What inspired your career?

Becoming a lawyer was never a career I even considered. I have always been very interested in science and biology and excelled in those subjects during my school years. I was less interested in languages and did not enjoy public speaking, in fact, I probably suffer from a level of performance anxiety or stage fright.

From a young age, I have always wanted to become a scientist and spent countless hours doing experiments in our backyard. It was thus an easy decision to go on to study microbiology and biochemistry at university. I ended up completing my Master's degree in Microbiology and thereafter worked as a research manager at the University.

In South Africa, the patent attorney field is very small and by that stage I had never met or even heard of a patent attorney. During my time working for the university, one of the employee

> The patent attorney field in South Africa is still very much male dominated and as a female we need to compete with them on an equal footing.

benefits were that I could study at no cost. Although I enjoyed working in the laboratory, I wanted to do something more. At that stage South Africa didn't have a thriving Biotech sector and it was difficult to find a position with a private company. Most people in my situation decided to complete a PhD and stay in the academic field, however this was not a career path I had envisioned for myself. I then decided to study a law degree, mainly because I thought it was a good degree, in general, to have and hoped that I could somehow combine it with my science qualification.

I truly enjoyed everything about my legal studies, and during an intellectual property module discovered the patent law field. Becoming a patent attorney just perfectly matched my vision and would allow me to stay in the science field, but not be bound to a laboratory or academia.

Due to the small patent law field in South Africa, it was very difficult to find a position at an Intellectual Property law firm, but after many attempts I managed to find a position at a boutique IP law firm in Pretoria, at which I could complete my apprenticeship.

It was thus not a case of my career being inspired by anything specific, but rather a path which opened up due to various previous decisions I had made.

How have you found the pathway to your current position? And can you offer advice from your experience?

The best word to describe the path is "long". Luckily, I initially didn't quite realize how long the path would be, and how much studying would be involved, otherwise I might have changed my mind.

I studied towards my MSc degree for five years, and thereafter worked at the University while studying law. By that time, most of my peers had started working and I was feeling rather behind in terms of my career. I then started working as a candidate patent attorney, while also completing the remainder of my four-year law degree. In addition to that, I had to complete the attorney board exams to qualify as an attorney in South Africa, and also complete the patent board exams to eventually qualify as a patent attorney. 10 years after finishing school I was finally qualified as a patent attorney. This was obviously only the first step of a career in patents.

I was lucky enough to start my legal career at an exceptional law firm, which made my path a lot easier than what it could have been. The firm is a boutique firm, and only specializes in intellectual property. The ethos of the firm is very much to work together as a team, to support each other, and thereby ensuring that our clients are serviced to the best of our ability. The firm comprises of mainly women, and it is also women who occupy all of the management positions at the firm. The founding director of the firm is very progressive, and I have thankfully never experienced any differential treatment between male and female employees.

I studied hard, worked hard, and tried to learn as much as possible from my colleagues. I was promoted to associate level in 2014 and became a director of the firm in 2017.

I can honestly say that I absolutely love my work. Being part of a smaller firm exposes me to many different types of technological inventions, and you learn something new every day. It drives me to assist clients to the best of my ability, and to add value to their businesses. Patent law must be one of the most intellectually challenging but satisfying professions in the legal field. When people ask me now what I would have been if I could choose a career again, I cannot think of any other field I would rather be in.

What challenges have you faced? And how have you overcome them?

When I initially started working in the legal field, it was a major challenge for me to engage with clients. I am a scientist at heart, and public speaking doesn't come naturally to me. I still remember the first client consultation I had to lead, I had anxiety for two days before that and had to drink a beta blocker that morning. Eventually, as I became more experienced, consultations became easier and easier. Today it is not an issue at all, and I actually enjoy consulting with new clients, learning from them, and from my side positively contributing to their business. It is important to not be held back by something you think you are not good at; we can learn to do anything we set our minds too, it might not be comfortable, but it is usually worth it at the end.

As a woman, I have unfortunately experienced some male clients initially being skeptical of my ability. It seems, that in their eyes, a woman would not as easily understand a technical invention, and they would prefer to work with a male patent attorney. Usually, this skepticism is over after the first few minutes of the consultation.

The patent attorney field in South Africa is still very much male dominated and as a female we need to compete with them on an equal footing. I have always made sure that I learn as much as possible, put in the extra hours, and worked hard to ensure that I can do my job to the absolute best of my ability. Maybe it comes easier for males, I am not sure, but I think as women we at least perceive our career paths to be harder, which makes us put in the extra effort. This leads to exceptionally skilled female attorneys.

A further challenge is obviously balancing family life (specifically kids) and work life. I am in the fortunate position where I work flexible hours, and work at a firm who supports and understands the challenges that come with having small children. I still feel guilty when I have to work from home to look after a sick toddler, but I think with the right work ethic and the support of colleagues, there is no reason that a mom cannot contribute as effectively to their work as others.

What would you consider to be your greatest achievement in your career so far?

After studying and working for many years, and jumping through what felt like endless hoops, eventually qualifying as a patent attorney was a major achievement for me. Everything that happened thereafter was a consequence of that initial effort. Being promoted to a director of the firm was also a significant step, which allows me to now be involved with a whole set of other functions, such as financial management, training, business development, and human resource management.

What are your future career aspirations? And how will you work to achieve them?

On a personal level, I aspire to continue learning and improving my skills as a patent attorney. It is important to not stagnate or be satisfied with your knowledge, but to learn more and become better. "If you think you know everything, you will never learn anything".

My aspiration for our firm is that we will grow, while retaining the special culture that we have. Our employees are exceptionally important to us, and their career growth and happiness is paramount to the success of the firm.

What changes would you like to see in the IP industry regarding equality and diversity in the next five years?

I would like to see the IP industry becoming more involved with the education of younger people. Change has to start with the way we raise our kids and how we educate them. Girls and boys need to be exposed to the possibilities of a career in intellectual property, and we need to create the opportunities for them to enter the field. IP professionals, specifically women IP professionals, need to get more involved with education. When you ask a child what they would like to be when they grow up, the answer is always: a doctor, a fireman, a policeman or the like. Kids follow role models, and ultimately this influences the career choices they make later. If we want to diversify the IP industry, more needs to be done to provide early, equal exposure for young people of all backgrounds.

How do you think the empowerment of women can be continued and expanded in the IP sector?

I personally feel women empower themselves, but I think the IP sector can do more to alleviate some of the difficulties women experience during their careers. Things like equal pay, equal training, equal career promotion is non-negotiable.

With the recent lockdowns around the world, it has been shown that people can work just as effectively from home as they do from the office. Flexible working hours go a long way in assisting women to balance their home and work lives more effectively, and I think it is something that should be promoted.

Women in the field also need to be willing to mentor and train younger women. We need to support everyone equally, while having cognisance of the different difficulties males and females in the field face.

> Flexible working hours go a long way in assisting women to balance their home and work lives more effectively, and I think it is something that should be promoted.

Will the Polish Patent Office operate more quickly than the EUIPO?

Dr Anna Sokołowska-Ławniczak questions the proposed changes to Industrial Property Law currently being drafted in Poland, asking if they are all actually beneficial for the industry.

This is the objective aspired to according to the premises of an amendment currently being drafted to the Industrial Property Law – procedures are to be handled more quickly and be more applicant-friendly. This is a very interesting prospect, especially as the bill itself is also intended to be passed quickly, as soon as Q1 2022, but what else is behind the envisaged changes, and are all of the changes a good thing?

Two issues are especially important regarding **patents**:

1. The time period for the Polish Patent Office to produce a compulsory report on the state of art will be reduced – from nine months to six months. In practice, this report is the first indication of the likelihood that a patent will be granted. If the report is produced more quickly, this may mean that the applicant has more time to take the next steps before the priority date.
2. A new *provisional registration* system will be introduced – the legislation will mean that the priority date for registration of an invention can be stipulated once the simple procedure has been completed, with no danger of it losing its innovative features. Provisional registration will be possible to reserve priority for a patent. Under the bill, the procedure will be made as simple as possible through various

Dr Anna Sokołowska-Ławniczak

means, such as no requirement to file the patent claims.

This quite revolutionary change applies to utility model registrations, for which a register system would be introduced (in the same way as for industrial designs) and not an examination system. The examination system is the system in place today – the Polish Patent Office examines the grounds for granting protection of the utility model. This would certainly reduce the time in which protection of the design is granted, while on the other hand this right could be 'devalued' – there would be a shift in stress from the registration procedure to a subsequent invalidation procedure, which would undermine certainty in legal transactions.

The major changes intended to streamline the granting of protection for trademarks include replacement of the objection system with an opposition system, and a reduction of the time limit for filing opposition from three to two months from the date of publication of the application. In addition, the current two-month compulsory cooling-off period will be abolished. It is interesting why Polish lawmakers wish to reduce these time limits, as they are effective in the EU procedure, and complaints about tardiness of the EU procedure are rare. Also, the abolishing of the compulsory two-month cooling-off period is not a good thing. It is clear from experience that this 'forced action' has meant that on several occasions settlement proceedings have been commenced and a settlement reached.

The coming months will reveal whether all of the ideas described above, and others as well of course, will be processed in the Sejm and adopted. QI 2022 promises to be interesting in this regard.

> **What else is behind the envisaged changes, and are all of the changes a good thing?**

Résumé

Anna Sokołowska-Ławniczak, PhD, Partner, patent attorney

Anna leads the industrial property and brand management team as part of the intellectual property practice at Traple Konarski Podrecki and Partners. She advises on every aspect of industrial property rights: from developing strategies to protect individual objects of industrial property to maintaining and enforcing industrial property rights under Polish, European and international procedures.

Anna has extensive experience in litigation before the Polish Patent Office and the EU Intellectual Property Office, as well as in court disputes concerning industrial property, combating unfair competition, and copyright law. She manages complex projects aimed at obtaining and maintaining industrial property rights.

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Patents in Latin American countries: exceptions to the rights conferred, patentable subject matter, and potential markets

Susana Ruiz Pérez, Patent Attorney at H&A, explains the importance of distinguishing the classification between resident and non-resident patent owners, what is exempt from patent protection in which jurisdictions, and the protection of technologies that mitigate climate change.

In terms of intellectual property, Latin America has taken steps to improve its position in recent years. For companies that must decide whether to invest in a country or region, it is key to consider whether their products and services are legally protected. Other important factors are political stability and government restrictions on investments or capital flows. According to the OMP, in 2017, 57,600 patents were registered in the Latin American and Caribbean region and there were 715,900 registered trademark applications in the same year.

In the last 20 years, considerable efforts have been made in Latin American countries to reform innovation policies, in particular by improving and modernizing the patent system.

Mexico, Colombia, Chile and Peru are also part of the agreement called "Patent Prosecution Highway" (PPH) since 2016. Patents reviewed and approved in member countries are candidates for an accelerated review within the Pacific Alliance. This helps companies get their inventions protected quickly in a range of countries.

Distinguishing who owns the patents and classifying between residents and non-residents within the countries of interest is important to know who has the knowledge registered in a country, whether generated there or elsewhere, and above all to identify the internal capabilities of a certain market.

Susana Ruiz Pérez

> **However, human cells could be protected if they are isolated and transformed.**

In leading industrial property countries such as Germany and the UK, domestic applicants drive patent growth; and in China and the Republic of Korea there was a significant increase in the number of resident applications compared to non-residents.

In Latin American and Caribbean countries, non-residents determine the number of patent applications filed.

Exceptions to the rights conferred by patents in Latin American countries

Latin America has incorporated figures such as compulsory licenses, government use and exemptions to research in its patent laws. These countries also have provisions for voluntary licensing, including prohibitions on certain anti-competitive licensing practices. Of course, the specific application and scope of these licenses vary from country to country.

In case of national emergency, uses such as teaching or research and when the patent owner has not been willing to grant licenses on reasonable terms, compulsory licenses are allowed under international law, always subject to the requirements stipulated in the TRIPS Agreement (Art. 31).

In practice, the number of cases where compulsory licenses have been used is extremely small.

Exceptions to patentability

Pharmaceutical compositions, animals and plants, human genes, and diagnostic or treatment methods have special considerations:

Pharmaceutical compositions are patentable in all countries, although the examination criteria are stricter in some of them. For example, in Argentina and Chile it is necessary to claim all the components, including excipients, together with the concentrations of each one; while in Brazil, Colombia and Mexico it is allowed to claim only those elements that are essential in the composition.

Microorganisms that are generally not considered patentable if claimed as they are found in nature. In Mexico and Chile, they can be protected if isolated. Genetically modified microorganisms are susceptible to protection in all jurisdictions.

Neither human beings nor their parts (organs or tissues) can be patented. However, human cells could be protected if they are isolated and transformed (Mexico) and if they are unable to produce a complete individual (Argentina).

Human genes are excluded from patentability in Argentina and Brazil, while in Mexico it is possible to protect them in their isolated or transformed form. In general, animals are not considered patentable in almost all jurisdictions, even if they are genetically modified (with the exception of Mexico).

In almost all Latin American countries, plants are ruled out of patentability, even if they are genetically modified (again, the exception is Mexico). The protection of plant varieties is prohibited in all countries and the same applies to those plants produced by improvement techniques assisted by molecular markers.

Diagnostic methods or medical treatments are excluded from being patentable if applied directly to the human body or animals, but are patentable when performed *ex vivo* or *in vitro*.

State of the art: fields better protected by patents

In Brazil, Argentina, Mexico and Chile, the pharmaceutical field is the most patented technology, followed by information and communication technologies (ICT) and medical devices. Nanotechnology patents represent only 3% but they have a great weight if their presence in other countries is taken into account.

The number of patent applications on technologies that mitigate climate change (CCMT) filed in Latin American countries by foreign applicants is an indicator of foreign interest in America as a market. Thanks to policies to promote renewable energy, a significant increase in the renewable market is expected in about five years. **Renewable energy, without hydroelectric provides a strong incentive for local and foreign investment in most of the region.**

Latin American CCMT patent applications show that approximately 2.8% of the global CCMT patent families have members of patent families filed in Latin America. In summary, **there appears to be an untapped potential market for CCMTs in Latin America.**

> **Latin America has incorporated figures such as compulsory licenses, government use and exemptions to research in its patent laws.**

Résumé

Susana Ruiz Pérez is a Spanish physicists and European Patent Attorney. She worked for nine years as Patent Examiner at the European Patent Office in Munich and is now head of the Nanotec., Renewal and Medical Technologies patent department at H&A.

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Patent infringement and invalidity actions in Brazil

Ana Paula Brito & Maria Eduarda Junqueira of Montaury Pimenta, Machado & Vieira de Mello give a brief outline of each proceeding and how courts assess the technical discussion in both.

In Brazil, there are basically two litigation fronts available when it comes to patent lawsuits:

(i) Enforcing patent rights against an infringer; and

(ii) Challenging the Brazilian Patent and Trademark Office (INPI)'s decision, either granting a patent or rejecting a patent application.

According to the Brazilian IP Act (Law no. 9279/96), a patent invalidity proceeding can be filed at any time during the patent term, either by the BPTO *ex officio* or by any entity which has a legitimate interest. In addition, any BPTO decision, including rejecting decisions and undue office actions are suitable to be challenged in the federal courts, also within five years from its publication in the BPTO's Official Gazette[1].

With respect to infringement action, although a patentee can also pursue a criminal action, in Brazil most lawsuits are addressed to a civil court, as criminal penalties are very weak and addressed to the individual instead of the company, reason why they have no economic repercussion. So, criminal lawsuits are rare and not as effective.

Thus, civil actions are the most common and efficient remedies to cease a particular patent infringement in Brazil, and most of them bring the combination of claims for damages, cessation of use and a preliminary injunction request.

In civil law, a preliminary injunction can be requested and granted at any time and even before the defendant becomes aware of the action (*ex parte* basis), especially considering the provision of Brazilian IP Law (nr. 9279/96), which establishes in article 209 (paragraph 1)[2] that the Judge may grant an injunction to suspend the infringement to avoid irreparable damages.

In order to obtain a preliminary injunction in Brazil, it is necessary to comply with some requirements[3], such as (i) providing clear and convincing evidence of the claimed rights and of the infringement – known as likelihood on the merits - and (ii) attesting the risk of irreparable harm.

Ana Paula Brito

Maria Eduarda Junqueira

> **Criminal lawsuits are rare and not as effective.**

However, generally in patent infringement cases, judges do not rely upon unilateral reports, a reason why obtaining an *ex parte* injunction is quite unusual, as the matter is highly complex and depends on an in-depth discussion of the technical issues.

In most cases, temporary reliefs should be grounded on solid and irrefutable evidence that shows a *prima facie* case. Permanent injunctions are only obtained on a final decision on the merits.

As a response to an injunction, the respondent can apply to discharge or vary an interim order, regardless of whether the order was granted with or without notice. In addition, it can also file an interlocutory appeal against the interim order, within 15 days of receipt of notification of the order (Article 1.015, I, CPC), so that the injunction relief is reanalyzed by the court of appeals, where a three-judge panel will confirm or overrule the trial court judge's decision.

The plaintiff may also seek to impose a daily penalty for failure to abide by the preliminary injunction.

If the interim relief sought is granted, the defendant will be hindered from using the infringing technology involved, pending a final and definitive ruling on the substantive lawsuit.

When assessing the infringement, there are three different possibilities:

- Literal infringement - when one of the claims is literally reproduced in the infringing product: the infringing party is not even concerned to present any variant to distinguish its product, or process, from the patented one.
- Equivalent infringement – a most common type of patent infringement in Brazil, whereby the infringing party includes subtle differences in the infringing product, or process, characterized in small details, that do not alter the essential constituent means of the patent, though.
- Contributory infringement - anyone who assists in counterfeiting, whether by supplying or simply offering to supply a constituent element of a patent, may be considered an infringing party and penalized for the crime of counterfeiting when such practices are not authorized by the patentee.

Infringement actions are brought before state courts, as the BPTO does not participate in such proceedings. On the other hand, invalidity actions are heard by federal courts, as the BPTO is a compulsory co-defendant, attracting the venue of the lawsuit to a federal jurisdiction, which are usually brought in Rio de Janeiro, where the BPTO is headquartered.

> **In order to attest the infringement, the plaintiff shall make a direct comparison between its patent and the infringing technology.**

In order to attest the infringement, the plaintiff shall make a direct comparison between its patent and the infringing technology, as to attest that the infringing product conflicts with at least one of the independent patent claims, and that it includes all the characteristics of said claim.

While to attest the invalidity of a patent, it is necessary for the plaintiff to attest that the patent does not meet at least one of the conditions set forth in the IP Act: novelty, inventive step, industrial application or sufficiency of disclosure.

Infringement and invalidity actions during the trial phase are heard by a single judge, who generally has no technical background. So, for both situations an unbiased expert will be appointed by the trial court judge, which counts with a broad list of registered experts in the most different areas of technology. The expert will be designated to prepare a technical report

Résumé

Ana Paula Brito

Ana Paula Brito is a partner at Montaury Pimenta, Machado & Vieira de Mello and heads a patent litigation team. She is a trial lawyer with extensive expertise in litigation before Brazilian Federal and State Courts, acting for both domestic and international clients. Her diverse practice includes the evaluation of potential litigation risks, collaborating with corporate departments, developing mitigation solutions and litigation strategies, as well as handling and monitoring complex litigation matters. Ana Paula has litigated diverse cases involving patents in the pharmaceutical, mechanical and telecom fields, trademarks, copyrights, domains, designs and unfair competition law.

Maria Eduarda Junqueira

Maria Eduarda Junqueira is a partner at Montaury Pimenta, Machado & Vieira de Mello and she is part of the patent litigation team. She studied Industrial Property Law at Nova University of Lisbon in 2016, as part of a graduation exchange program, obtained her law degree from PUC-Rio (Pontifical Catholic University of Rio de Janeiro) in January 2020, and is currently a post-graduate student in Intellectual Property Law, at the same university. Her experience includes complex cases related to patents in the pharmaceutical, mechanical and telecom fields, trademarks, dealing with copyright and unfair competition practices issues as well, assisting clients with judicial and extrajudicial matters in the area.

1 Set forth by Decree nr. 20910/32

2 Article 209 - The aggrieved party is reserved the right to receive losses and damages in compensation for losses caused by acts of violation of industrial property rights and acts of unfair competition that are not provided in this law but which tend to prejudice another's reputation or business or to cause confusion between commercial or industrial establishments or providers of services, or between products and services placed on the market.
§ 1 - The judge may, in the formal record of the same action, so as to avoid irreparable damages or damages that would be difficult to recover, grant an injunctive order to suspend the violation or act that has such in view, before summonsing the defendant, against, if he judges necessary, monetary caution or a fiduciary guarantee.

3 Set forth by section 300 of the Brazilian Code of Civil Procedure

to ground the trial court decision.

The technical assessments of the court expert to attest the infringement or invalidity/validity of a patent are the most relevant steps of the proceeding, either in State or Federal Courts.

As to ensure the accomplishment of a well-grounded technical report, the designated unbiased expert must be a skilled person in the patent's technology field and must have Industrial Property knowledge. Additional experience in judicial discussions is also important: the combination of knowledge in theory + practice enables a fair trial, since most judges will tend to follow the technical report's conclusion, considering that they do not have enough technical background to assess the technology involved.

Thus, when the judge indicates a certain expert, parties can either agree or disagree with such nomination. Usually, skilled attorneys in the area will carry an in-depth analysis of the nominated expert qualification and experience to attest if they have enough technical and scientifical background in the patent's field to properly conduct the evidence phase.

In case one of the parties, or both, understand that the expert does not meet the expectation provided for the patent technical discussion, it is possible to challenge such nomination with the courts. In case the trial court judge does not comply with the plead, it is even possible to file an interlocutory appeal addressing the discussion to the second instance level.

> **A patent invalidity proceeding can be filed at any time during the patent term, either by the BPTO *ex officio* or by any entity which has a legitimate interest.**

Once the expert's nomination is confirmed by the trial court, the parties can appoint its own technical assistants and submit queries to the expert, which will guide their assessments and conclusion. So, the expert technical report is a combination of the overview of the technology involved, answers to the queries of the parties, and a conclusion assessment. Normally, specialized Judges tend to submit their own queries to the expert in order to contribute with the final discussion.

After the expert's technical report is submitted to the court records, the parties can submit their considerations, agreeing or disagreeing with the expert's conclusions. By that time, the parties can appoint potential inconsistences, requesting clarifications or even schedule a trial court hearing.

The Brazilian Code of Civil Procedure sets forth a provision which helps the parties to avoid, or at least reduce the chances of dealing with an expert without enough technical background: according to section 471[4], parties, nowadays, can mutually chose the expert who will conduct the evidence phase.

Such provision is considered an important advantage of the Brazilian system, since it aims at procedural economy (parties can avoid spending several months challenging the expert's nomination, for instance) and has as its background the principle of self-determination interest.

Nevertheless, depending on the complexity of the case, it is also possible for the judge to indicate more than one expert to conduct the evidence phase, according to section 475[5], when the patent's discussion involves more than one area of expertise (i.e., pharmaceutical, telecom, and software fields).

Such measure tends to increase the costs of the evidence phase, as generally the Plaintiff will have to bear the experts fees. However, depending on the relevance of the case, and the difficulty of finding a single expert skilled in the patent's fields, which also has knowledge in IP matters, the combination of experts tends to be the best course of action for the lawsuit outcome.

With respect to the discussions that take place in the federal court, regarding patent invalidity actions, there is one more point worth highlighting: the BPTO is a compulsory co-defendant, obligated to take part in the lawsuit challenging its administrative act of granting or rejecting a patent/patent application. So, the BPTO must submit its defense brief, highlighting if its position is of restressing the legitimacy of the administrative act (consequently, for the lawsuit's dismissal) or, agreeing with the plaintiff's plead, admitting the possibility of changing its own opinion carried during the administrative phase.

In addition, the BPTO's participation as a co-defendant requires its active participation on further developments, including during the technical evidence phase: agreeing or disagreeing with the expert nominated by the judge, appointing its technical assistants, submitting queries to the expert, participating in the meetings with the expert during the evidence phase, submitting agreeing or disagreeing reports, and so on.

A particularity of the invalidity action arises when the BPTO's conclusion is not the same as the trial court's expert conclusion: which one shall the trial court judge follow to issue the decision on the merits?

The BPTO's administrative acts are covered by a presumption of legality, as they are issued by the agency responsible for analyzing IP matters on an administrative level. On the other hand, it is assumed that the unbiased expert designated by the court is a skilled person in the area as well, who also has enough knowledge to analyze the matter.

> **It is also possible for the judge to indicate more than one expert to conduct the evidence phase.**

Thus, the trial court judge decision will be upheld by a careful analysis of the arguments submitted by the parties, combining it with the relevant arguments brought by the BPTO and the expert's conclusion. Whenever such controversy occurs in a nullity action, the Judge shall consider the particularities presented by the parties throughout the lawsuit, which shall be carefully and timely analyzed when issuing a final decision on the merits.

In this regard, besides the importance of having a skilled expert to conduct the technical evidence phase in patent infringement or invalidity actions, another discussion which is gaining strength in the past few years is the importance of having specialized courts/chambers to handle IP matters.

The Rio de Janeiro federal and state court, in addition to the São Paulo state court, fortunately count with IP specialized courts, reason why the judicial decisions are now very technical and well-grounded in the right IP assessments.

Having judges with deep knowledge in Intellectual Property helps to increase the quality of decisions, as well as the quality of the experts involved. At the same time, it also helps to reduce the number of appeals filed with the 2nd instance challenging the 1st instance decisions, as the inconsistences regarding the Brazilian IP Act provisions are decreasing.

Undoubtedly, the specialization of courts, judges and experts is contributing to a fair and solid IP enforcement system in Brazil, whose controversies are discussed at a high level whenever conducted by skilled IP attorneys.

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[4] Art. 471. The parties may, by mutual agreement, choose the court-appointed expert, by means of a request, provided: I – they are fully competent; II – the dispute may be resolved amicably by the parties themselves.
§ 1 When choosing the court-appointed expert, the parties must nominate their respective retained experts who shall monitor the production of expert evidence, which shall be carried out on a previously disclosed date and place.
§ 2 The court-appointed expert and the retained experts must submit their respective reports and opinions within the deadline determined by the judge.
§ 3 The production of expert evidence by mutual agreement substitutes, for all intents and purposes, the one that would be carried out by an expert appointed by the judge.

[5] Art. 475. When dealing with complex expert examinations embracing more than one field of expertise, a judge may appoint more than one expert, and the party may appoint more than one retained expert.

Patent term adjustments in Mexico

Sergio Olivares & Mauricio Samano, of OLIVARES, examine the history of Patent Term Adjustments in Mexico from Pipeline Patents to the current Supplementary certificate that is available for patent owners.

Since the beginning of 2020, businesses around the world have faced unexpected challenges and law firms are no exception to this. The COVID-19 pandemic has made social distancing a necessity and has led us to rethink the way we work. We are now avid users of electronic platforms and spend long hours at the office, which for many is our home office. As a result of the pandemic, almost all patent applications in Mexico are now filed through the official online platform, which has been perfected by the Mexican PTO and works smoothly.

Also, on November 5, 2020, a new Mexican IP law entered into force, which contains numerous modifications to the previous law. This completely new Mexican IP law elaborated on many practices currently performed by the Mexican Patent Office (IMPI) and clarified many gray areas that were present in the previous law. As it relates to inventions, this new law incorporated several positive changes, which are in line with the requirements of the new U.S. Mexico Canada (USMCA) Treaty, such as the possibility of applying for a patent term adjustment in the case of unreasonable delays (more than five years between the filing date in Mexico and the date of grant), directly attributable to IMPI during the prosecution of a patent application. Of course, this was well-received by IP practitioners and owners of patent rights, and it demonstrates that Mexico is heading toward a more harmonic IP protection system that meets international standards.

On the other hand, in the context of COVID-19, patent term extensions have become worrisome for some countries, such as Brazil, in which their Supreme Court ruled that patent extensions are unconstitutional and applied this provision retroactively for pharmaceutical patents.

Ahead is some of the history of patent term adjustments in Mexico, given that this has not been an isolated experience.

Pipeline patents, Mexico's first experience

Prior to 1991, the IP law that was in force had been on the books and enforced since 1976. This 1976 law was significantly limited and pharmaceutical inventions, among others, were not considered patentable subject matter.

At that time, Mexico was negotiating the North American Free Trade Agreement (NAFTA) with the U.S. and Canada, a situation that triggered a dramatic change to the state of IP in Mexico, with a new IP law that was published in the Official Federal Gazette on June 27, 1991, which was then modernized to generally comply with the IP chapter of NAFTA.

In this new law, pharmceutical inventions, among others, were now considered patentable. This 1991 law contained a new concept for providing so-called 'pipeline protection' for patents that had fallen in the public domain, since they had not been considered patentable in the previous law of 1976, which was included in the 12th Transitional Provision of the 1991 IP Law.

In the 1991 Law, the conditions for obtaining Pipeline protection were the following:

- The corresponding Mexican patent application had to be filed within 12 months of the enactment of the law and should have been filed by the first applicant of the corresponding foreign application or by the assignee thereof.
- The applicant had to prove they had filed the application in any of the member countries of the PCT or had to prove they had obtained the corresponding patent.
- The exploitation of the invention, or the import on a commercial scale of the patented product or of the product obtained by the patented process, must not have been initiated by any person in Mexico prior to the filing of the application in Mexico.

The last paragraph of the 12th Transitional Provision of the 1991 IP Law read that *"The term of the patents granted under the provisions of this article will end on the same date as the patent granted in the country where the first application was filed, but the term will never exceed 20 years as of the filing date in Mexico."*

Based on the above provision, patents were granted following the term granted in the country where the first application was filed, and a correction of up to 20 years, as of the Mexican filing date, could be granted by the Federal Courts as a consequence of litigation. Of the total amount of pipeline cases that were litigated, our firm achieved patent term corrections in 12 of them of a total of around 20 that were litigated.

This was Mexico's first experience with patent term adjustments and ended many years ago, as the patents that qualified for such adjustment also ended many years ago.

Supreme Court of Justice case. Compensation due to unjustified delays

On October 14, 2020, the Mexican Supreme Court ruled for the first time that the owner of a patent (in this case Bayer) should be compensated by an adjustment in the life-term of the patent due to unreasonable delays by the Patent Office. It is important to clarify that this Supreme Court decision was a divided one

Sergio Olivares

Mauricio Samano

> **"As a result of the pandemic, almost all patent applications in Mexico are now filed through the official online platform."**

Résumés

Sergio L. Olivares, Jr., Partner

Sergio Olivares, Jr. joined OLIVARES in 1987 and today leads the firm with strength and a commitment to transparency, client satisfaction, and personal service. He has been a partner since 1994 and Chairman of the Management Committee since 2009. Mr. Olivares' breadth of experience is extensive; he is skilled in the prosecution and litigation of intellectual property rights. He is proficient across all areas of intellectual property law but works most closely with the firm's Patent Group. Mr. Olivares is highly recommended by leading industry publications and directories as a leader in IP. He has been influential in ensuring that Olivares remains highly innovative, helping to support the firm's effort to add new practice areas and industry groups enabling the firm to offer its clients a more comprehensive approach. Mr. Olivares has played a key role in the establishment of many of these new groups, including the Regulatory and Administrative Law Groups and the Life Science & Pharmaceutical and Information Technology Industry Groups. After his graduate work, Mr. Olivares trained with two prominent IP law firms in New York City—Morgan & Finnegan and Kenyon & Kenyon—before joining Olivares. This deep understanding of US intellectual property law allows him to offer clients clear comparative analyses of the US and Mexican legal systems and to explain complex matters in a way that suits the needs of the firm's international clients.

Mauricio Samano., Engineer

Mauricio Samano works in the patent department of our firm. His work at OLIVARES mainly focuses in prosecuting Chemical, Biotechnological and Pharmaceutical patent applications, as well as in providing technical opinions regarding patent infringement. He has experience in conducting state of the art searches and drafting patent, utility model and industrial design applications. Additionally, he has participated in interviews with examiners of the Mexican Institute of Industrial Property (IMPI) and the United States Patent and Trademark Office.

(three vs two), and since it was not unanimous, it did not become jurisprudence and was not binding. Thus, any other party that sought such compensation would have to independently litigate.

The rationale of the Supreme Court was that NAFTA provided that a life term of a patent could be of 17 years as of the granting day of a patent. Thus, it was suitable to compensate the life term of the specific patent subject matter of that litigation (which was granted under NAFTA and the previous 1991 IP Law) so that it is in force for 17 years, starting from the date of grant, due to unjustified delays during patent prosecution.

In Mexico, international treaties such as NAFTA have a higher hierarchy than domestic law, which was a key factor in this decision.

The Supreme Court ordered IMPI to issue an official communication and establish the term of validity of the specific patent in that particular case, according to the 17 years from the granting date, as established by NAFTA.

Since the decision was not binding to IMPI, it is expected that IMPI will not adopt the criteria to compensate life term patents in similar cases without a court order. For the Mexican Courts, the precedent is not binding either, but highly persuasive.

The decision was surprising by all measures, especially considering that the new Mexican IP Law had already been approved by Mexico's congress and senate and was scheduled to be published on November 5, 2020. The new IP law already contemplated patent term adjustments due to unreasonable delays by the Patent Office and even specified the timeframes for deciding when patent term adjustments would apply.

Supplementary Certificate of life term correction due to delays in prosecution

On November 5, 2020, the new IP Law (LFPPI) entered in force in Mexico and included a scheme to address patent term adjustments derived from unjustified delays by IMPI in prosecuting and granting patents by way of a "supplementary certificate."

The main features of this supplementary certificate are as follows:

- The duration of the supplementary certificate should not exceed five years.
- The patent holder may request a supplementary certificate only once, by a brief that complies with the requirements set forth in the IP Law and its Regulations.
- The application must be submitted independently, when replying to the notice of allowance.
- When the granting of the supplementary certificate is authorized, IMI will notify the applicant so that, within a period of one month, the proof of payment of fees corresponding to the issuance of the certificate's title is submitted.

> **Patent owners can now be compensated in case of unreasonable delays directly attributable to the IMPI.**

Additionally, for the processing and resolution of an applicant's request for a supplementary certificate filed before IMPI, the following conditions should be met:

- The prosecution of the patent should have exceeded five years, otherwise, IMPI will resolve the inadmissibility of the petition.
- If the prosecution of the patent has exceeded five years, IMPI will determine the amount of time that corresponds to 'reasonable delays' and will subtract that amount from the prosecution period.
- If the time calculated for the reasonable delays is less than five years, IMPI will reject the request for a supplementary certificate.
- If the time calculated after considering reasonable delays is still greater than five years, IMPI will determine the number of days that corresponds to an unreasonable delay, which will be included in the extension listed in the supplementary certificate, as an extension valid for one day for each two days of unreasonable delay.

The LFPPI considers the following to be reasonable delays:

I. The period that elapses between the date of receipt and the date of the favorable resolution of the formal examination;
II. The periods attributable to actions or omissions of the applicant, tending to delay the procedure for granting the patent and the extensions to answer deadlines;
III. The periods not attributable to actions or omissions of IMPI or that are beyond its control, such as those that pass in the substantiation of any means of administrative or jurisdictional challenge or that derive from them; and
IV. The periods attributable to force majeure or fortuitous events.

Any other delays attributable to IMPI are those that will be considered as not reasonable and will be considered for the supplementary certificate. An example is if IMPI issues the first office action more than six years after the filing date in Mexico.

These new provisions will apply to patent applications that are filed starting from November 5, 2020, so there will be quite some time before we see a petition for a Patent Term Adjustment under the new IP law. Seeing how this will work in practice and celebrating that patent owners can now be compensated in case of unreasonable delays directly attributable to the IMPI is certainly something to look forward to.

Mexico's current prosecution scenario and future expectations.

IMPI has significantly reduced the backlog for patent applications and is issuing the first office action in some cases less than two years after the filing date in Mexico.

Also, options for expediting granting such as the well-known PPH agreements that IMPI has with several patent offices around the world have proved to be very useful in getting patent applications allowed as quickly as two-three months after a PPH request is filed.

Furthermore, IMPI has recently signed a Parallel Patent Grant (PPG) with the USPTO, which contemplates the possibility of obtaining an expedited grant in Mexico based on a published US patent. Unlike the PPH, participation in the PPG program is not requested by the applicant. In the PPG, IMPI will issue an office action in which they will invite the applicant to participate in this program and adapt the set of claims to those that issued in the corresponding US patent. This office action is one of the four office actions that IMPI issues per each application, and if the applicant accepts participation in the PPG program, the notice of allowance would follow. Even though it is not necessary to file a request for participation in the PPG, if the applicant is interested in voluntarily participating in the PPG program, they can do so by filing a voluntary amendment and adapting the Mexican claims to those of the corresponding issued US patent.

> **Mexico is on the fast track to having several options to accelerate granting.**

In short, Mexico is on the fast track to having several options to accelerate granting, and for those cases that indeed end up being forgotten, the applicant will now have options to receive compensation through the issuance of the Supplementary Certificate.

One item remains pending in Mexico's new IP law, and this is patent term adjustment due to regulatory delays. Since this is also contemplated in the recently signed USMCA, Mexican law will have to incorporate it within the next four and a half years, starting from the date the USMCA entered in force, on July 01, 2020.

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A changing landscape: prosecution of pharma patent applications in Brazil

Daniela Fasoli, Senior Partner at Simoes IP Law Firm, reviews the changes to Brazilian Patent Law in the pharma space and what these will lend to the field.

As they say, Brazil is not for amateurs… Changes in the patent landscape are so drastic and frequent that it is often difficult to keep up. Patent portfolio management strategies need to be constantly updated. In the pharmaceutical field, things are even more intense.

Pharmaceutical products were excluded from patent protection in Brazil until 1996, when the "new" Industrial Property Law 9,279 of 05/14/1996 (IPL) was enacted, effective from 1997. Article 18 defines the matter that is not patentable in Brazil – it includes an important innovation towards the former IP Code, as it does not contain prohibitions related to the patentability of chemical, pharmaceutical and food technologies.

> **"There are important limitations in the law."**

In addition to the patent legislation, the granting of pharmaceutical inventions is governed by resolutions, regulations, and examination guidelines, such as the Patent Application Examination Guidelines, including the Areas of Chemistry and Biotechnology. Such documents are frequently updated and reflect the PTO's understanding of the IPL and how these criteria are applied in practice.

Patentability of pharmaceutical inventions

As already mentioned, Article 18 does not exclude pharmaceutical inventions from patentability. However, there are important limitations in the

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> **These cases will no longer be sent to ANVISA for prior approval.**

Daniela Fasoli

law and especially in the internal PTO's Guidelines that affect the way these cases are examined.

Article 10 of the IPL defines that therapeutic or diagnostic methods applied to the human or animal body are not considered inventions. Although this is an important limitation for method claims, the Guidelines for the Examination of Patent Applications in the Chemistry Area defines a specific wording applicable for some of these inventions – Second medical use claims are potentially patentable in Brazil as Swiss-type claims. It is important to note, however, that the requirement of inventive step of a second medical use is quite specific. The examiners analyze e.g., the mechanism of action, the etiology of the new vs previous diseases involved, the structure-activity relationship, the side effects and the symptoms of the disease to be treated.

Another controverse relates to polymorphs. In this case, although considered patentable, the Guidelines rule that the characterization of the crystalline form is supported by data obtained by techniques for physico-chemical characterization of solids, such as the single crystal X-ray diffraction (XDR) technique. If the specification is not filed with the required support, it is not possible to file such data in reply to an Office Action as it is considered addition of new matter.

Markush formulas are also acceptable, however, in this case, the current practice of the examiners is even more strict than the PTO's Guidelines. Although the Guidelines rule that the manufacturing processes disclosed in the specification should be sufficient to enable the preparation of the claimed compounds, in practice, many examiners tend to require limitations of the claims to the illustrative examples.

Résumé

Daniela Fasoli, Senior Partner

Daniela advises global companies on how to protect, defend, enforce, and manage their intellectual property rights. Her practice encompasses all aspects of intellectual property law, including patent drafting and prosecution, IP litigation, validity and infringement opinions, client counseling in intellectual asset management and appeals before the Brazilian Patent and Trademark Office, especially in the fields of pharma, chemistry, biotechnology, oilfield technologies and nanotechnology.

Daniela is often a speaker on panels around the globe discussing topics including the IP landscape in Latin America.

Before joining Simões IP, Daniela worked for more than 12 years in the area of industrial and intellectual property. As a Corporate Director of an international IP Company, she was responsible for managing all IP legal and technical services Departments from 10 countries of Latin America and Europe. As a pharmacist, Daniela also has field experience in the pharma industry.

ANVISA

Law n. 10,196 of 02/14/2001 included a single paragraph to article 229 and articles 229-A, 229-B and 229-C of the IPL. Pursuant to art. 229-C, the granting of patents for pharmaceutical products and processes would depend on the prior consent of the National Health Surveillance Agency (ANVISA). Prosecution of pharmaceutical applications became a nightmare with several changes in the workflow between the PTO and ANVISA and a very controversial, and many times "political", examination criteria by ANVISA.

Recently, Law n. 14,195 of 08/26/2021 which deals, among others, with the reduction of bureaucracy of procedural acts, revoked art. 229-C of the Brazilian IP Law. From now on, pharmaceutical patent applications should have the same treatment as any other application in Brazil – i.e., these cases will no longer be sent to ANVISA for prior approval. That is great news for the IP practice in Brazil!

Patent term

In Brazil, the IPL used to guarantee a minimum term of 10 years from grant for patents which prosecution lasted more than 10 years.

This provision of the Law was recently challenged by a Direct Action of Unconstitutionality (ADI 5529). This is the legal measure to challenge provisions of a law in Brazil.

For decades, and due to a strong local Generics industry, this provision of the law has come under criticism, especially for pharma-ceutical patents. When Brazil passed through the worst moment of the COVID-19 pandemic, the local press pushed for a final judgment on the unconstitutionality of this minimum term. Obviously, this was a misinterpretation of the Law and the suspension of the 10-year term did not affect the access to COVID's medicines or vaccines in Brazil.

The topic was ruled for judgment in the Supreme Court in April 2021. The Brazilian Supreme Court decided for the suspension of the effect of the sole paragraph of art. 40 of the IPL (ratified by Law n. 14.195 of 08/26/2021).

Therefore, from April on, patents are no longer issued with a minimum term of 10 years from grant, even when prosecution lasted more than 10 years.

This decision affects all patents granted after April 2021 (*ex nunc* effect), independently of the technical area. *Ex tunc* effects, based on the BRPTO's understanding, are limited to pharma-ceutical patents. The PTO is publishing reviewed letters patent for the affected pharma cases.

The backlog

The Brazilian patent backlog was, until recently, among the most time-consuming of all the member countries of the World Trade Organization.

Before the first results of the Backlog combat plan, launched by the PTO in 2019, almost all pharma patents issued by the PTO had a prosecution timeframe of more than 10 years.

The objective of the Combat Plan is reducing (until the end of 2021) the backlog (149,912 patent applications filed until the end of 2016) in 80%.

In order to reach this goal, the PTO invested in technology, a home-office program to improve productivity, new projects to expedite prosecution such as PPH and two pilot programs called "pre-examination" and "preliminary Opinion" were launched. In these programs, the examiner issues a simplified office action containing a list of the prior art cited during the examination of counterpart applications, especially European and American, without comments or analysis. If no reply is filed within 90 days, the application is lapsed with no right to appeal. If a response is filed, the examination procedure continues.

Two objectives are attained by doing this:

- Applications which the Applicant is no longer interested in are quickly removed from the examination row (if the Applicant fails to respond to the office action); and
- By encouraging the Applicant to conform the claims to those already allowed in other jurisdictions, examination proceeds smoothly.

Until September 2021, around 104,000 applications were decided, which represents a reduction of 70% of the backlog, leaving 45,000 applications to be resolved.

The Combat Plan is extremely important, especially now that the sole paragraph of art. 40 of the IP Law was revoked and Applicants no longer benefit from the 10-year from grant patent term.

EXPEDITING EXAMINATION

Alternatives to an expedited examination are not new in Brazil. For many years, the PTO offered options for Applicants interested in having a quicker prosecution. However, until very recently, these options were used in very few specific cases. Most applicants, especially involved in long shelf-life technologies, such as pharma, had no interest in expediting the prosecution as they used to benefit from the minimum term of 10 years from grant, considering that their cases had a prosecution that lasted more than 10 years.

Now, with the changes in the patent term, the number of requests for an expedited examination jumped from 366 to 1800 requests (May – Aug 2020 v May – Aug 2021).

Among modalities, we have:

Potential Infringement (applications involved in possible infringement), Green Patents (applications with technologies similar to the one mentioned at the WIPO inventory), PPHs (shared examination

> **Therefore, from April on, patents are no longer issued with a minimum term of 10 years from grant, even when prosecution lasted more than 10 years.**

Compulsory licenses would then be granted, *ex officio*, for a specific period and on a non-exclusive basis.

with USA, Japan, Europe, etc), Pharma products related to public health (especially developed for technologies related to HIV, cancer, rare or neglected diseases), National emergency or public interest, Covid-related technologies, technologies already in the Brazilian market etc.

The prosecution using most of these modalities is usually reduced by half.

Compulsory licenses

Articles 68 and 70 of the IPL provide five possibilities for competitors to seek a compulsory license in Brazil. These possibilities require an administrative procedure to be filed by the third party before the BRPTO:

(a) Exercise of patent rights in an abusive manner;
(b) Practice of abuse of economic power;
(c) Non-exploitation of the subject matter of the patent by lack of manufacture or incomplete manufacture of the independent claims (local working);
(d) Supply that does not meet the needs of the market;
(e) A situation of dependency of one patent on another.

Article 71 of the IP Law provides two possibilities of a temporary *ex officio* non-exclusive compulsory license for the exploitation of the patent, pursued by the Government. It is implemented by Decree #3,201 of 1999, as amended by Decree #4,830 of 2003:

(a) In cases of national emergency;
(b) Public interest for public non-commercial use.

The act of granting the compulsory license may also establish the obligation for the patentee to share the necessary and sufficient information for the effective reproduction of the matter.

In the case of a national emergency or public interest that characterizes extreme urgency, the compulsory license may be implemented regardless of prior publication in the DOU and without a fixed term of validity for the license or the patentee's compensation.

The only case of compulsory license in Brazil is from 2007. The Brazilian government issued Decree #6,108 establishing a five-year non-exclusive compulsory license of Merck's patents PI1100250-6 and PI9608839-7 covering Stocrin (efavirenz), for public non-commercial use. In 2012, President Dilma Rousseff issued Decree #7,723 extending the compulsory license for five more years, in light of public interest, for both patents.

With the recent COVID-related discussions, the provisions of the IPL on compulsory licensing of patents in cases of national emergency or public interest were also reviewed. The changes are defined in Law n. 14,200 of 09/02/2021.

Whenever there is a national or international emergency, public calamity or public interest, the Brazilian Government must publish a list of patents or patent applications related to the situation. Patent owners who satisfy the local demand, or who have granted voluntary licenses may request that the corresponding patents are excluded from the list.

Compulsory licenses would then be granted, *ex officio*, for a specific period and on a non-exclusive basis.

For granted patents, the patent owners would receive a remuneration corresponding to 1.5% of the net sales price of the product covered by the patent.

Now, a compulsory license might be granted not only to meet the Brazilian domestic needs, but also for export of the product to lesser-developed countries.

Conclusion

Due to the differences between the practices of the countries and the radical changes in the treatment of pharmaceutical applications over the years, especially in view of the restrictions imposed by the IPL, the interference by ANVISA and controversies regarding inventions in the pharmaceutical area, the prosecution of pharma patent applications in Brazil is a challenge.

It is important to always be aware of these changes and update the patent portfolio strategy quickly and effectively.

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An overview of the latest inventions presented at the Technosreda Festival in Moscow at VDNKh on September 25-26

Ludmila V. Lisovskaya, of Zuykov and Partners, discovers the emergence of "intellectual wealth" in Russia having attended the Technosreda Festival, highlighting the need for intellectual property protection.

The year 2021 was declared the Year of Science and Technology. This year for specialists in intellectual property protection provided an excellent opportunity to get acquainted with innovative projects and developments of various Russian technology companies, research laboratories, and institutes and participate in solving issues related to ensuring the protection of copyright and exclusive rights for these technical solutions.

The Ministry of Science and Higher Education of the Russian Federation on September 25 and 26 at VDNKh organized the Tekhnosreda Festival 2021, which was very representative of the scientific breakthrough and development achieved in 2021 in various technology fields by Russian inventors.

Ludmila V. Lisovskaya

Technosreda 2021 was presented in several pavilions and spread across the entire exhibition area. The following thematic zones dominated in particular: "Universities and Research Institutes," "Inventors," "Future Today" zones.

The leading Russian experts and scientists presented about 500 of their scientific developments. These are products, devices, hardware, and software systems applicable in various life spheres, such as medical equipment, prostheses, exoskeletons, telescopes, microscopes, industrial automated conveyors, robots, cars, aircraft (drones), nuclear complexes (models), and even artificial intelligence capable of creating artwork or providing life safety.

In addition, several presentation places were organized, interesting reports were represented, such as those devoted, for example, to improved wheelchairs, prostheses for animals, intelligence robots, and mobile homes on wheels.

Besides, it should be noted that one of the implemented and well-proven solutions of the national research institute "Tomsk Polytechnic University" (Tomsk) and the veterinary clinic "Best" (Novosibirsk) - bionic prosthetics of paws in animals (3D prostheses), carried out with the use of four technologies: bioengineering modeling, 3D printing, microarc oxidation, and prostheses implantation. Such a complex technology for creating internally and externally adapted prostheses for a healthy limb of the paws is not found in any veterinary clinic in the world. It enables disabled animals who have undergone limb amputation to regain a normal life, even after losing one, two, or all four paws. (Video 1: bionic prosthetics of paws in animals.)

Another incredible prosthetics example is the bionic hand prosthesis developed by Motorika. This tool is successfully used to rehabilitate and improve the life quality of people with disabilities. The video shows a demonstration of how such a prosthesis work. "Cybergirl" confidently shakes hands and picks up objects with ease. Let's figure out how this prosthesis works. Special electrical potential sensors are implanted under the hand skin. During the hand tension of the remaining muscle tissues, the sensors read the generated electric potential and transmit it to the microprocessor, which processes the information received by a computer program. As a result, the microprocessor generates commands in the shortest time and sends them to the motors, which set the prosthesis in motion. The prosthesis is powered by batteries and is equipped with a mobile application that allows controlling the "cyber hand" work. (Video 2: bionic hand prosthesis.)

At the Festival, the ExoAtlet company presented an extraordinary exoskeleton that can be used for industrial or medical purposes. The reinforcing external exoskeleton helps people lifting weights, allowing the user to distribute the load and prevent various injuries.

Another exoskeleton design was created to help people with disabilities or rehabilitation after leg or spine operation. In addition, it is also suitable for children with cerebral palsy and in other musculoskeletal system disorder cases. (Video 3: exoskeleton design was created to help people with disabilities.)

Bauman Moscow State Technical University presented an interesting project implemented as a natural prototype. The "Rodstrer Crimea" project is a budget sports car for public roads on Lada Kalina units and assemblies.

> **"It enables disabled animals who have undergone limb amputation to regain normal life, even after losing one, two, or all four paws."**

A private engineering company Drive Electro has developed a completely eco-friendly electric truck Moskva, which reduces carbon dioxide emissions into the atmosphere compared to a diesel analogue by almost 87 tons per year. The electric truck is fully adapted to the Russian climate and does not create noise pollution. Charging is provided in two modes: fast 20 minutes and night eight hours; the power source is an industrial network with a voltage of 380 volts. The power reserve is 200 km, which is one of the highest in the world among analogs.

It was surprising that besides devices and software solutions, production processes were also presented, such as the latest automated technologies implementation in the sorting and processing waste sector. The conveyor belt, along which the mixed waste in the form of cardboard, paper, plastic moves, is equipped with a robotic grip with sensors that instantly and clearly recognize the material quality and reject unnecessary waste to the side. (Video 4: latest automated technologies implementation in the sorting and processing waste sector.)

These events make it clear that a completely new system of creating "intellectual wealth" is emerging in our country, based on innovations born through education and numerous researches. Such "intellectual wealth" must be protected and requires investment in scientific knowledge, patents for utility models, inventions, and industrial designs.

To view mentioned videos scan this QR Code or click to link

Résumé

Ludmila Lisovskaya has worked as Patent Specialist and a Chemical Specialist with Zuykov and Partners LLC since 2017. Ms. Lisovskaya specializes in Patent search on inventions and utility models, Preparation and filing of patent applications on inventions, utility models, software and database, Response preparation on request for substantive examination on inventions, utility models, software and database applications, etc. Her previous professional experience also includes working as a Head of Department in the preparation and implementation of new technologies, at JSC "Togliatti Institute of nitrogen industry".

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LOT Network 2021 Report

The world's largest portfolio reduces risk from Patent Assertion Entities.

Patent Assertion Entity Risk

Understanding PAEs

Patent Assertion Entities (PAEs) are companies whose business model is to acquire patents and assert them against companies that sell products. By one estimate, PAEs are responsible for 87% of US high-tech patent litigation[1]. Operating companies spend billions each year litigating and settling with such companies. This is particularly frustrating to operating companies because they can't use their patents in response, and this expenditure is not being put towards research and development, improved manufacturing, new products, or returned to investors.

[1] https://www.unifiedpatents.com/insights/2019/12/30/q4-2019-patent-dispute-report.

In the past 12 months, PAEs asserted 1,375 patents in over 2,000 litigations worldwide.

This includes PAE litigation in China and Europe. Chart 1 analyses the top 10 technology areas of the patents that were the subject of these litigations in the US. Not surprisingly, PAEs are leveraging the convergence of technology and using patents in their campaigns that are likely to have broad applicability across multiple industries. This strategy maximizes the total available market (TAM) that a patent may be asserted against. As technologies such as AI, wireless communications, software, security, cloud computing, etc., migrate across industry borders, and claim language remains agnostic, more and more companies potentially become defendants.

As reported in the recent Richardson Oliver Law Group study for the past six years, corporate sellers supply the vast majority of the patents to PAEs. From 2014 to 2020, on the open patent market, operating companies have sold 6,999 patents to PAEs, representing 65% of the total patents sold to PAEs. In 2020, operating companies sold 80% of the patents purchased by PAEs. Chart 2 shows what percentage of the patents bought by PAEs came from which source. Operating companies generally supply the lion's share of patents on the secondary market, but in particular, they are the largest supplier to PAEs.

Each year, corporations supply between 500 and 1,600 patents to PAEs through this channel. This may seem like a drop in the bucket. But the story does not end there. Once PAEs buy patents from an operating company, they tend to buy more patents; Richardson Oliver's analysis shows that PAEs continue to return to the same seller again and again once they have made the first purchase. Often these subsequent patent purchases are made privately meaning that even if you had wanted to bid on those patents, the opportunity did not exist.

Chart 3 shows how PAE purchases have increased over time. In 2020, PAE purchases jumped to over 50% of the purchases in the open market, but declined in 2021 as operating companies loosened their budgets and began buying again. Richardson Oliver Law Group tracks patent sales and particularly focuses on patents on the open public patent market – these are typically patents sold by patent brokers and repeat direct sellers. Every year, about 10-20K patent assets enter the market this way. Whether used for patent licensing, defensive strategy through counter-assertion, or some other purpose, these patents have a much higher chance of being "used." PAEs continue to acquire assets from operating companies and expect to make a reasonable return on their investment by asserting them against operating companies.

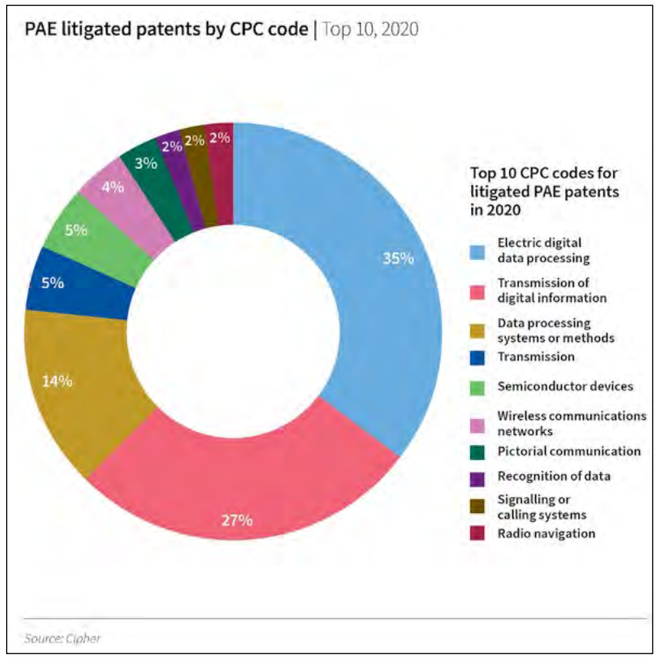
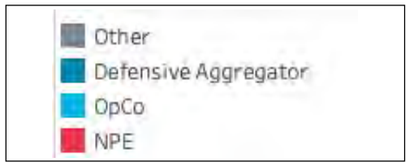
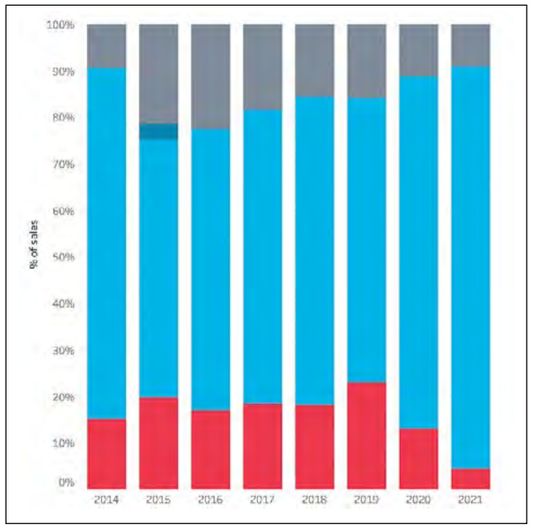


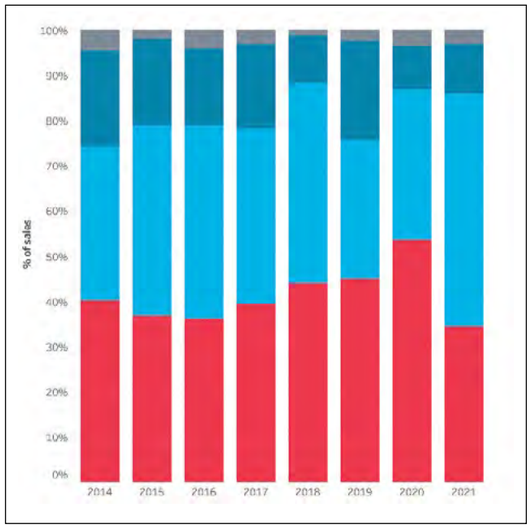
Chart 1: Software, data/image processing, wireless communications most commonly used patents by PAEs.

> **In the past 12 months, PAEs asserted 1,375 patents in over 2,000 litigations worldwide.**

Below: Chart 2: Who supplies PAEs with patents
Below right: Chart 3: Percentage of patents bought by PAE








Ken Seddon


Nigel Swycher


Kent Richardson

Résumés

Ken Seddon, CEO of LOT Network

Previously, in his more than 20 years of experience managing all areas of intellectual property, Ken was with some of the largest patent holders in the world including Apple, Micron, Motorola, Intel, and ARM. Ken holds a BS in Computer Engineering from the Georgia Institute of Technology, a master's degree in Solid State Device Physics and a Juris Doctorate from Arizona State University.

Nigel Swycher, CEO and Co-founder of Cipher

Prior to joining Cipher, Nigel served as an IP lawyer with Slaughter and May of London for 20 years. Throughout his career Nigel has focused on the creation, defense, and exploitation of IP assets, and helping companies, their advisers and investors understand the importance of intangible assets. Nigel is a director of ORoPO (the Open Register of Patent Ownership) and is recognized as an expert by the IAM Strategy 300.

Kent Richardson, Partner at Richardson Oliver Law Group

Kent counsels clients on a variety of patent and business matters including patent buying, selling, licensing, valuation, prosecution, and operations. Kent's patent licensing and marketing experiences have resulted in more than $600M of patent license bookings. Kent has served as an expert witness on patent monetization and licensing practices in cases in England and the United States. He holds a JD and a BSc in Computer Engineering from the University of Alberta, Canada.

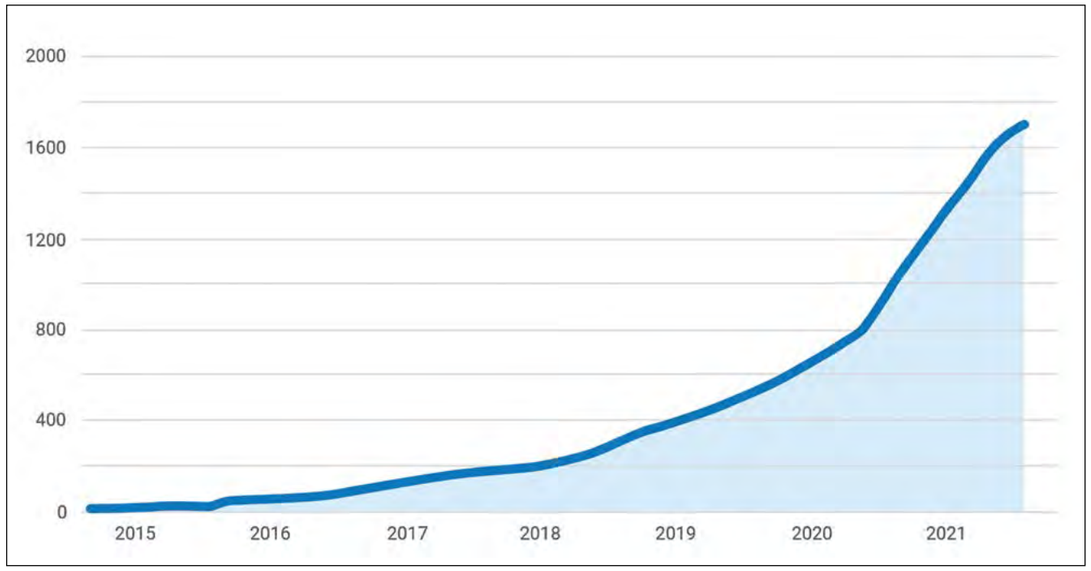


Chart 4: LOT Network - Membership growth over time

Understanding LOT Network

Since operating companies are primarily the ones who are causing the PAE problem by selling their assets to PAEs, LOT Network was formed as a community of companies who are taking responsibility for this problem through a private ordering solution. LOT Network members agree to grant each other a non-exclusive, conditional license if any of their patent assets are ever transferred to a PAE[2]. At the same time, LOT members respect the traditional uses of patents, and are free to continue to use their patent assets in any way they see fit. In effect, LOT Network members have addressed the root cause of the PAE issue and immunized themselves from the risk of PAEs, while preserving all the normal uses of their patents.

To date, LOT Network has identified over 2,200 US patents now owned by PAEs that were formerly owned by LOT members. There were at least six direct transfers from a LOT member to a PAE that were either a direct sale, or the result of a settlement negotiation (i.e., a LOT Network member wanted to reduce the amount of cash they had to pay to a PAE, so they transferred some patents as part of the settlement).

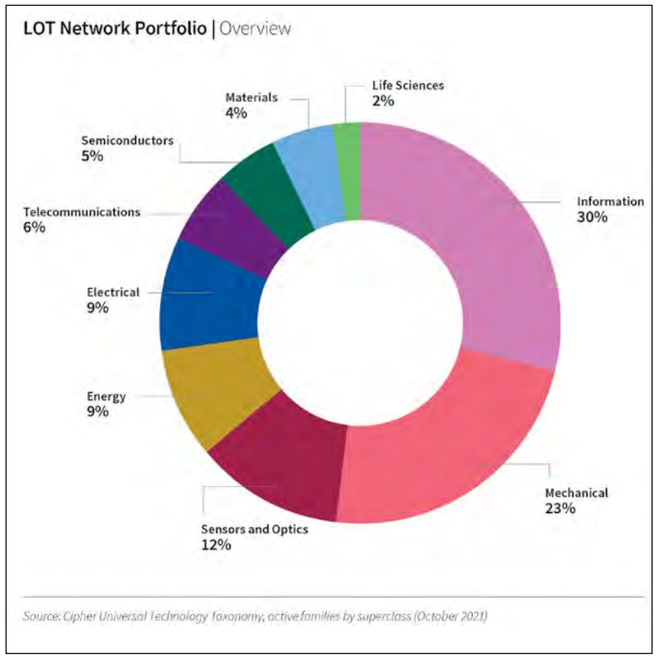
In other instances, the patents passed through the hands of more than one entity before ending up in the hands of a PAE. Regardless of how the PAE obtained the assets, those in the community receive a free license, but those not in LOT may be at risk of being sued.

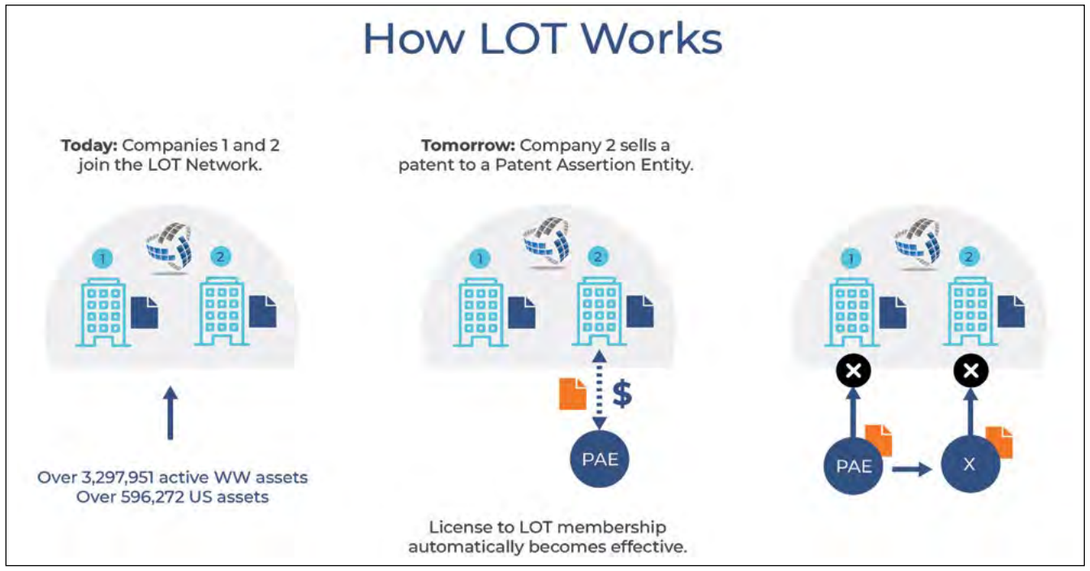
LOT Network today

LOT Network has grown its membership to over 1,800 members (November 2021) that are headquartered in 54 different countries. Those members collectively own 3.3 million active patent assets worldwide, which are protected in 86 different countries. LOT Network counts the second, third, and fourth largest patent owners in the world who use their patents to protect their innovations and to support their business as members of the non-profit community.

[2] LOT Agreement version 2.0, 05.10.18

Below: Chart 5: Breakdown of LOT Network Portfolio using Cipher Universal taxonomy





LOT Network is simply self-defining a community of companies who are voluntarily deciding, in advance, that they do not want to be the ones who are unlicensed when the assets are transferred to a PAE. Members gain value by sharing their rights in return for other rights which they value. They are not disposing of value or devaluing, but rather gaining value. Ultimately that is why LOT has grown as quickly as it has.

How LOT Network works

Each member of LOT Network, regardless of their revenue or size of their patent portfolio, signs the exact same document. Under the LOT Agreement, members are committing to give the other members of the community a free license to any patent assets if and when those patents assets are transferred to a PAE as the above diagram illustrates.

The more companies and the more assets that are within the network, the greater the protection afforded to members.

The LOT Network Portfolio

With its rapid growth in membership, LOT Network has aggregated rights to the largest patent portfolio in the world. There are now over 3,297,951 active worldwide assets subject to the LOT Agreement. This includes all active patents and applications owned by a member during their membership. Patents that have expired or applications that have been abandoned or rejected are not included in this number. In the following sections, the aggregate of these patents and applications are referred to as the LOT Network Portfolio.

The diversity of LOT Network members means that the LOT Network Portfolio offers protection for all companies, whatever size they are, the sector in which they operate, or their geographic location. In the sections that follow, Cipher has analyzed the LOT Network Portfolio

> **In 2020, operating companies sold 80% of the patents purchased by PAEs.**

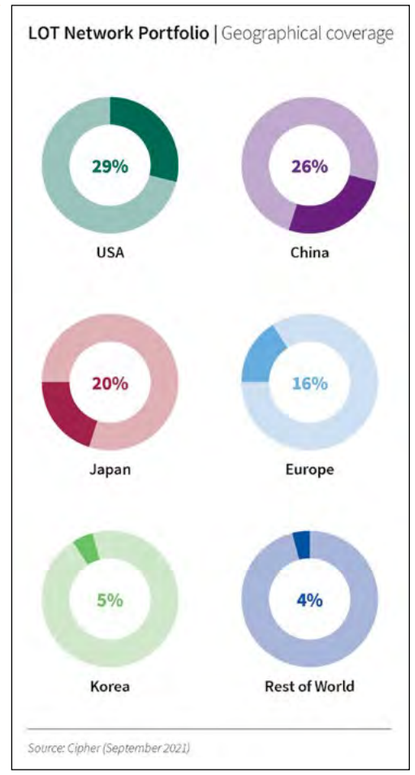


Chart 6: LOT Network Portfolio by geography

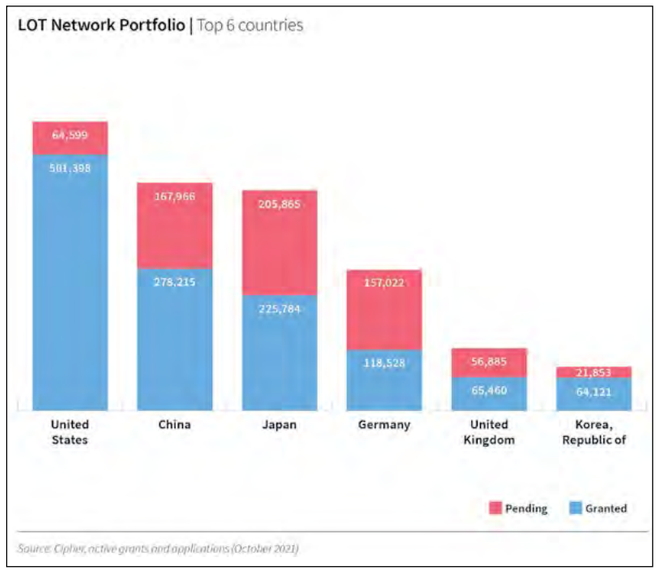


Chart 7: Number of active patents and applications currently owned by country

by both sector and technology. We start with an overview.

The LOT Network Portfolio has the greatest coverage in the US, closely followed by China (26%) and Japan (20%).

An alternative view is to analyze the LOT Network Portfolio by territory (rather than region), and to analyze patents and applications independently (rather than at family level). This data is contained in Chart 7.

The LOT Network Portfolio covers a very broad range of technologies, and one way to appreciate this is to analyze the LOT Network Portfolio by the CPC classification system widely used by all major patent offices. Chart 8 represents the top 20 areas within the LOT Network Portfolio. As the LOT Network Portfolio encompasses thousands of CPC codes, it may be difficult for a company to fully appreciate the value received when joining LOT Network. Using advances in AI and machine learning, Cipher is able to classify the LOT Network Portfolio in an objective and repeatable way.

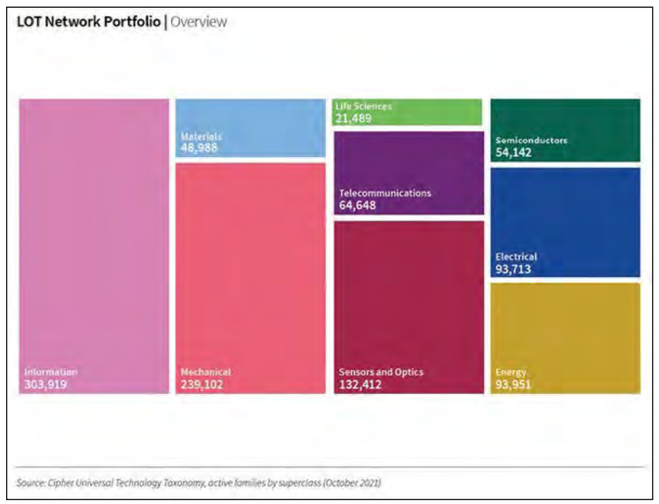


Chart 8: LOT Network Portfolio - top 20 technologies

LOT Network Portfolio by Sector

LOT Network members come from a broad range of sectors (see Chart 5), and the LOT Network Portfolio is analyzed below by reference to a number of taxonomies developed by Cipher for companies engaged in the financial services and semiconductor industries.

Financial Services

LOT Network's membership includes nine of the 10 largest banks in the United States, including the largest J.P. Morgan Chase, along with all four major credit card companies, 14 members of The Clearing House, bitcoin exchange leaders like Coinbase, digital payments platforms like Ant Financial and Square, ecommerce platforms like eBay, Amazon, and Alibaba, and hundreds of fintech startups. In the aggregate, the companies represent the largest financial services patent portfolio in the world. Chart 9 is a breakdown of the 621,731 patent families owned by these members.

Semiconductors

With large and diverse patent holders like IBM, Bayer, DOW Chemical, Boeing, Verizon, Bosch, Canon, the LOT Network Portfolio includes assets in essentially all technology areas. One area that has drawn attention in purchasing from PAEs is semiconductors. Chart 9 illustrates the number of semiconductor assets LOT Network members own by sub-class. Year over year, LOT Network has grown by over 235% just in the number of semiconductor assets under license alone.

What does the future hold?

PAEs have been part of the IP landscape for over 30 years. Given the hundreds of millions of dollars being invested to acquire assets, or being invested through litigation finance, it is clear PAEs are here to stay. Fortunately, there is now a proven solution to address this problem.

As LOT Network continues to grow, we can further strengthen the impact of the immunization it provides, and the value of being part of the community. In addition to the immunization benefit, LOT Network members are also fortunate in that they may be able to purchase a license to some of the patents acquired by AST to help

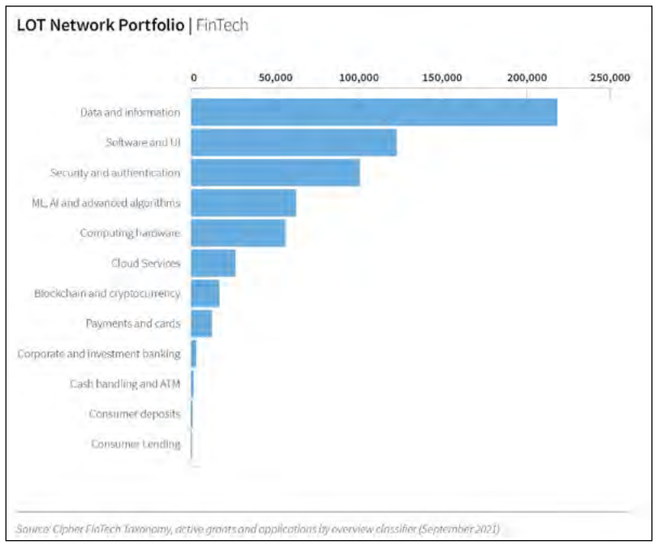


Chart 9: Breakdown of Financial Services IP owned by LOT Network members

further reduce the risk of attacks from PAEs.[3]

Since operating companies are the primary cause of the PAE issue, LOT Network provides a solution for companies to solve this problem on their terms and conditions. Fortunately, many in the industry have stepped up to join and become part of the solution. Hopefully, the others will follow, because as each new member joins LOT Network's community, the pool of companies that can be sued by a PAE using a LOT Network Portfolio patent shrinks. Thus, for those without a license, the risk that they may be sued grows.

[3] www.iam-media.com/defensive-aggregation/lot-and-ast-announce-new-deal-making-relationship

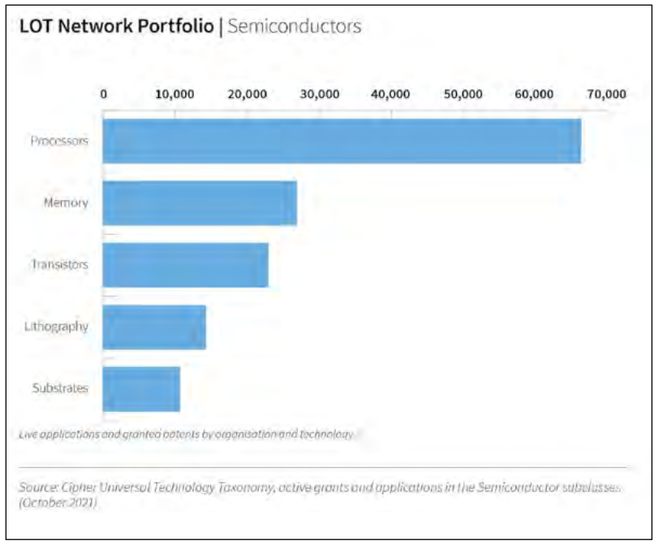


Chart 10: Semiconductors

About Cipher

Cipher is the leading strategic patent intelligence platform, and a member of LOT Network. Cipher maintains the master list of all patents owned by members and captured by the LOT umbrella. All data in this report is generated by Cipher and accurate as of November 2021, unless otherwise indicated. The sector and technology classification is generated from Industry and Technology classifiers developed for and used by many of the leading patent owners in their sectors.

All charts in this report may be reproduced with the following attribution: Source: Cipher from LOT Network Report 2021, November 2021. For more information, go to **www.cipher.ai** or email **info@cipher.ai**

About Richardson Oliver Law Group

ROL Group has over 60 years of IP strategy and execution experience, both in-house and at large law firms. ROL focuses on business questions first. We guide companies through unique IP challenges –like buying and selling patents, developing licensing programs, defending against patent assertions, and creating a value-driven IP portfolio. We give direction to businesses that share our passion for new ideas, creative problem solving and forward motion. For more information, visit **www.roipatents.com**

About LOT Network

LOT Network is an international community of the world's leading high-tech companies committed to protecting its members from costly litigation from patent assertion entities (PAEs). LOT Network currently protects more than 1,800+ members in 54 countries from litigation from over 3.3 million worldwide patent assets and counting. Members include market leaders such as IBM, Red Hat, Toyota, Visa, Canon, Google, Tesla, Cisco, Amazon, Microsoft, Alibaba and Salesforce, as well as innovative companies across industries.

Visit **www.lotnet.com** to learn more or download LOT Network's agreement.

Diversity, equity, and inclusion with Suzanne Wertheim. Chapter 4: DEI in law

In this six-part series Dr. Suzanne Wertheim, of Worthwhile Research & Consulting, talks to *The Patent Lawyer* about diversity, equity, and inclusion: what it means; the current challenges; DEI in law; gender bias; and what we can all do to improve.

How do you train for diversity?

One of the most useful tasks is educating people about the many, many ways that people can be diverse. Sometimes people from dominant groups, like white people, think that diversity as a concept doesn't apply to them. But with education, many of these people eventually start to understand that diversity applies to them as well – and that there's much more going on than just race or ethnicity or gender.

In my workshops, I demonstrate this with all kinds of real-world anecdotes. For example, involving people who are celiac and forgotten about when it comes to lunch planning. People who are in a different time zone and not taken into consideration when meetings are scheduled. People with young children who have time restrictions that should be taken into account, especially during a pandemic. People who are neurodivergent and should be accommodated - lots of people have ADHD, or are on the autism spectrum, or have Tourettes. Or someone may be a "class straddler" – a person who started from the working class, or even abject poverty. They might look like a young and carefree middle-class white person, but in reality be living ultra-frugally, supporting their whole family, and with lived experiences that aren't being taken into account.

Some people face obstacles because they grew up in a very rural area, or because they speak with a non-prestige accent. Once, during a training, we were talking about the most prestigious accents in English, and I pointed out how "fancy" and "sexy" many English speakers find French accents. And a manager, who had moved to the US from France around 10 years previously, told us his story. He was from Marseilles, a city in the South of France with what is seen elsewhere in France as a low-prestige accent. He told us about his boss in Paris who would say, "Come to my office and talk with me. I need a laugh." And the boss was actually just laughing at how he was talking, at his accent. So again, here we have a white man who is a high-level manager, making a good income – but he is also someone who has experienced bias and discrimination.

Dr. Suzanne Wertheim

> **There's much more going on than just race or ethnicity or gender.**

What's more, **everybody** contributes to diversity. A lot of people think that diversity is about other people. Like if you're white, or male, or heterosexual, or born in a body that aligns with your gender identity. But diversity is actually about everybody – and everybody has a role to play. The goal of a more diverse and inclusive workplace isn't to get rid of straight white men! It's just to create a better balance; to look at who has been left out of the conversation and left out of consideration. And to bring them to the table and really hear them when they speak.

In fact, white men have a really important role to play when it comes to diversity and inclusion. The higher status you are, the more power you have to make change. For example, higher status people get listened to more. Their voices get amplified. And when they say things that people disagree with, they face less blowback and less retaliation. White men have the most social power in many, many countries. And research has shown that this social power, which often translates into organizational power, amplifies diversity work done by white men. In fact, the only people who don't face professional penalties for diversity work are white men – instead of penalties, they get praise. So I like to tell the white men I work with through my training and consulting that they are like superheroes. Their one step is like seven steps for someone else. And they're wearing bulletproof armor. So if they push for something, they can make a real difference – and with way less effort or danger than for other people, like women of color.

I like to think of diversity and inclusion as an important form of process optimization. How do you get to an optimized workplace culture? Where everyone can thrive? Clients are well-served? Revenues are leading edge? Well, having a diverse leadership and employee base is correlated with good business outcomes, including higher revenue. And carefully adjusting workplace policies and practices so everyone feels comfortable and can do good work – this is also correlated with good business outcomes.

What's more, everyone likes to work at an optimized workplace. Everyone! You bring in more money, there's more innovation, it's less toxic, meetings go better, you feel like your work is seen - it doesn't matter who you are. When high-ranking people are being especially honest with me, it becomes clear that they think they're going to have to give stuff up. That it will be painful and difficult. But if you're bringing in more revenue, there's new room for more partners or more vice presidents. You can diversify your leadership by adding new roles, not by firing white men. The pie gets bigger: it's not a zero-sum game. So I like to be very optimistic in my training and show people that we can all play a role in making things better. We all matter.

What advisnter problematic bias from a client?

My advice is to keep yourself safe. If you're on the receiving end of bias, it is usually way more dangerous for you to advocate for yourself than it is to remove yourself from the situation. Research that shows that when you're a member of a group and you call out bias against that group, then you are usually penalized. So, for example, if an Asian person points out that someone has said racist and anti-Asian things, then most of the time, that Asian person is now in way more danger of retaliation – to the point of even getting fired – than the person saying racist things is in danger of actual professional consequences. It sounds incredibly unfair. And it is! But it's also how it works most of the time. So, what you need is someone else to advocate for you. The higher ranked they are in terms of social or organizational power, the better. Most of the time, the most effective advocate for you will be a white man who is high up in your organization, like an equity partner or managing partner.

But when you've been a target of bias, there's a good chance that you won't be believed. And there's a dilemma for your organization – if they take action to protect you, it can damage their client relationship. It might be uncomfortable, or they might lose money, or they might even lose the client altogether. What we often find, especially on the junior level, is that people are sacrificed to sexual harassment, to toxic yelling, to rude questions on competency when they're actually being very competent. A lot of people are sacrificed. My advice is to ask to be removed from that client if possible and seek out a potential advocate who will protect you. And if that doesn't work, look for an organization with a strong commitment to inclusion and anti-bias work, one that will actually work to protect you from toxic client interactions.

> **The bias that's out there in the world comes right into the courtroom. Some voices are amplified, seen as more credible, and just heard more.**

What impact can unconscious bias have on lawsuits?

In my experience, the biggest problem is credibility. There's a credibility gap that comes from unconscious bias and it has profound legal ramifications. There's been a lot of good research by linguists and linguistic anthropologists on testimony and credibility in the courtroom, and the bias that's out there in the world comes right into the courtroom.

Some voices are amplified, seen as more credible, and just heard more. And some voices are muted and seen as less credible. People who are amplified and seen as more credible are generally white people, male people, and people who speak a standard dialect. People who are seen as less credible and muted are people of color, people who present as female, and people who speak in a nonstandard dialect or foreign accent. Of course, sometimes this is all the same person, and then you've really got some unconscious bias penalties when it comes to how your testimony will be received.

There was an award-winning paper a few years ago about testimony in a big case here in the US. An unarmed teenage boy, just walking home from buying candy, was shot by a neighborhood vigilante who said that he felt threatened. It probably won't be a surprise to learn that the victim was Black. He was on the phone with his best friend at the time of the shooting, so she gave testimony for what she'd heard through the telephone. But because she was young, Black, and female, and spoke a non-standard English dialect associated with Black people, her testimony was perceived as much less credible. In fact, her testimony was widely derided on social media. But scholarly analysis showed that it was actually excellent testimony, using all the criteria for what is credible and convincing. It is widely believed by people who think about racialized dialects that if the same testimony had been presented in a standard dialect by a white man, it would have been seen as much more credible, and might have changed the outcome of the trial.

So, I think that this is an enormous problem for justice in lawsuits; some people's words are perceived as more credible while other people's are less credible. And who they are and how

> When there is a supposed meritocracy, one of the biggest problems is recognizing that bias is a real problem and distorting outcomes.

they are speaking turns out to be way more important than what they're saying and the actual content of their testimony.

What do you think is important for the improvement and continuation of diversity in the legal world?

One of the biggest problems is the idea of the legal profession as a meritocracy. Research has demonstrated that a profession that thinks of itself as a meritocracy is one where bias is more entrenched and more severe. What we find is that the highest "merit" goes to the people in the dominant groups, whoever they are. So it is the people in those dominant groups who rise to the top. I've heard the word "mirror-tocracy" used to describe tech, where you see white male company founders hiring white men as their first employees, who then hire white men to work for them, etc. When there is a supposed meritocracy, one of the biggest problems is recognizing that bias is a real problem and distorting outcomes. That the idea of the meritocracy is flawed and presumes a fair and equitable world that doesn't actually exist. That in many cases, someone's rise has been less about merit and more about distortions that have pushed some people down and pulled other people up. Until these systematic distortions are recognized and addressed, it's going to be an enormous problem. The supposed meritocracy and disregard of bias in academia is brutal. It's brutal in tech and all STEM fields. And it's brutal in the legal profession.

The whitest, male-est room I've ever presented to in all my years of teaching and training was when I was asked to give a continuing legal education course to only the partners of a California law firm. I was asked to train people about bias in the legal profession, a course that fulfills the California anti-bias requirement. I went into the room and had to turn around and pretend to dig through my bag so I didn't burst out laughing. This was a room full of partners. And I saw one white woman. And one man of color. And that was it. Everyone else was a white man, just filling up that room. I myself am technically white, even though I don't look particularly white. But again, in this room everyone except for one person was white. And it was amazing to me when I got to the slides talking about how much diversity dropped off in US law firms as you moved from the associate to partner level. How there were way more women of color, white women, and men of color who were associates at firms than ever made it up to partner. Because the numbers I was giving, which were pretty bad, were nothing compared to this firm! I mean, from what I could see, literally 5% of the partners were **not** white men.

And these partners watched me with what looked like complete unconcern. I got one desultory question during the Q&A portion, and then they got up and got lunch from the back of the room.

This was a particularly striking moment, but it is a reminder of what seems to be a terrible lack of self-awareness on the part of the legal profession. I very honestly think that the biggest motivation for change on the part of law firms is going to be external forces.

What I'm hearing in the US is that some companies are telling their external counsel if they don't make some changes when it comes to diversity and inclusion, they will drop them. I think we're at the very beginning part of this trend, where there will be an "inclusion rider" as part of the contract template. Very honestly, I think this is the only way that the legal profession will actually buckle down and make real changes. Changes at the institutional level, like law firm policies involving recruiting, hiring, work allocation, and promotion. And changes at the interpersonal level, where so much bias sneaks in. So you make sure people aren't being insulted and demeaned in everyday conversations; that they're invited to the right meetings and are getting the necessary emails; and that they are being mentored and introduced to the right clients and the right opportunities.

Join us in The Patent Lawyer January/ February 2022 for Chapter 5.

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- ☐ Cashflow efficiency
- ☐ Manual data entry
- ☐ Bank fees
- ☐ Currency risk

Billtrader is a niche fintech solution that was purpose-built for IP firms and designed to solve the cost and efficiency challenges related to making payments and being paid by foreign agents.

Get in touch with us at sales@billtrader.com to discuss how Billtrader can help you transform your foreign agent payments and receivables.

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