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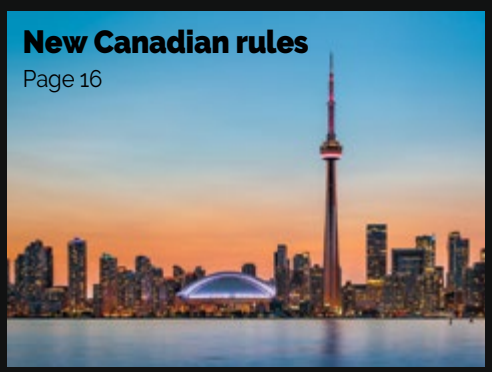

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CTC Legal Media

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Editor's welcome

Owner rights are a much-debated topic and, with the recent decisions in China, the conclusion remains unanswered. What is clear, however, is that the increased R&D costs for new technologies are the driving force behind service invention-creation, supporting employer ownership over employee ownership. Does this call for a change to statutory Chinese law to encourage an agreement-based ownership status? Find out in our cover story.

This issue's guest interview features Amit Gaikward, Senior Patent Analyst at GE. We discussed the development of technology roadmaps, how to analyze sector trends, and the focus on developing sustainable technology.

> *Does this call for a change to statutory Chinese law?*

Read about the updates to Canadian rules that could increase the cost of patent applications; find out how best to protect your design patents with disclaimers; a review on how the unitary patent will affect Polish patents; an overview of the opportunities Big Data is offering to the life sciences sector; and an interesting review on the patented developments within the field of dentistry.

Our *Women in IP Leadership* segment features Jennifer Bailey, Patent Director at HGF. Contact us to find out how you can support the segment and the continued empowerment of women in the sector.

This issue also features a special DEI article, discussing ADAPT – a collaborative effort to scale DEI programs in the patent industry. Find out more from three of its members, Judy Yee of Microsoft, Micheal Binns of Meta, and Ken Seddon of LOT Network.

Enjoy the issue.

Faye Waterford

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*

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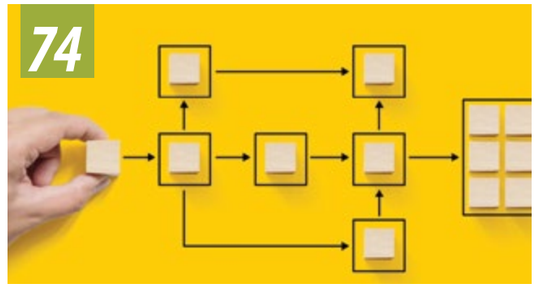


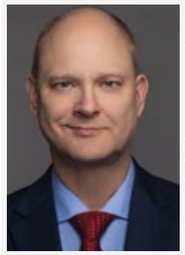
MEET THE EDITORIAL BOARD

Ken Adamo – Principal, Law Offices of KRAdamo. United States

Ken has extensive trial experience as lead counsel in jury and nonjury cases before state and federal courts and before the United States International Trade Commission, as well as *ex parte* and post-grant PTAB experience in the U.S. Patent and Trademark Office.

Pravin Anand: Managing Partner, Anand & Anand. India

In a career spanning over four decades, Pravin has emerged as an IP trailblazer having strengthened India's IP jurisprudence with a practice encompassing all areas of IP litigation including patents, copyright, design, trademarks, enforcement and dispute resolution.



Mark Bloom, CLP®, RTTP™: Patent Agent & Senior Consultant, MB Global Consulting. United States

Mark's primary areas of expertise are the IP and data-use aspects of academic technology transfer, government funding of basic research, public-private partnerships, and human and animal medical research.

Rafael Beltran: Principal & Partner, Beltran Fortuny y Beltran Rivera, S.C. Mexico

Rafael oversees the Patent, Trademark, Copyright, Plant Breeder's Rights, Internet, and Enforcement Groups. Served in the Mexican Association for the Protection of Intellectual Property AMPPI, AIPPI Mexican group. Current Vice-Chair of AIPPI's Standing Committee on PCT. Appointed INTA's Trademark Office Practices Committee 2022-2023.

Noel Courage: Partner, Bereskin & Parr. Canada

Noel's practice focuses on the patenting of biotechnological, chemical, and mechanical inventions. He also drafts and negotiates IP agreements, such as research collaboration agreements and licences.

Jacqueline Chernys: Senior Intellectual Property Counsel, BASF SE. Belgium

Jacqueline is a lawyer and patent attorney. Jacqueline worked in private practice before becoming lead IP counsel at an international oil and gas company. She has since specialized in the agri-industry, and currently is employed at BASF where she advises on all aspects of IP.

Stefan Schohe: Partner, Boehmert & Boehmert. Germany

In addition to prosecution of IPR for German and foreign clients, a main part of Stefan's work is litigation, especially pre-litigation advice, representation of clients in court, and coordinating international patent litigation. His main technical field is technology.

Eugene Goryunov: Partner, Haynes & Boone. United States

Eugene is an experienced trial lawyer that represents clients in complex patent matters involving diverse technologies. He has extensive experience and regularly serves as first-chair trial counsel in post-grant review trials (IPR, CBMR, PGR) on behalf of both Petitioners and Patent Owners at the USPTO.

Sarah Taylor: Senior Practice Development Lawyer, Pinsent Masons' IP practice. UK

Formerly a practicing patent litigator, she specializes in European patent matters. She advises and supports her team and clients on all aspects of patent law and litigation strategy across all sectors, with a particular focus on Life Sciences and Technology. Sarah has written extensively on a wide range of topical patent matters, including AI and UPC.

Dr. Claudia Tapia: Director IPR Policy and Legal Academic Research at Ericsson. Germany

Claudia's main responsibilities relate to strategy, policy and research in the IP field. Prior to joining Ericsson, Claudia was the Director of IP Policy in the department Patent & Standards Strategy at BlackBerry where she focused on IPR policies in standards, global patent policies, as well as licensing and litigation.

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

Osamu Yamamoto: Partner, Yuasa & Hara. Japan

Osamu is a patent attorney specializing in the fields of biotechnology, pharmaceuticals and diagnostics. Osamu is extensively experienced in all aspect of patent issues in these technical fields.

Discussion on Chinese service invention-creation and rights ownership thereof

Zhongling HAN and Xiaodong WANG of Beijing Sanyou Intellectual Property Agency Ltd. offer advice for determining an "Employer-First" and "Employee-First" duel model as a solution for invention-creation ownership.

Chinese legislation has always adopted the principle that Statutory-First and the Agreement-Supplemented for the rights ownership of service invention-creation. However, there have been more contracts that stipulate the rights ownership of service invention-creation with the increase in participants of the service invention-creation. In order to adapt to this trend, the scope of rights ownership of service invention-creation should be expanded and corresponding restrictions should be applied. In addition, the provisions on statutory ownership should be changed, and a dual system of "Employer-First" and "Employee-First" should be established, so as to establish an ownership model suitable for the current trend of patent law reform in the world to achieve the optimal allocation of rights.

Zhongling HAN

Xiaodong WANG

Problems

The emergence of service invention-creation originated from a separation of an intelligence provider from a material provider. Most of the inventive technologies were previously based on experience without consideration of cost. Subsequently, since the research and development cost of new technologies continued to rise with the development of science and technology, and cooperation was often required, personal invention-creation was replaced by service invention-creation to some extent. In fact, the number of service invention-creation reached 92.0% of the total number of Chinese domestic invention patent applications in 2021 according to the 2021 Annual Report of CNIPA.

For the service invention-creation, according to Article 6 of the Patent Law of China, "an invention creation made in the performance of the tasks of the entity or mainly by making use of the material and technical conditions of the entity is a service invention creation. The right to apply for a patent for a service invention creation belongs to the entity. After the application is approved, the entity shall be the patentee", that is, the Patent Law of China adopts the ownership model of "Employer-First", and further stipulates the principle that Statutory-First and the Supplemented-by-Agreement for the rights ownership of service invention-creation. However, in practice, it is often unable to meet the needs of Chinese technological innovation and ownership distribution, which thus restricts the way for the reasonable distribution of rights and interests between employers and employees to some extent, and also prevents the R&D and utilization of service invention-creation. In real life, employers and employees can often exert the highest utilization value and efficiency of invention-creation at low cost by independently agreeing on the ownership of service invention-creation.

Therefore, most countries in the world have stipulated a model that the rights ownership by agreement should be used as priority to determine the right holder of the service invention-creation. However, China has not yet stipulated the right ownership model of Agreement-First and Statutory-Supplemented, which is no longer in line with the international development trend,

and is not conducive to the protection of the mutual rights and interests of employers and employees and the reasonable distribution of the scope of rights.

From "Statutory -First" to "Agreement-First"

Under the current background of the rapid development of science and technology and the higher requirements for the material level and intellectual level provided by service invention-creation, the more refined division of labor in society is realized, however, relying on the ability of one person is no longer enough. It often requires the cooperation and joint efforts of a team or even multiple teams. At this time, the rights ownership of invention-creation will be contracted by parties. However, China still adopts the statutory-based rights ownership model, which is not conducive to balancing the rights of employers and employees, or is not conducive to promoting the renewal and further development of invention-creation.

In fact, intellectual property still falls within the field of Civil Law, so autonomy of will is an important principle of Civil Law. As for the rights ownership of invention-creation, if both parties can reach an agreement before R&D or reach a supplementary agreement after R&D, we believe that the freedom of autonomy of will of both parties should be respected. Since this is a provision of allowing both parties to freely dispose of their rights, it does not violate the legal provisions and conforms to the fundamental spirit of Civil Law. Chinese law should support it rather than restrict it.

> **"It often requires the cooperation and joint efforts of a team or even multiple teams."**

As a practical matter, the rights ownership for invention-creation developed by multiple teams together is problematic. Generally speaking, there will be multiple teams, including multiple employers and employees, to discuss the rights

Résumés

Zhongling HAN is an attorney-at-law and senior patent attorney at Beijing Sanyou IP Agency Ltd., which is a full service IP law firm founded in 1986 in Beijing, P.R. China. He has a wide-ranging expertise, including patent filing, evaluation, investigation, reexamination, invalidation and litigation in the fields of electronics, mechanics, communication, Internet of Things, semiconductors, blockchain, etc.

Xiaodong WANG is a partner and senior patent attorney at Beijing Sanyou IP Agency Ltd., with about 18 years' experience in the IP industry, she has a wide-ranging expertise, including patent prosecution, invalidation, reexamination, administrative and infringement litigation, patent search and analysis in the fields of medical equipment, mechanical engineering, electronics, and computer systems, etc.

ownership. If the "one size fits all" is adopted directly in accordance with the Chinese laws, it will undoubtedly infringe upon the rights of employers and employees, and thus lead to the ossification of relations, which is not suitable for the development of Chinese society and the goal of building a harmonious society.

However, it should be noted that the statutory ownership model should supplement the agreement ownership model. Some employers and employees also use the rules of statutory ownership as a baseline to design their own agreement contracts, so the statutory ownership provides more detailed content for employers and employees to choose from. In addition, when dealing with disputes over the ownership of invention-creation, judicial authorities should make fair judgments on the premise of respecting the autonomy of both parties and in combination with the relevant norms of statutory ownership in China.

The previous statutory ownership model in China adopted the "Employer-First" model to guarantee the interests of those who invest in the invention-creation or provide funds for the invention-creation, and to encourage more invention-creation in the early stage of intellectual property development in China. However, more attention has been currently paid to the rights of Chinese employees, and employees also occupy a more important position. Nowadays, the more refined division of labor in society is realized, and teamwork is increasingly demanding, so new problems have been brought about to some extent. These problems often need to be solved through the cooperation of multiple teams, thus it is not conducive to invention-creation that still adopt the Employer-Based model.

Therefore, we suggest that China adopt a dual model of "Employer-First" and "Employee-First". If an invention-creation is completed in the performance of the entity's task, it mainly embodies the employer's dominance, and the ownership should be enjoyed by the employer. However, if the invention-creation is completed solely by the technical and material conditions of the entity, the "employee" can enjoy the ownership of the invention-creation. To some extent, this has balanced and protected the interests of both employers and employees.

> **In fact, intellectual property still falls within the field of Civil Law, so autonomy of will is an important principle of Civil Law.**

Conclusions

There should be fewer statutory ownership models in China as the society develops. We need to establish an Agreement-Based and Statutory-Supplemented ownership model. In addition, a dual system of "Employer-First" and "Employee-First" needs to be established. For invention-creation completed in the performance of the entity's task, it mainly embodies the employer's dominance, and the ownership should be enjoyed by the employer. However, if the invention-creation is completed solely by the technical and material conditions of the entity, the "employee" should enjoy the ownership of the invention-creation.

There are still multiple imperfections in the Chinese patent legal system, which is determined by the Chinese patent legal tradition and history. However, the Patent Law of China still has a lot of room for development. The issue of the ownership of service invention-creation requires not only the revision of the Patent Law, but also the cooperation of other norms under the legal system, and even the support and efforts of the judicial system.

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An interview with Amit Gaikwad, Senior Analyst, Patents & Analytics Center of Excellence, GE Research, General Electric Company

Amit sits down with The Patent Lawyer to discuss his experiences as a Patent Analyst and his passion for working towards a zero-carbon energy future.

What inspired your career as a patent analyst?

My first experience with patent analytics started during my PhD days. We were planning to file a patent application and worked with the technology transfer and incubation unit of our university. Through this unit, dialogues with a law firm started and I was exposed to the world of IPR. I have always been attracted to the ever-changing world of technology and its business implications. Patent analysis became a medium through which I could get involved in new topics all the time and could have the opportunity to read and understand the next big thing before it reached the public. What initially drew me to it was the chance to work in a discipline that combined my skills in engineering with my love of cutting-edge technology. On a lighter note, I am reminded of the following Dilbert comic strip quote – "Great minds don't think alike. If they did, the Patent Office would only have about fifty inventions." And a patent analyst would not be required.

How long have you been with GE and what attracted you to the company?

I have been with GE for 14 years now. What attracted me personally to this company was the sheer breadth of cutting-edge technologies that GE works on, the culture & values which are at the forefront of everything that we do and the best patent analytics team to learn from & work with. Every day at GE is a new opportunity to collaborate with creative minds globally, to develop solutions that make a difference to millions of people. Our company is one that invests in its people in a way that leadership, innovation, growth, and unyielding integrity becomes a way of life.

Your focus is on Advanced Technology Programs in Sustainable Energy, what can you tell us about your work in this area and the hopes you have for a greener future?

We have been working in the development of advanced technologies for our businesses through our R&D centres in Niskayuna (New York, US) and Bangalore (India). To help you appreciate the full depth of technologies we get to work on and impact, we just published GE's 2nd annual Sustainability Report[1]. This 125- page document highlights a whole portfolio of product and technology solutions across our three major industries in energy, aviation and healthcare that are helping to build a more sustainable planet. I'm proud to be a part of the team working on the next generation of green technologies that help realize the dream of a zero- carbon energy future.

What do you look for when identifying key interests in a patent? And how do you determine 'new' aspects of a patent?

You cannot patent something that is already publicly known. The innovation must be new (called novelty). Every patent has one inventive feature, and our primary aim is to identify what differentiates one patent vs. other similar ones out there. The inventive feature forms the crux of this invention and is identified based on what is already out there (prior art). This requirement of an inventive step relates to the 'obviousness' of the new product, process, or invention. If it is 'obvious' to a skilled person, it is not patentable. Also, patenting something just because it's novel and inventive is not sufficient. It must solve the problems or unmet needs of the customers; it must have an industrial applicability. It's not innovation for the sake of innovation.

> **"Every day at GE is a new opportunity to collaborate with creative minds globally, to develop solutions that make a difference to millions of people."**

[1] https://www.ge.com/sites/default/files/ge2021_sustainability_report.pdf

Amit Gaikwad

How do you analyse sector trends?

For a given sector we look at patent data trends, open literature information, conferences and trade shows, as well as market data and financial data. We gather all the relevant information and connect the dots to gain insights from this data. We can analyze where a given sector is now, or where it's potentially headed in the near future. In the analysis phase, you can't simply describe — you must infer and extrapolate where the world is headed. Anyone can see what is, but what we are trying to identify is "what might be" or "what may not be apparent."

Can you explain how you go about developing technology roadmaps?

Technology roadmaps are a direct outcome of sector trends. Once we know where a given sector is potentially going, we identify the critical bottlenecks that need to be overcome and what could be the potential technologies that can help in mitigating these bottlenecks. Once these technologies are identified, the next challenge is to identify the pain points in these technologies which need to be addressed to successfully commercialize the technology.

How will the Intellectual property currently being developed at GE benefit the future?

GE is built on innovation. Our technology, global network, and exceptional team is fuelled by our core mission of building a world that works. For more than 125 years, GE has been inventing the future of industry. GE is pioneering technologies that are spurring world-transforming changes and improving the lives of billions. We believe that investing in technology is what sets us apart from our competitors. It puts us in a position to help solve big global challenges and to deliver value to our customers. Innovation is the one tool that will make better & affordable

Résumé

Amit Gaikwad, Senior Analyst, Patents & Analytics Center of Excellence, GE Research, General Electric Company

Amit Gaikwad is a Senior Analyst with the Patents and Analytics CoE (PACE) for GE, based out of John. F. Welch Technology Centre (JFWTC), Bangalore. He is responsible for IP & technology Analysis, IP strategy and monetization analytics in the Energy sector for GE's Research and Licensing divisions globally. Prior to this, Amit was an Assistant Professor with the India Institute of Technology, Guwahati (IIT-Guwahati). Amit has over 12 years of experience in the field of IP analytics & competitive intelligence and is passionate about using IP & technology intelligence for corporate strategy & decision making. Amit holds a PhD in Chemical Engineering from IIT Delhi (India).

solutions. The intellectual property being currently developed forms the basis of the next generation of technologies and product offerings from GE. Some of this IP also addresses improvements in our current product lines and can benefit our customers and GE in the near future. Also, we actively collaborate with partners who can deliver these offerings around the world.

How closely do you work with GE's legal team? How does your role impact theirs?

We are very closely connected with our legal teams at GE. Most of what we do is done as a team, whether its patentability analysis or freedom to practice or monetization opportunities. The analysis involves inputs and guidance from our legal team. For example, the patentability analysis helps them in better understanding of the prior art and deciding on the path forward for the disclosure or patent application based on what they see in the prior that we have uncovered.

Do you ever work with external/private practice lawyers? If yes, under what circumstances?

GE works with the external lawyers regularly on different matters like patent filing/ prosecution etc.

Out of the patents that you have worked on, are there any that stand out and why?

There was one patent I came across, in my search, a few years back. Although it was not related to what we were working on, I still remember that because of its length. It was more than 700 pages long (a typical patent document is 20-40 pages) and had more than 1,900 claims (a typical patent has around 20-30 claims). In the energy sector, you do not usually come across such huge patents.

What are the greatest challenges you face as a Patent Analyst?

The first challenge is to make sense of all the data that we analyse. It's not just about going through one patent and understanding what's in it or just counting patents. It's the insights that are more critical & challenging – why such solution was proposed in this patent, how is it different than others in this domain, why foreign filings in certain countries only, how this patent fits in the overall landscape and how key it is in the overall scheme of things etc. Strong technical and analytical skills are required. Another challenge we as analysts face is to translate the research language into a legal one and *vice versa*.

What is your favourite patent and why?

My favourite patent is my first one granted titled, "An alternate fuel" filed when I was pursuing my PhD. It's my favourite not just because it's mine, but also because we were solving a very challenging problem, how to reduce the consumption of fuel like petrol by adding water to it. Now as we know petrol and water don't mix and even if we somehow are able to mix the two, will an automobile engine run on such a water-based fuel? The whole journey of finding a solution to these problems and my first tryst with IPR commenced with this innovation.

> **"I'm proud to be a part of the team working on the next generation of green technologies that help realize the dream of a zero- carbon energy future."**

What aspect of your job role do you enjoy the most?

There are three important parts of a technology-based business. There is technology (can we make it?), there is IP (are we allowed to make/ sell it?), and there is market (will someone out there buy it?). A career in IP gives exposure in some measures to all three areas. Looking at technical advances through patents and other sources of information exposes the IP professional to the cutting edge of technology. What I love about being an analyst is the fact that you get involved in new topics all the time. Every day, conversations with our colleagues & customers provide new challenges and provide me with a great deal of new insights. Every new patent teaches us something, and there is no monotony in work because of that. Understanding the patents, and the thought process of intelligent minds behind them, makes work interesting. It has broadened the horizons of my thinking, processing and analysing too. These are self-motivating factors which make me work more passionately every day. The most satisfying thing about my job is being able to help my colleagues & fellow researchers make the right technology decision. This is what really drives me.

Patent applicants dash to avoid costly new Canadian Rules

Noel Courage, Partner at Bereskin & Parr, explains the changes to Canadian Rules introduced to improve examination efficiency that may increase prosecution costs.

Résumé

Noel Courage, Partner

Noel is a member of the Life Sciences practice group. Noel's practice focuses on the patenting and licensing of biotechnological, chemical and mechanical inventions.

Noel Courage

The Canadian Intellectual Property Office has been importing patent rules based on those in other jurisdictions, such as the USA and Europe. Sometimes these Canadian updates are due to treaties. For example, Canada implemented the Patent Law Treaty which primarily harmonizes procedural requirements. The Canadian free trade agreement with the US and Mexico requires creation of a system of patent term adjustment. Canada also signed a trade agreement with Europe that led to patent term extension. There is nothing new about treaty obligations leading to updates in Canada's intellectual property laws.

> **"As of October 3, there will be, for the first time, excess claim fees, and a cap on the number of Office Actions prior to incurring fees to continue the examination process."**

Other times Canada has imported bits and pieces of patent law on its own initiative, such as the adoption of US-style file wrapper estoppel and the creation of patent agent privilege. These ideas have typically been adopted in a modified form, without meaningful stakeholder consultation. A piecemeal approach to patent law, without broad input from interested parties is not the best way to evolve patent law. There has been a steady flow of change to the Canadian patent system in recent years.

This article will look at a couple of key aspects of the newest Canadian Patent Rules that have caught the attention of patent filers.

Many applicants are currently taking immediate action to avoid the new rules and get grandfathered under the current rules. As explained below, action is required before October 3, 2022 (really before September 30, 2022 in view of CIPO holidays) to avoid the new rules. This article will also comment on steps to take if a patent application is going to be proceeding under the new rules.

The New Rules

Canada has again looked abroad for inspiration for its latest new rules. As of October 3, there will be, for the first time, excess claim fees, and a cap on the number of Office Actions prior to incurring fees to continue the examination process. The new Rules are said to be intended to improve examination efficiency.

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> **Canada has again looked abroad for inspiration for its latest new rules.**

Excess Claim Fees

Under the current rules there are no excess claim fees under any circumstances. There will soon be excess claim fees of CAD$100/claim for each claim in excess of 20. The fees will be due when requesting examination. The request for examination is due no later than four years from the Canadian filing date (PCT international application filing date). Fees are initially assessed based on the number of pending claims at the time of requesting examination. Additional claim fees will be owed at the time of paying the patent grant fee if the total number of claims increased during prosecution.

RCE

After three Office Actions, a request for continued examination (RCE) will have to be filed and an additional fee paid. This fee will be the same as the usual request for examination fee. If prosecution continues to an additional two Office Actions, an additional RCE fee will have to be paid to proceed further.

The RCE will also become the new mechanism to reopen and continue prosecution after a notice of allowance of claims has been issued. Typically prosecution is only reopened where the applicant wishes to add additional claims to a patent application. Due to Canada's strict rules against double patenting, all claims should typically be pursued in a single patent application where possible, which is why applicants sometimes want to go back and add more claims after allowance.

There are other revisions to the rules being implemented, which are less drastic, and will not be discussed here.

Recommended Actions

If you are reading this article before October 3, 2022, any applicant that intends to pursue over 20 claims in Canada should consider the impact of excess claim fees on their patent budget. Likewise, if a complex case could have a long prosecution, the budget may need to be increased. There may be no consequence of going under the new rules if there are 20 or fewer claims and the applicant has a clear, confident position on patentability.

Applicants that wish to avoid the new rules should consider filing their patent applications in Canada and requesting examination prior to October 3, 2022. For example, PCT national phase applications may enter Canadian national phase early, prior to October 3. Applicants with applications already pending should consider requesting examination. Taking these steps will avoid the caps on Office Actions, and request for continued examination fees.

> **Applicants with a lot of claims will have to consider either paying excess claim fees or reducing their claim set to reduce fees.**

If you are reading this article on or after October 3, 2022, Applicants with a lot of claims will have to consider either paying excess claim fees or reducing their claim set to reduce fees. To minimize the likelihood of RCE fees, proactive claim amendments and full arguments early on in examination would be a good way to try to expediently conclude prosecution.

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Adaption of the description: the new praxis at the EPO and implications for applicants

Felix Hermann of Boehmert & Boehmert provides an insight into the discussion between the EPO and the user community, the related legal issues and the implications of the EPO's practice resulting from the revised EPO GL 2022 on the examination of European patent applications.

CTC Legal Media

The EPO regularly updates, based on the developments in European patent law and practice, the Guidelines for Examination[1] at the EPO (EPO GL) which are a guide to the examiners and formalities officers of the EPO and applicants and their representatives to standardize search, examination, and grant of patent applications before the EPO.

Back in 2018, the EPO started to extend the sections related to clarity and interpretation of claims in section F.IV.4 of the EPO GL. The focus of the revisions over the past years has been on adaption of the description of the patent application in the light of the (amended and allowable) claims for grant of the patent application. Sections F.IV.4.3 and 4.4 EPO GL 2022 define more explicitly how the description must be adapted to the claims. The requirements, definitions and examples for adapting the description in the EPO GL have resulted in ongoing criticism and started a debate between the EPO and the user community[2] on whether all those requirements, definitions, and examples are indeed in line with the (development of) the case law of the Boards of Appeal (BoAs) as argued by the EPO. Other

[1] https://www.epo.org/law-practice/legal-texts/html/guidelines/e/index.htm

[2] including European associations, such as BusinessEurope, epi – European Patent Institute, Union-ip – UNION of European Practitioners in Intellectual Property, etc., and also international associations, such as AIPPI and FICPI – International federation of intellectual property attorneys

Résumé

Felix Hermann is a German Patent Attorney and European Patent Attorney having a telecommunications background and more than 20 years of experience in the drafting and prosecution of patent applications before the EPO and GPTO and patent litigation before national courts in Germany. As an *ad personam* member of the Standing Advisory Committee before the EPO (SACEPO) Working Party of Guidelines (WP/G), Felix is involved in discussing the yearly updates and revisions of the Guidelines for Examination at the EPO with EPO representatives.

aspects of the debate are the legal risks and the potentially significant additional workload and costs for applicants resulting from the explicitly imposed requirements on the level of adaption of the description now required.

This article provides readers with an insight into the discussion between the EPO and the user community, the related legal issues, and the implications of the EPO's practice resulting from the revised EPO GL 2022 on the examination of European patent applications.

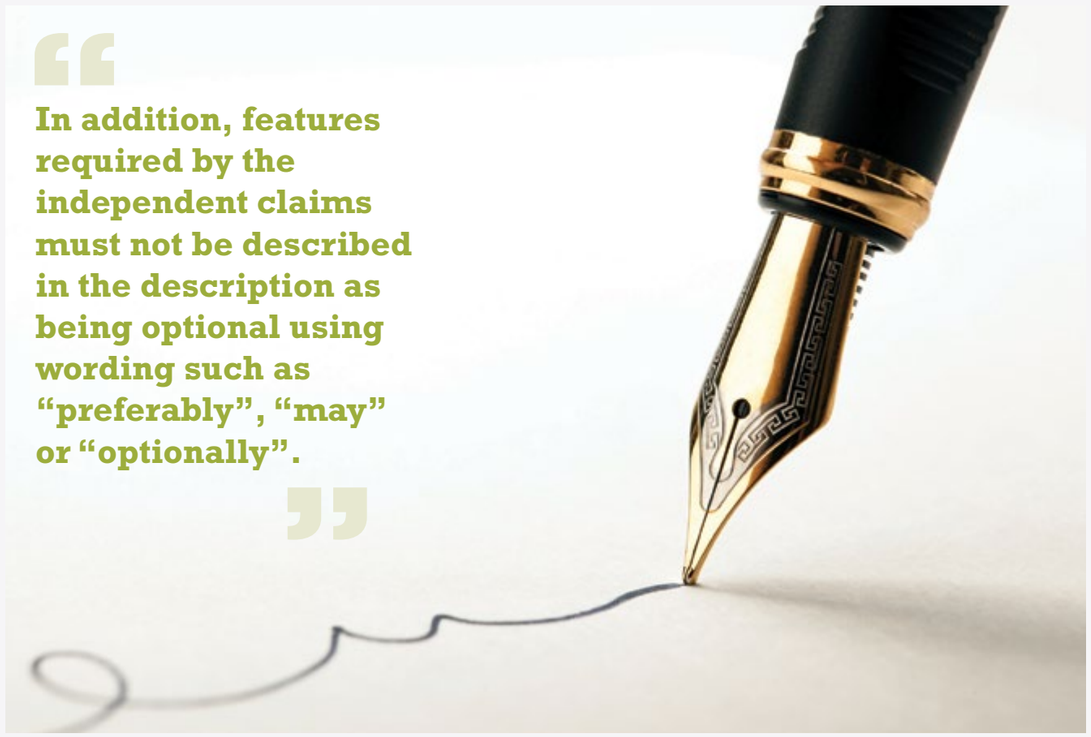
Felix Hermann

Legal basis for the EPO demanding adaption of the description

The legal basis for demanding applicants to adapt the description to the claims is provided in Article 84 EPC, which requires that the claims "shall […] be supported by the description." Somewhat like the "written description requirement" in 35 U.S.C. 112(a), "supported by the description" requires the specification to contain a description of the matter claimed. Yet, "supported by the description" also requires that the entire description must be consistent with the claims imposing the requirement that the description must be made consistent with the (amended) claims.

In revising the section F.IV.4 EPO GL, the sub-sections related to avoiding "inconsistency" between the description and the claims of a patent application (section F.IV.4.3 EPO GL) and to the handling of general statements in the description "which imply that the extent of protection may be expanded in some vague and not precisely defined way" (e.g. "spirit of the invention" and "claim-like clauses"[3] – section F. IV.4.4 EPO GL) have been in the focus of the revisions since 2018. Several of the revisions attempt to define the meaning of "inconsistencies" that require adaption of the description, and examples of amendments considered acceptable and inacceptable to remedy "inconsistencies" in the description.

> **In addition, features required by the independent claims must not be described in the description as being optional using wording such as "preferably", "may" or "optionally".**



One may side with the EPO that the updates of section F.IV.4.3 EPO GL aim at "codifying" what are the commonly accepted requirements on adaption of the description. When looking closer, some details of those requirements now found in sections F.IV.4.3 and 4.4 of the EPO GL appear to go beyond the requirements found in the case law of the BoAs. Those details appear based on the EPO's interpretation of the few BoAs decisions[4] dealing with the adaption of the description. In fact, there are even fewer BoAs decisions that provide explicit guidance on how amendments for removing "inconsistencies" from the description should look like. Some (older) decisions that were relied on by the EPO for updating sections F.IV.4.3 and 4.4 EPO GL in the past years mention that any disclosure in the description and/or drawings inconsistent with the amended subject-matter should normally be excised (e.g. T 1808/06, reason no. 2, T 1883/11, reason no. 2; T 1252/11, reason no. 34, etc.[5]), but they also state that embodiments that can reasonably be "considered to be useful for highlighting specific aspects of the amended subject-matter" can stay in the description, but the fact that an embodiment is not covered by the claims "must be prominently stated" (e.g. T 1808/06, reason no. 2).

There are also several new decisions of the BoAs on this topic (e.g. T 1989/18 and T 1444/20 *vs.* T 1024/18, T 121/20, T 2766/17 and T 2293/18.) dating into 2021 and 2022, which either diverge from or confirm some of the findings in the above noted decisions. Both, diverging and confirming decisions have been now mentioned in the latest BoAs' book "Case Law of the Boards of Appeal", 10th edition of July 2022 (see section II.A.5.3). This book summarizes the relevant case law of the BoAs and "takes into account decisions of the Boards of Appeal which were issued in writing in the period up to the end of 2021, as well as a number of particularly important ones from the first months of 2022."[6] The citation of the diverging decisions and the explicit identification of their divergence could yield that there is no settled and common understanding of "adaption of the description" across the BoAs. It must be seen whether these developments and divergence in decisions of the BoAs related to the adaption of the description under Article 84 EPC will finally lead to a referral to the Enlarged Board of Appeal of the EPO[7] seeking for a clarification of this topic.

Legal issues and the implications of the EPO's practice

In general, it seems correct that the adaption of the description required in the EPO GL can improve legal certainty as to the scope of the granted claims. Yet, updated sections F.IV.4.3 and 4.4 EPO GL 2022 strongly impact the examination procedure in terms of time and costs that applicants will have to spend on the adaption of the description. For example, as per section F.IV.4.3 EPO GL, to remove an inconsistency, every specific embodiment not encompassed by the claims must be marked as an inconsistent embodiment (e.g., by adding "not encompassed by the wording of the claims", "not according to the claimed invention" or "outside the subject-matter of the claims"). Simply replacing the terms "embodiment" or "invention" by, e.g., using one of the terms "disclosure", "example", or "aspect" is stated to be not sufficient. In addition, features required by the independent claims must not be described in the description as being optional using wording such as "preferably", "may" or "optionally". The description must be amended to remove such terms if they make a mandatory feature of an independent claim appear as being optional. Section F.IV.4.4 EPO GL further requires that claim-like clauses (e.g., an "example embodiments" section at the end of the description) must either be deleted or amended so as to conform with the amended claims.

> **The required adaption of the description also comes with several legal risks that impact the EP patent (application).**

Noting that many US-based patent applications frequently use the above noted "predicated" terms and expressions and numerous claims or features not included in the claims of the EP patent application are often appended as "claim-like clauses" at the end of the description, revising the description of an EP patent application for grant can require substantial time, consideration and also costs for the applicants.

Further, the required adaption of the description also comes with several legal risks that impact the EP patent (application). This is also why the debate between EPO and user community questions whether the intended improvement of legal certainty as to the scope of the claims granted by the EPO resulting from the adaption

3 "Claim-like clauses" are clauses present in the description which despite not being identified as a claim, appear as such and usually comprise an independent clause followed by a number of clauses referring to previous clauses (e.g. "additional embodiments" or "examples" section at the end of the description.

4 Some few tens of decisions over the past decades in comparison to 1000+ decisions of the Boards per year.

5 Decisions of the BoAs can be searched at https://www.epo.org/law-practice/case-law-appeals/advanced-search.html

6 https://www.epo.org/law-practice/case-law-appeals/case-law.html

7 The Enlarged Board of Appeal is to ensure the uniform application of the EPC and decides on points of law of fundamental importance referred to it either by a BoA or by the pre

of the description is proportional to the legal risks that can result from the adaption. Legal issues can arise in post-grant opposition/nullity proceedings, where the scope of protection may not be extended beyond the patent as granted (Article 123(3) EPC): For example, a post-grant amendment that relies on the original disclosure of an embodiment in Fig. X may well lead to an unallowable extension of the scope of protection, if the EP patent states that the embodiment of Fig. X is "not part of the claimed invention". Likewise, the EP patent stating the embodiment of Fig. X to be "not part of the claimed invention" will also impact the doctrine of equivalence of the EP patent in litigation as applicable in the validation states of the EP patent.

Despite those post-grant issues, Article 123(2) EPC requires that all amendments in an EP patent application or granted patent must not extend beyond the original application as filed. While a deletion of clearly non-covered embodiments from the description or marking them as "not covered by the claimed matter" might appear straight forward, the adaption of the description is often more complex, specifically, if it comes to revising "intermingled" embodiments. In the above example, consider that the embodiment of Fig. X does not read on the claimed matter because it uses a parameter A in a process but the claimed process requires to the use of a parameter B, which is disclosed as an alternative to the parameter A in some separate passage of the description. It seems not really clear from the guidance given in the EPO GL, whether the entire embodiment of Fig. X must be marked "not according to the invention", even though several details of the process steps are disclosed in connection with Fig. X are reflected in the claimed matter (and might be relevant also for a post-grant amendment).

Further, adding statements such as "not covered by the claimed matter" may also impact the scope of protection of the counterpart patents that have been granted with claims identical to or very similar to the claims of the EP patent, for example in the contexts of claim construction and doctrine of equivalence.

Dealing with adaption of the description at the EPO

So how to deal with this situation when the client's patent strategy has (also) a focus on EP patents? Noting that patent applications are often drafted for worldwide prosecution, it proves difficult to minimize time and costs for adapting the description before the EPO and to have the patent application "prosecution ready" in other jurisdictions (U.S., China, Korea, Japan, etc.) at the same time. One consideration would be to avoid "deprecated terms" mentioned in the EPO GL such as "embodiment", "invention", "aspect", "may", etc. as much as possible when drafting applications so that the passages that may need adaption for grant can be minimized. A further consideration is to draft the description of all relevant embodiments without reference to another embodiment (e.g., as an alternative) to avoid difficulties in adapting the description to the embodiment finally claimed.

> **Hopefully, new decisions on the adaption of the description by the BoAs will help to clarify the applicable practice.**

Another consideration is to revise the EP patent application before Paris convention filing or at EP phase entry to proactively adapt the description. This might provide an advantage in arguing post grant that certain amendments in the description were not made for complying with the "supported by the description" requirement of Article 84 EPC, which could improve proprietor's arguments on claim construction and under the doctrine of equivalence in litigation of the EP patent and might also favorably impact claim construction in foreign counterpart patents.

The new EPO GL 2023 will likely contain only minimal updates and clarifications in sections F.IV.4.3 and 4.4 and EPO's demands on the adaption of the description will likely not be lowered soon. Hopefully, new decisions on the adaption of the description by the BoAs will help to clarify the applicable practice. In the short run, applicants prosecuting their patent applications before the EPO will have to accept the EPO's "demanding" practice on adapting the description and associated legal issues and may need to reconsider drafting strategies to reduce the efforts in adapting the description to the claimed matter in prosecution of the EP patent application.

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Design patents: the name of the game is the [dis]claim

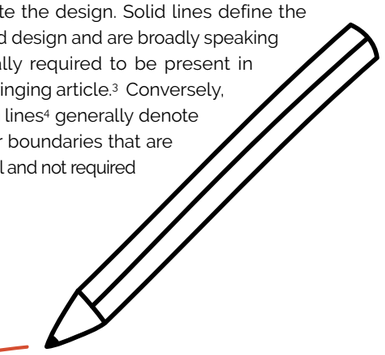
Alexander Czanik of Frost Brown Todd discusses strategies and associated risks of utilizing partial designs.

In 1990, Giles Rich, then Chief Judge of the Federal Circuit, coined the phrase: "the name of the game is the claim." A modified version of this phrase rings true for design patents, where claiming less than the whole results in broader, more competitively significant, patent protection. However, the applicant must claim enough to overcome the prior art but not too much so as to exclude commercially valuable variations. This article will discuss strategies that applicants may employ to minimize filing expenses while maximizing design patent protection through the use of partial designs as well as the associated risks.

Alexander Czanik

First, it is important to provide some background on partial designs. According to the United States Patent and Trademark Office (USPTO), partial designs claim, "a unique or particular portion of a full product design" and are often "part of a product that cannot be separated, sold, or used independently."[1] The utilization of partial designs ensures that competitors cannot avoid infringement through a trivial variation on an otherwise substantially identical design. Moreover, partial designs allow applicants to be more efficient in their design filings by avoiding separate filings for each minor variation in a product line.[2] While design patents are significantly cheaper than utility applications, filing separate design applications or separate embodiments within a single design application for each design variation is typically not financially feasible.

For partial designs, applicants use a combination of solid lines and broken lines to illustrate the design. Solid lines define the claimed design and are broadly speaking generally required to be present in the infringing article.[3] Conversely, broken lines[4] generally denote lines or boundaries that are optional and not required to be present in the infringing article.Broken lines are commonly used in patent applications to disclose unclaimed environmental elements related to the claimed design. As a result, a structure that is not part of the claimed design but is considered necessary to show the environment in which the design is associated, may be represented by broken lines. However, broken lines may not be used to show hidden planes and surfaces that cannot be seen through opaque materials.[5] Different types of



1 United States Patent and Trademark Office, *Protection for Partial Designs*, (Sept. 8, 2022), https://www.uspto.gov/ip-policy/industrial-design-policy/protection-partial-designs.
2 *Id.*
3 Infringement of design patents under the "ordinary observer test" is outside the scope of this article.
4 United States Patent and Trademark Office, *supra* note 2.
5 37 C.F.R. § 1.152.

Résumé

Alex Czanik is an attorney based in Frost Brown Todd's Cincinnati office. He assists clients with the preparation and prosecution of U.S., international, and foreign patent applications and conducts patentability, freedom-to-operate, and patent infringement investigations for a variety of industries including health care, transportation and energy.

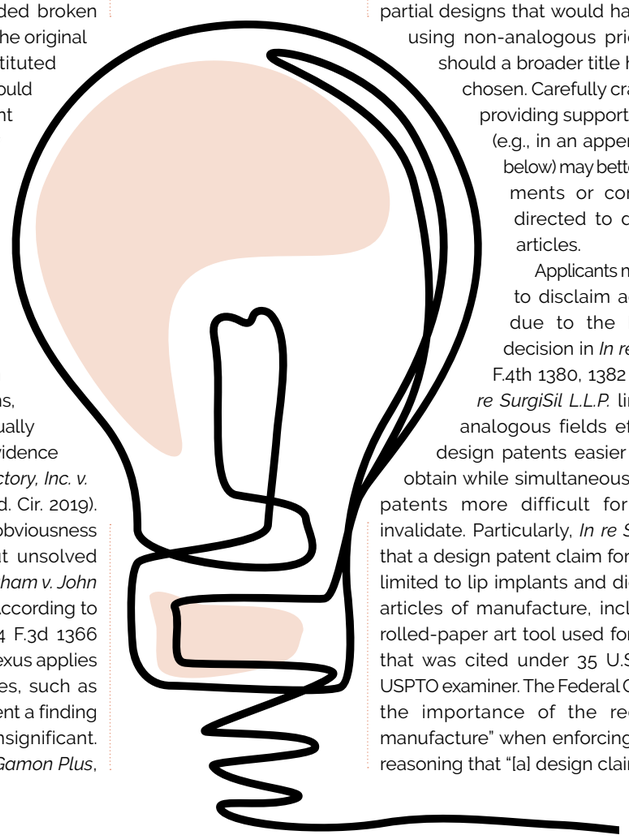
broken lines may be used for different purposes in the same design.

The claimed subject matter in the drawings may be varied in related applications that claim priority to the same original application or as different embodiments within the same application. For example, a majority of the design may be shown in solid lines in a first application, while broken lines may be introduced in place of select solid lines in a second application to claim less (and disclaim more) than the first application. Similarly, additional broken lines may be introduced in place of select solid lines in a third application to claim less (and disclaim more) than the second application. The prosecution, including the identification of prior art, in the first application may inform the strategy in the second application, and so on to ensure enough is claimed to overcome the prior art but not too much so as to exclude commercially valuable variations.

However, there are limits to modifying drawings in continuation applications as the Federal Circuit held in *In re Owens*, 710 F.3d 1362 (Fed. Cir. 2013). *In re Owens* involved the addition of an unclaimed boundary line for a Crest® Pro-Health Care mouthwash container. Particularly, the applicant permissibly converted several solid lines to broken lines; however, the applicant impermissibly added a new broken line bisecting a pentagonal front panel. This added broken line boundary was not disclosed in the original application, and as a result, constituted new matter. As a result, applicants should avoid adding new lines in subsequent design applications, even if the new lines are merely broken lines.

“Applicants should avoid adding new lines in subsequent design applications, even if the new lines are merely broken lines.”

Additionally, applicants may find it challenging to prevail using objective indicia of nonobviousness for partial designs. For background, objective indicia of nonobviousness may outweigh prior art that has the same overall visual appearance as the claimed design provided there is a nexus to the claims, i.e., “there must be a legally and factually sufficient connection between the evidence and the patented invention.” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). Examples of objective indicia of nonobviousness commercial success, long felt but unsolved needs, and failure of others. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). According to *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019), no presumption of nexus applies where there are unclaimed features, such as broken lines in a partial design, absent a finding that the unclaimed features are insignificant. According to *Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268 (Fed. Cir. 2021), cert. denied, 142 S. Ct. 1129 (2022), the nexus may be shown if the objective indicia are the direct result of unique characteristics of the claimed design rather than a feature that was already known in the prior art. According to the Federal Circuit, to establish the requisite nexus when no presumption exists, the patentee needed to present evidence that the objective indicia was derived from the unique characteristics that distinguished the claimed design from the prior art.



Applicants should carefully craft the title and the claim, as the particular words in the title and the claim matter when seeking to obtain or enforce a design patent. According to 37 CFR 1.153, “[t]he title of the design must designate the particular article.” The description of the article in the claim should be consistent in terminology with the title of the invention.[6] More specifically, “[t]he title of the design identifies the article in which the design is embodied by the name generally known and used by the public and may contribute to defining the scope of the claim.”[7] Narrow titles help the USPTO classify designs and narrow the potential prior art pool available to the examiner, thereby making it more difficult for an examiner or patent challenger to locate anticipatory prior art. For applicants, narrow titles may make obtaining design patent protection easier, particularly partial designs that would have been rejected using non-analogous prior art references should a broader title have been initially chosen. Carefully crafting the title and providing support in the application (e.g., in an appendix as discussed below) may better allow for amendments or continuation filings directed to different types of articles.

Applicants may be encouraged to disclaim additional aspects due to the Federal Circuit’s decision in *In re SurgiSil, L.L.P.*, 14 F.4th 1380, 1382 (Fed. Cir. 2021). *In re SurgiSil L.L.P.* limited prior art to analogous fields effectively making design patents easier for applicants to obtain while simultaneously making design patents more difficult for challengers to invalidate. Particularly, *In re SurgiSil L.L.P.* held that a design patent claim for a lip implant was limited to lip implants and did not cover other articles of manufacture, including a prior art rolled-paper art tool used for artistic blending that was cited under 35 U.S.C. § 102 by the USPTO examiner. The Federal Circuit emphasized the importance of the recited “article of manufacture” when enforcing a design patent, reasoning that “[a] design claim is limited to the article of manufacture identified in the claim; it does not broadly cover a design in the abstract.”[8]

The article of manufacture recited in the title, description of the figures, and the claims limits the scope of enforceability of the design patent. In *Curver Luxembourg, SARL v. Home Expressions Inc.*, 938 F.3d 1334, 1336 (Fed. Cir. 2019), the Federal Circuit held that the claim at issue was limited to the particular article of manufacture identified in the claim, i.e., a chair. Particulary, the Federal Circuit construed the claimed invention as being directed to “an ornamental design for a pattern of a chair,” not a “pattern for a chair,” which is applicable to other articles. As a result, the design patent was not infringed by the defendant’s baskets. The claim language supplied the only instance of an article of manufacture, which appeared nowhere in the figures, thereby limiting the scope of the claimed design. Once again, applicants should carefully craft the title and the claim.

While a narrowly defined article of manufacture may make prosecution of the design application more straightforward by limiting the scope of applicable prior art, it may make broad enforcement of the issued design patent more difficult. It is important to keep these competing interests in mind while preparing the design application.

An appendix may accompany a design patent application and include a variety of information including additional line drawings, CAD screenshots, photographs, and/or description. This appendix may be beneficial to correct information that was inadvertently omitted to rebut rejections set forth by the USPTO. Without an appendix, the applicant is constrained to the originally filed specification and drawings, which may make it difficult to overcome the rejection without adding new matter to the original application. For example, additional perspective views may allow for the three-dimensional structure of the article to be better discerned.

Using partial designs may limit inadvertent dedication to the public. A design patent application may include multiple embodiments. Filing a design application with multiple embodiments increases the preparation cost due to the additional drawings. Filing multiple embodiments in a single application will likely trigger an examiner to issue a restriction requirement, requiring the election of an embodiment to prosecute and the cancellation of the non-elected embodiments. Once the original application issues, the non-elected designs generally enter the public domain unless a divisional application is filed. Applicants may file a preliminary amendment prospectively canceling embodiments that are likely subject to a restriction requirement. Applicants may then subsequently refile these canceled embodiments in one or more continuation applications and avoid the restriction requirement.

“Narrow titles help the USPTO classify designs and narrow the potential prior art pool available to the examiner, thereby making it more difficult for an examiner or patent challenger to locate anticipatory prior art.”

Partial designs are not just limited to the United States. In a long-awaited change, China recently approved the use of partial designs which was a precondition to joining the Hague International Design System. Previously, applicants in China were forced to pursue protection as to the look and feel of the product as a whole and could not protect individual components if the individual components were inseparable from other components or individual components could not be sold or used independently. With this change, applicants are able to apply for Chinese design patent protection for innovations directed to parts of their products.

The use of partial designs will likely increase both in the United States and abroad as applicants become more familiar with their benefits. However, applicants must continually assess the benefits and risks of partial designs on a case-by-case basis.

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6 *See* M.P.E.P. § 1503.01(I).
7 M.P.E.P. § 1503.01.
8 In re SurgiSil, L.L.P., 14 F.4th 1380, 1382 (Fed. Cir. 2021).

Straightening out the world of dentistry with innovative patents

Ludmila Lisovskaya, Patent and Chemical Specialist at Zuykov and partners, provides an overview of modern technological innovation in the dentistry field.

This article analyzes breakthrough technologies used in dentistry and orthodontics around the world. As you know, dentistry is one of the fastest growing areas of medicine, which constantly patents innovative technical solutions that allow people to undergo treatment more comfortably and painlessly.

Orthodontics

Correction of the bite is achieved through the use of mechanical static forces that cause bone remodeling, which allows the teeth to move. This widespread approach to treating malocclusion takes an average of about 24 months, using orthodontic braces consisting of a wire that applies a constant static force to the junction of teeth with braces attached to each tooth. Clinical malocclusions include malocclusion, crossbite, open bite, and crooked teeth for both aesthetic and functional or structural reasons.

Removable transparent devices (aligners) for dental treatment are also widely known. Removable appliances, as well as traditional components of orthodontic systems, such as dental braces and wires, are disposable. At the first visit, during a procedure known as bonding, orthodontic braces are attached to the teeth with cement or some similar substance with adhesive properties. Except in cases of damage or loss of braces, the same braces are retained throughout the course of treatment. At the end of treatment, orthodontic braces are removed. The wires are usually changed during corrective visits as needed. The previous archwire is discarded each time a new one is attached to the brackets. The cost of consumables is the responsibility of the patient each time.

In addition, orthodontic treatment with braces can be complicated by the fact that it often causes discomfort and pain to patients, including initial placement and adjustments between visits. Post-treatment stability and tissue integrity are also important factors associated with orthodontic treatment. Stability is usually achieved and improved by wearing retainers continuously, in many cases indefinitely. Failure to comply with the wearing regimen of retainers can lead to relapses requiring additional treatment.

> **US patent 11173014 B2, published on 11/16/2021, protected another breakthrough technical solution in the field of orthodontics - a minimally invasive way to increase the speed of tooth movement.**

Proposed by the American "Association for Advanced Orthodontics and Education", an innovative system for correcting malocclusion, disclosed in the application for invention **US 20200405444 A1**, published on December 31, 2020, for which a positive decision on the issuance of a patent is expected soon, allows you to correct the bite and change the position of the teeth without retainers, pain and discomfort in three to six months, while putting on the system only at night.

The proposed system of orthodontic remodeling includes an extra-oral vibration source connected to the bite block, while the extra-oral vibration source drives the bite block to vibrate with a frequency in the range from 0.1 to 400 Hz. The bite block is designed to transmit cyclic forces simultaneously to the teeth of the maxillary and mandibular arches, and the bite block and the extraoral vibration source are held during use only due to clamping by the teeth. The battery is designed to power the extraoral vibration source, and the processor is configured to control the extraoral vibration source. Electronic media may collect data indicating duration and frequency of use so that patient compliance can be determined.

Thus, constant vibration quickly forces the teeth to line up in the form of a cap, while the patient does not experience pain and discomfort, without interfering with their sleep at night.

Correction of the curvature of the teeth and, as a result, the bite occurs due to the restructuring of the periodontal ligament between the teeth and bone tissue, while there is no collapse of small vessels (capillaries), as occurs when installing braces, due to which the cells that provide blood flow to the teeth are not released, and the mechanism of natural tissue regeneration does not start, which slows down the process of teeth alignment.

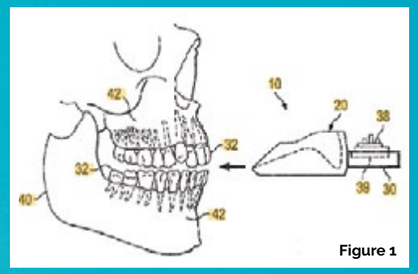


Figure 1

US patent 11173014 B2, published on 11/16/2021, protected another breakthrough technical solution in the field of orthodontics - a minimally invasive way to increase the speed of tooth movement ("BAST" technology).

If an adult decides to move their teeth for any reason, the speed at which they can move safely is so slow that treatment can take years. In turn, given the slow speed of movement, adult teeth tend to return to their previous, sedentary or other undesirable position after they have been moved with braces or aligners.

> **The claimed method provides an opportunity to restore the teeth so that they correspond more to the desired or ideal sizes, as well as to reduce the time required to achieve a stable and lasting result.**

This unwanted result can occur even if the retainer is worn or attached to multiple teeth.

It is also now accepted that dental implants, once placed in the mouth, cannot be moved.

In addition, in some patients, the tooth may usually be more parallel to the plane of the jaw than perpendicular, and may not erupt at all because it does not grow to the gingival surface.

Often, the treatment in these cases consists of the surgical removal of the tooth by cutting the gums and removing the tooth, sometimes part of the bone, with dental forceps. The prevailing opinion is based on the belief that unerupted or partially impacted teeth cannot function in the dentition.

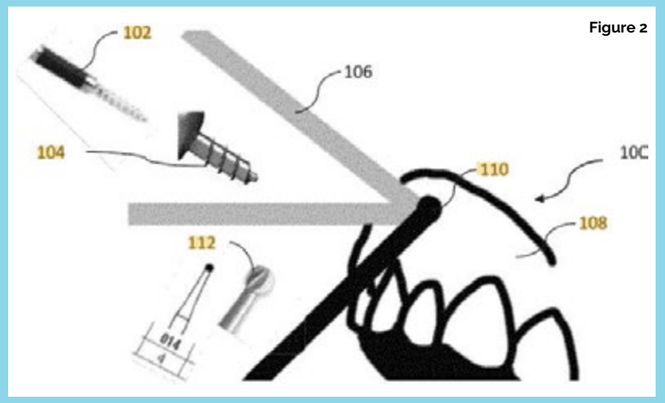
The method proposed in the present invention solves the above problems.

A method for increasing the speed of at least one moving tooth along the jaw bone includes placing an abrasive bur of the desired diameter between adjacent roots of at least one tooth in the jaw bone, the abrasive bur is rotated using a manual device to penetrate the gum tissue covering the space between adjacent roots of at least one tooth in the jaw to remove the desired amount of gum tissue and expose the underlying jawbone, and to bring the bone into contact with a rotating burr to abrasively vibrate the jawbone adjacent to at least one tooth without drilling into the cortical bone.

The claimed method provides an opportunity to restore the teeth so that they correspond more to the desired or ideal sizes, as well as to reduce the time required to achieve a stable and lasting result.

Figure 2 and Figure 3 illustrates the "BAST" technique performed on the gum and bone of a real patient in accordance with an embodiment of the claimed invention.

Figure 2



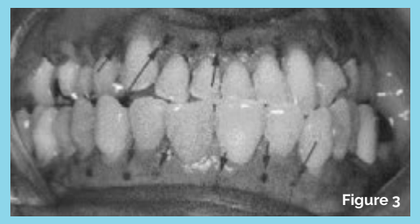


Figure 3

Prevention in dentistry

Another progressive technical solution is the use of ozone for the treatment of a prepared carious cavity, including teeth whitening.

Recently, ozone therapy has become a new alternative, atraumatic therapeutic method in medicine and dentistry. Ozone, which is a triatomic particle of oxygen (O3), is negatively charged and is a natural oxidizing agent. Bad cells in our body, such as bacteria, viruses, and cancer cells, are usually positively charged and do not have antioxidants on their cell membranes, so they attract ozone particles that destroy them. Dentistry uses a stream of liquid ozone (ozonated water) or ozone gas that is delivered to the teeth and gums for 30 minutes to treat periodontal disease by flushing below the gum line with ozonated water. Ozone is also used in both liquid and gaseous form in root canal treatments, to kill bacteria, sterilize the canal system, and promote healing. As a gas, ozone can get into places in the mouth that are inaccessible to liquids. This is because the gas can enter tiny tubules that cannot otherwise be accessed, thereby providing a truly sterile, bacteria-free root canal system prior to canal filling.

From **US patent 9539076 B2**, published on January 10, 2017, an apparatus and system for conducting two-level oxidative therapy in dentistry is known. The device is a mouthpiece made of rubber or thermoplastic elastomer, which provides full or partial coverage of the treated teeth and gums, first with hydrogen peroxide vapor, and then with ozone gas. The design of the mouthpiece, which includes several injection tubes, which allows you to treat all surfaces of all teeth and gums at the same time, thereby providing a fast, painless and economical procedure for the patient.

The therapy of the present invention includes biofilm cleansing (removal of bacterial pathogens), periodontal pocket disinfection and bone disinfection, caries prevention, endodontic treatment, tooth extraction, tooth sensitivity, temporomandibular joint treatment, gingival recession (exposed root surfaces), root canal treatment, pain relief, infection control, accelerated healing, tissue regeneration, bad breath control, tooth surface remineralization and whitening.

Figure 4

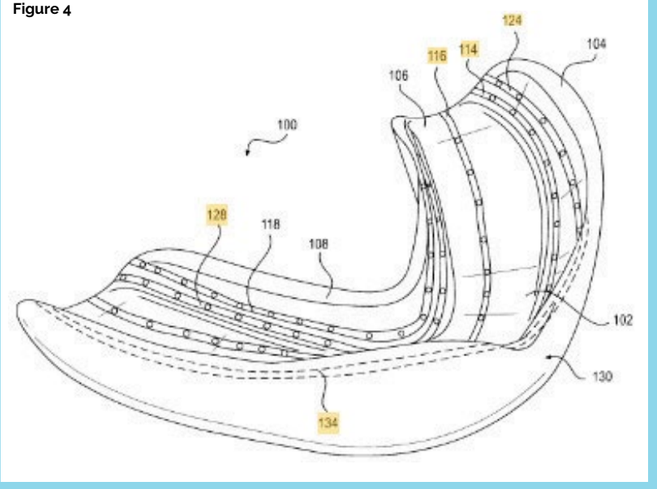
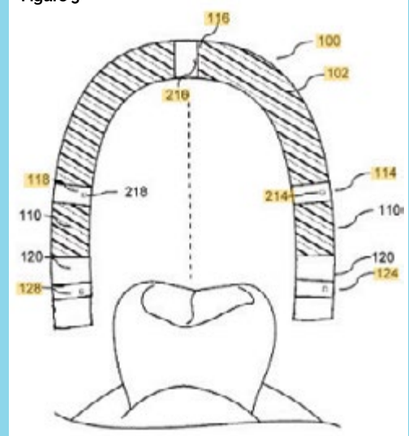


Figure 5



Dental materials ("Liquid filling")

English company "Lucite International Speciality Polymers and Rubbers Limited" proposed a curing multicomponent acrylic composition, for which a patent for the invention **RU 2712216 C2** was issued in the Russian Federation, published on January 27, 2020.

The invention includes a solid first part and a storage-stable liquid second part, which parts are intended to form a cement which, when stirred, solidifies to form a solid mass. The composition further includes an acrylic monomeric component in the second part, an initiating component, a first subset of acrylic polymer granules in the first part, a second subset of emulsion-polymerized acrylic microparticles in the first part, and a radiopaque filler, wherein the radiopaque filler is encapsulated in bulk and/or adsorbed on the acrylic polymer granules. The first subset and at least 90% of all acrylic polymer beads with encapsulated and/or adsorbed radiopaque filler of the first subset are present in the first part of the composition.

The advantage is that room temperature curing compositions (so-called " self -curing systems" or "cold cure systems" have a setting time which is determined by the rate at which the viscosity of the composition containing solid and liquid components begins to increase immediately after mixing, and is controlled by a number of factors such as the particle size and shape of the granulated polymer, the molecular weight of the polymer, and the composition of the polymer.

Radiopaque fillers are a necessary ingredient that is added to the composition for it to function as a radiopaque agent that shows the position of the cement when implanted into the body.

Dental applications of the claimed composition, in addition to fillings for restoring teeth, include denture bases, denture base plates, denture liners, denture repair materials, custom trays, crown and bridge veneering, artificial teeth, veneers, and materials for treating natural teeth.

"Growing" a new healthy tooth

Japanese developers have proposed a technology for the manufacture of restorative material used to restore the area of a lost tooth in the oral cavity. This technology is protected, including in the Russian Federation, by patent **RU 2521195 C2**, published on June 27, 2014.

To do this, the first cell mass formed by cells or a cell from mesenchymal or epithelial cells and the second cell mass formed by another cell or other cells from mesenchymal or epithelial cells are placed on the carrier. In this case, one of the mesenchymal or epithelial cells is obtained from the tooth germ and these cell masses are placed in close contact with each other without mixing. These cell masses are grown with the formation of a whole restored tooth or its germ. Then, the orientation of the whole restored tooth or its germ formed by growing is determined, which allows the implantation of the whole restored tooth or its germ in the area of the lost tooth so that the coronal part of the tooth is directed inside the oral cavity, while the tooth germ or tooth is used as a restorative material to obtain the equivalent of a lost tooth in the area of a lost tooth. This group of inventions makes it possible to restore the area of a lost tooth by introducing a restored tooth germ or a restored whole tooth, manufactured by the above method.

Ludmila Lisovskaya

"This group of inventions makes it possible to restore the area of a lost tooth by introducing a restored tooth germ or a restored whole tooth."

Résumé

Ludmila Lisovskaya has worked as a 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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BIG Data unveiling BIGGER opportunities for life sciences ecosystem & innovation

Manisha Singh, Founder Partner, and Neha Ruleha, Senior Associate, of LexOrbis review the prospects that Big Data is offering to the industry and the IPR regulation that innovators should monitor.

Sherlock Holmes' classical quote: "Data! Data! Data! I can't make bricks without clay" conveys the inevitability of minute details and logic for solving a mystery. In the similar vein, modern-day Big Data holds the key to unlocking the doors of latent patterns in the real world of the digital era.

Big Data, since its advent, has become a fascinating buzzword for academia, governments, and several businesses, e.g., Industry, telecom, finance, insurance, and the healthcare sector. Put simply, Big Data refers to huge, diverse, rapidly growing information which may be used for drawing valuable inferences. It is said that nearly 90% of the global data was generated over the last two years alone. The exponential trend of data is being triggered by the growth of the Internet of Things (IoT). Coupled with the power of artificial intelligence, Big Data applications pour into the realm of innovation too.

Industries and startups are keen to tap into the potential of the complex web of interlinked information and enormous data being generated every second in life science verticals, be it, pharmaceuticals, biotechnology, healthcare, or MedTech. Big Data holds great promise in this regard. This optimism is reflected in rising investments and also supported by various outlook studies.[1,2]

In this article, we will explore emerging trends and applications of Big Data Intelligence in the life sciences ecosystem and present glimpses of opportunities that Big Data offers in innovations along with the challenges it faces, particularly in the Indian Intellectual Property Rights (IPR) regime.

Manisha Singh

Neha Ruleha

[1] World Intellectual Property Report *'The Direction of Innovation'* (2022)

[2] Deloitte *'Global Life Sciences Outlook'* (2019-2022)

'101' of Big Data – the basics

Wider connotation

'Big Data' is an umbrella term that describes increasing streams of data, as well as advanced approaches and techniques being used to gain valuable insights from this voluminous data.

The five Vs of Big Data

Rather than defining formally, most literature characterize Big Data in terms of five V attributes seriatim:

Volume: The phrase 'Big' suggests that a huge amount of data is a *sine qua non*. Its size is too large and complex to be dealt with using the traditional approach. Think of large-scale data in genomics, patient data which runs into millions of past records and are continuously added.

Variety: It refers to diverse data sets from various sources. It could be conventional structured data arrayed in row-column and semi-structured or unstructured data such as text, image, audio, video, GIS, GPS, sensor, social media data etc. Advanced computing takes care of heterogeneity arising from the latter class. Think of collection of all prior-art literature, clinical trial data.

Velocity: It is the high speed at which streams of data are generated. It refers to how rapidly data moves. Big Data can deal with intricacies of near real-time processing so as to enable prompt business responses. Data flows from medical devices and sensors are to be tracked and tapped quickly and dynamically.

While said three Vs are intrinsic features, the next two Vs are utilitarian in nature.

Veracity: It refers to quality and accuracy of collected or generated data. Generally, Big Data is messy, noisy, inconsistent, and even may have some bias. The incomplete data of a patient's medical history could be fatal at times. Multiple checks and data cleaning can be done beforehand, and missing points can be imputed suitably. The quality of output analytics and insights evidently rests upon the veracity of input data.

Value: The last V refers to potential value, which can be derived from Big Data insights. It is where innovation comes into play. Entities can use the same Big Data tools, but the way they utilize value from that data is unique to them. Innovative ideas when applied correctly may lead to data monetization and the 'right decision at right time'.

AI-driven Big Data analytics

Big Data (BD) and Artificial Intelligence (AI) are seemingly inseparable. AI 'mimics' real-world conditions. AI requires high-quality data, and the more data AI receives, the more accurate and efficient 'learning' we can expect. Big Data Intelligence (BDI) includes various algorithms and techniques such as Deep Learning, Machine Learning (ML), Predictive Modeling, Classification Algorithms, Natural Language Processing (NLP), Image Processing and is used to discover actionable insights, find new patterns, and unveil relationships in massive and diverse data.

Now, let us have a look at some practical aspects.

BDI applications in the life sciences ecosystem

Pharmaceutical & biomedical sector

Given the small patent window of 20 years and the lengthy, risky, and complex process of drug development, BDI enables pharmaceutical companies to accelerate the discovery process of new drugs in order to realize maximum return on investment and reduce R&D costs.

BDI also assists in enhanced and targeted recruiting of niche patients for clinical trials. A cost-effective, faster, and better clinical trial could be achieved by analyzing the participants' demographic and historical data, genomics, real-time remote patient monitoring (RMP) data, and reviewing past clinical trial events data.

Data mining of Adverse Drug Events (ADEs) along with data from healthcare service providers, pharma companies, regulators, and social media could lead to proactive pharmacovigilance and better drug safety surveillance and signals.

> **"The global personalized medicine market is expected to increase at over 11% CAGR by 2024, with the aid of advances in healthcare analytics and AI."**

Résumés

Manisha Singh – Founder Partner, LexOrbis

Manisha Singh is the Founder Partner of LexOrbis. Manisha is known and respected for her deep expertise in prosecution and enforcement of all forms of IP rights and for strategizing and managing global patents, trademarks, and design portfolios of large global and domestic companies. Her keen interest in using and deploying the latest technology tools and processes has immensely helped the firm develop efficient IP service delivery models and provide best-in-the-class services. She is also known for her sharp litigation and negotiation skills for both IP and non-IP litigations and dispute resolution. She is involved in a large number of intellectual property litigations with a focus on patent litigations covering all technical fields – particularly pharmaceuticals, telecommunications, and mechanics. She has been involved in and successfully resolved various trademarks, copyright, design infringement, and passing off cases in the shortest possible time and the most cost-efficient manner applying out-of-box strategies and thinking.

Neha Ruleha, Senior Associate, LexOrbis

Neha is a registered patent agent and her proficiency ranges in life sciences, IP practice and law. She holds a master's degree in Biotechnology and earned research experience at the Indian Institute of Technology, Bombay. On a professional front, she deals with drafting, prosecution, opposition and advisory matters, especially in biotechnology, biomedical, pharmaceuticals, nanotechnology and polymer-related inventions. Ms. Ruhela has a profound understanding of patent laws and regulations and keeps herself abreast the latest trends in the sector.

UK-based MedChemica, specialized in Big Data cheminformatics, enables knowledge sharing without sharing partner organisations' intellectual property. It facilitates accelerated drug development by massive scale analysis of the relationships between chemical structures and biological properties. Novartis' Data42 program claims to bring transformational change in healthcare data and research. Pharma giants agreed to share historical cancer trial data through Project Data Sphere which leverages the power of pooled data for the discovery of new treatments.

National Brain Research Centre (NBRC) in India has developed an integrated BDI framework 'BHARAT' for early diagnostic biomarkers of Alzheimer's disease using brain imaging, metabolic, and neuropsychological scores.[3]

In contrast to the 'one-size-fits-all' medical approach, personalized medicine is perceived as 'the right treatment for the right person'. A huge amount of Electronic Medical Records (EMRs), genomic data, and clinical trial data are being analyzed to produce targeted medicine and spot new opportunities. Pfizer formulated XALKORI® (crizotinib), a precision medicine, which is used specifically to treat lung cancer patients with the ALK gene mutation. The global personalized medicine market is expected to increase at over 11% CAGR by 2024, with the aid of advances in healthcare analytics and AI.

Healthcare: MedTech & InsurTech

The Internet of Medical Things (IoMT), the connected infrastructure of medical devices, software applications, and health systems and services, is transforming MedTech's role in healthcare. MedTech Intelligence is harnessing the power of BDI where innovations such as Digital Therapeutics (DTx), Wearables, Medical Devices, and Software-as-a-Medical Device (SaMD) are helping the healthcare industry.

Wearables technology through devices, sensors, and health-apps provide a vast amount of historical as well as real-time health, lifestyle, and activity data. BDI empowers InsurTechs, Life and Health Insurers to come up with innovative personalized insurance products based on evidence-based risk assessment and also extend incentives to 'healthy' customers, e.g., discount on the renewal premiums.[4]

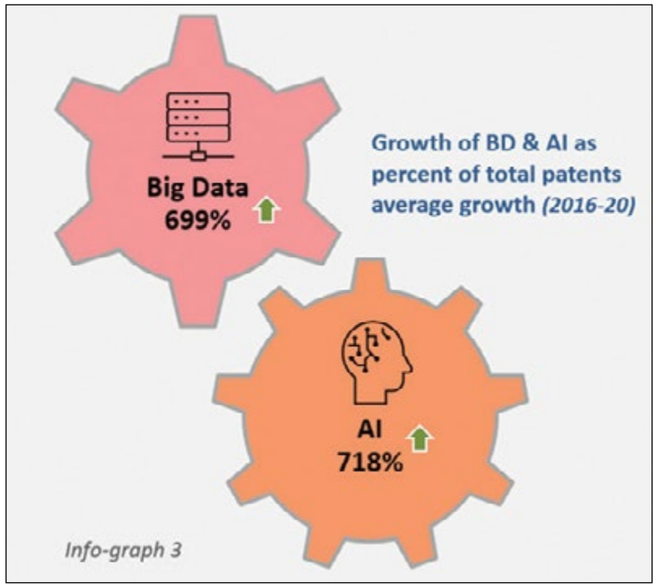
The Indian Health Ministry has broadened the scope of 'medical devices' to accommodate and regulate SaMD. By bringing suitable changes in Medical Devices Rules, software or app used for diagnosis, prevention, monitoring or treatment has been classified as a medical device with effect from April 2020.[5] AI-based analysis tools such as Automated Radiological Image Processing Software are now recognized as medical devices.

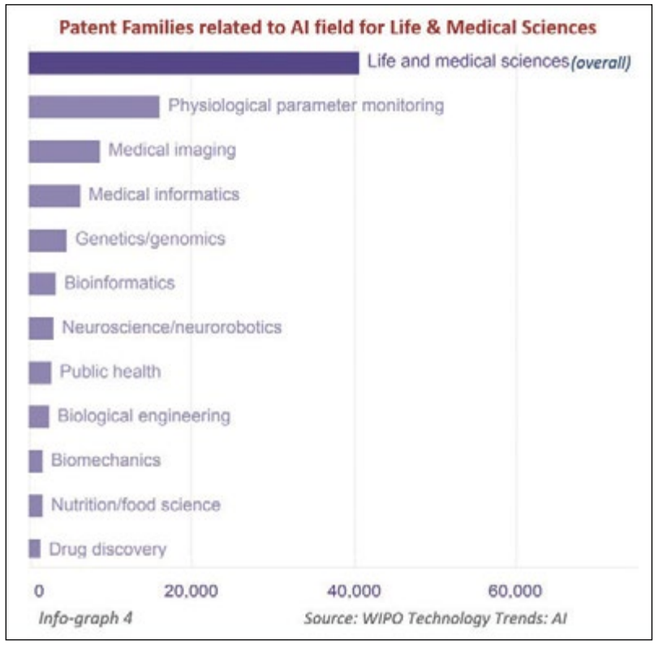
Interplay of BDI & IPR

Global scenario

World Intellectual Property (WIPO) Report – 'The Direction of Innovation' (2022) reveals that AI and BD-related patents have each grown around eight times faster than all patents during 2016-2020 (see graph 3). China and the United States share the largest pie in BDI-related filings.

WIPO findings[6] indicate that the top industries in the AI field are telecommunications (15% of all AI-related patents), transportation (15%), and life & medical sciences (12%). The distribution of patent families related to AI applications for life & medical sciences can be seen in graph 4.

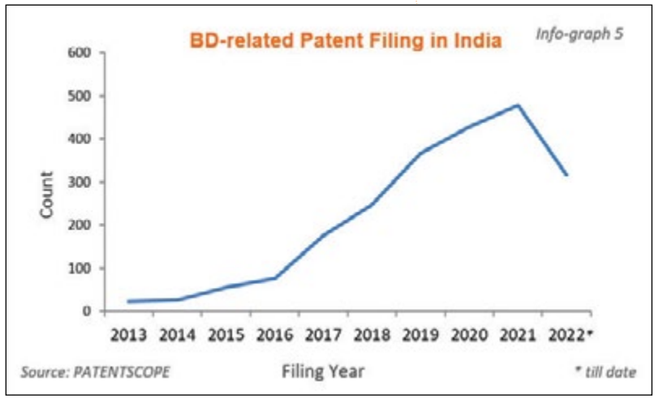




Indian context

PATENTSCOPE portal suggests filing of more than 2,200 BD-related patent documents under Indian jurisdiction so far. Graph 5 illustrates that the increasing trend of BD-related patent numbers (excluding the ongoing 2022 figure) is an aspiring one. A 2021-study[7] mentions that the four largest categories for AI patents in India, in sequence, are personal devices and computing, business, telecommunications, and life sciences.

India is now home to more than 1900 AI, 570 BD Analytics, and 25 life sciences deep-tech startups are on the right track.[8] That said, innovators in India still have scope for enhancement so as to utilize the full potential of the BDI ecosystem, provided the issues they face are resolved properly.



Challenges

Patentability

BD-related patents, being based on AI applications and tools, suffer from Schrödinger's cat paradox – simultaneously both dead and alive. Standalone software or AI applications or computer program *per se* are hit by Section 3(k) of the Indian Patents Act and thus non-patentable. However, this statutory eclipse can be cured in light of Computer Related Inventions (CRIs) examination guidelines and settled judicial precedents.[9] If a mathematical method or computer program or algorithm is associated with an invention along with some essential hardware or device, then such an invention might be patentable.

The lack of explicit mention or explanation of the term 'AI' or 'BD' in the Act and guidelines leads to ambiguity. The implied and net effect, in practice, would be that the protection of AI and BD-related innovations is subject to varied assessment and discretionary interpretation by Controllers in the Indian Patent Office.

Indian Parliamentary Standing Committee, in its 2021 Report10, also took cognizance of the inadequacy of existing IPR laws to facilitate emerging technologies such as AI, ML, & BDI and made recommendations accordingly.

Another hindrance lies in the prerequisite that the inventor should be a natural person, and AI or BD system cannot be considered as an inventor.

Privacy

As life sciences & allied industries hold treasures of highly sensitive and personal information, BDI environment needs to maintain a balance between innovations and data privacy by adopting fair practices and better compliances – a feasible *quid pro quo* between rights and responsibility. Informed consent, full data policy disclosure, prudent cross-border, and third-party data sharing are crucial to ensure in today's world.

Given the Indian Supreme Court's declaration of the fundamental right to privacy in 2017 and European Union's General Data Protection Regulation (GDPR) already in place; repeated delays in bringing safeguarding framework as was proposed under Indian Personal Data Protection Bill 2019, are disheartening.

'Big' way forward

Though the booming prospects of BD applications have set the tone for enthusiastic incubators, the life science analytics market is yet to be ripened by scaling up the size,

3 https://www.thehindubusinessline.com/news/science/big-data-may-help-get-new-clues-to-alzheimers/article26111803.ece

4 https://www.intel.in/content/www/in/en/financial-services-it/solutions/insurance-analytics-wearables.html

5 Notification No. S.O. 648(E) dated 11-02-2020, Gazette of India

6 World Intellectual Property Report *'Technology Trends 2019 – Artificial Intelligence'* (2019)

7 Center for Security and Emerging Technology (CSET) Paper *'Mapping India's AI Potential'* (2021)

8 NASSCOM *'India's DeepTech Start-Ups – The Next Big Opportunity'* (2022)

9 *2020 (81) PTC 489(Del)* (Ferid Allani vs Union of India)

investment and coverage of products and services. At the same time, we consider the Government to act as an enabler and catalyst for the AI-BD ecosystem. Innovative policies, adaptive regulations, and favorable business climates will cherish the sentiments of all stakeholders.

With regards to legislative and policy response in India, we can expect an expeditious review of some time-worn IPR provisions in line with best global practices and a re-assessment of the National IPR Policy, 2016 so as to protect and foster innovations in emerging technologies. While re-shaping, the approach in linking the mathematical methods or algorithms to a tangible technical device (UK practice) or a practical application (US practice) as a process should be adopted in India to facilitate their patentability.[10] Another possibility of creating a separate category of rights for AI and BD-related inventions is also gaining global traction.

After finalization of the proposed data protection law in India, a 'sandbox' initiative is likely to be launched for live testing of products or services in a relaxed regulatory environment to encourage innovators in AI, ML & BDI, particularly start-ups.[11]

The government as the sole owner of public service data may enforce 'Open Data' program more proactively. Through the digital platform Covid Vaccine Intelligence Network (COWIN), India's herculean immunization drive has administered more than two billion doses so far. This rich data-hub might help epidemiologists and the pharma sector attain unprecedented insights to combat future pandemics.

With the portrayal as sketched above; lastly, we foresee increasing demand for well-equipped IP professionals having techno-legal expertise with Big Data Intelligence portfolios.

[10] Parliamentary Committee on Commerce Report *'Review of the Intellectual Property Rights Regime in India'* (2021)

[11] Joint Parliamentary Committee's *'Report on Personal Data Protection Bill, 2019'* (2021)

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Women in IP Leadership

Celebrating achievements and continuing the empowerment of women

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.

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.

Dr Jennifer Bailey: Patent Director, HGF

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

Jennifer is a European Patent Attorney and Chartered Patent Attorney (UK) at HGF Limited. During her career she has drawn on her varied technical background to advise clients across a wide range of sectors spanning life sciences, chemistry, and materials, and has a particular interest in microbiology and food science.

Jennifer enjoys helping her clients to maximize the value of patents to their businesses, and believes in empowering innovators by raising awareness of IP. She is experienced in invention capture and filing strategy, managing worldwide portfolios, and freedom-to-operate. Jennifer has also represented clients in numerous EPO Opposition and Appeal proceedings, particularly in the food and drink sector.

What inspired your career?

A love of science, across its spectrum, and learning new things. I came across the patent profession during an industrial placement at AstraZeneca as part of my chemistry degree. At that point I wasn't quite ready to leave the lab bench behind but didn't see myself as a synthetic chemist so I chose a PhD in a different subject – molecular microbiology. Although I really enjoyed the practical side of my PhD, I missed the breadth of different topics I had covered during my degree and A-levels. I think one of the best things about the patent profession is that you get to work on inventions across a wide range of technologies, and you're always learning something new.

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

It has definitely not been linear. Sometimes I have felt like I've made quite rapid progress, whereas at other times it's felt more like I've run into a wall. I have also taken a few sideways steps in order to widen my experience. Even when the path is relatively smooth, it's a career in which there are always ups and downs as you have to constantly adapt to different clients, cases and other demands.

> Recognizing those individuals who have a lot to contribute but may not be so adept at pushing themselves forward will help empower women.

Some useful advice I received is to define success for yourself. For me, success is about building good client relationships, having the skills to do the best job I can for my clients, working in a great team and enjoying the intellectual challenge that the role brings. Also, in the times when everything seems difficult, it can be helpful to look back and see how far you've come to remind yourself what you're capable of.

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

One challenge I constantly face is feeling like I never know enough. As a trainee I think I expected that once I qualified I'd feel fully competent. Of course the reality was different! Qualification is just the beginning and, for me, the feeling that I am fully capable of handling everything has never really arrived. The more experience I have, the more I realize I have yet to learn.

I've come to deal with that by striving to keep on learning and developing, and by trying to remember that no-one is the "finished" article. I have also found being part of a great team and support network immensely helpful – if I don't know something someone else in the team may do, and if there isn't an answer then at least we can bounce around ideas.

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

I can't really pick one single success. Instead I prefer to try to recognize all of the small successes – securing a new client, getting a difficult application granted, receiving an email from a client thanking me for a great job – these small wins help me to stay motivated and balance out the day-to-day challenges that come with the role.

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

I think my main goal is to achieve my potential and be the best attorney I can be. I would love to get to the point where I feel confident in what I'm doing all of the time, but I don't think that's really my personality. So instead I hope to keep on gaining new experiences and making a wider contribution, such as by training others, in order to have a well-rounded career. I'd also like to expand my practice to work with more clients in areas of technology that are important to me personally, such as sustainability.

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 more women at higher levels. I think there has definitely been change in the right direction over the last few years but IP is quite a traditional profession and there is still plenty of room for improvement. I think the profession could also benefit from including a broader spectrum of people from different backgrounds.

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

Unfortunately, I think that in most sectors women are still penalized for taking time out to have a family. I have had friends in other firms who were denied the chance to apply for promotions due to taking maternity leave. Thankfully, this has not been my own experience and I felt very supported during my recent maternity leave. However, from talking to other new parents, it seems that it is mostly women who take a step back from their careers to have families. I think that better parental leave policies across all sectors, which pay for both parents to take time out of work, would help to give more women in IP the opportunity to return to work earlier after having children, if they wanted to.

I also think that transparent promotion processes which are truly based on merit and contribution will help empower women (and men) in all sectors, including IP. Although it isn't always the case in all firms, generally I think it's been quite common that people who are more willing to speak up about their achievements, or those that are seen to "fit-in", are more likely to get promoted than people who are perhaps a bit quieter. Recognizing those individuals who have a lot to contribute but may not be so adept at pushing themselves forward will help empower women and work towards gender balance at the top of IP organizations.

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LAW FIRM RANKINGS 2022

Asia-Pacific

A comprehensive list of the 10 most well-respected law firms from the Asia-Pacific region.

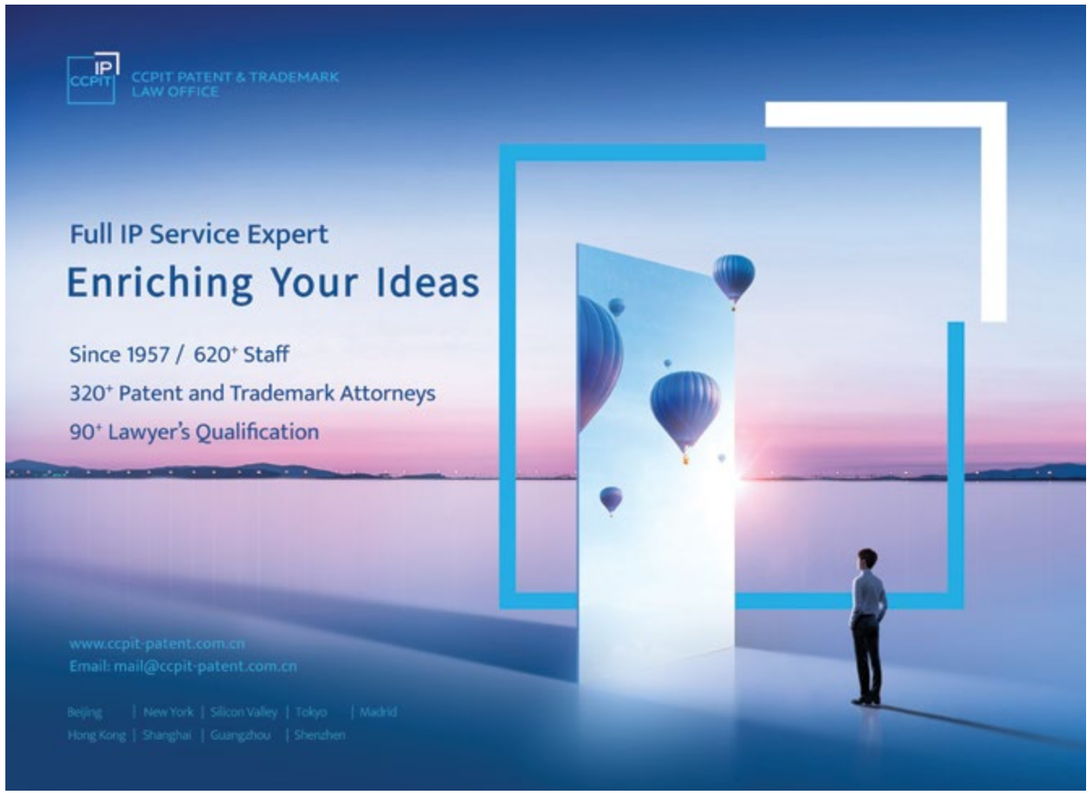
The Patent Lawyer Magazine

GLOBAL REACH, LOCAL KNOWLEDGE

Throughout the next few pages, you will view a comprehensive list of the 10 most well-respected law firms from Asia, in alphabetical country and company order.
Our focused list is derived from a multifaceted methodology, which uses months of industry research and feedback from our readers, clients, and esteemed connections around the world. All firms are ranked top 10 in their jurisdiction but are displayed alphabetically to avoid bias.

China

- Anjie Law
- Beijing Sanyou IP Agency
- CCPIT Patent & Trademark Law Office
- Chang Tsi & Partners
- China Patent Agent (H.K) Ltd.
- Hong Fang Law
- IP March
- Lifang & Partners
- Unitalen Attorneys at Law
- Wanhuida Intellectual Property



Australia

- Allens
- Ashurst
- Clayton Utz
- Davies Collison Cave
- Gilbert + Tobin
- Griffith Hack
- Herbert Smith Freehills
- Madderns
- Phillips Ormonde Fitzpatrick
- Spruson & Ferguson

Hong Kong

- Baker McKenzie
- Bird & Bird
- Deacons
- Eagle IP
- Hogan Lovells
- Letters & Thoo
- Mayer Brown
- Norton Rose Fulbright
- Wenping Patent & Trade Mark Agent LTD.
- Wilkinson & Grist

India

- Anand & Anand
- K&S Partners
- Krishna & Saurastri Associates
- Lakshmikumaran & Sridharan
- LexOrbis
- L.S. DAVAR & Co.
- Obhan & Associates
- Remfry & Sagar
- R K Dewan & Co.
- S Majumdar & Co.

Indonesia

- Am Badar & Am Badar
- Biro Oktroi Roosseno
- FAIP Advocates & IP Counsels
- Hadiputranto, Hadinoto & Partners
- Januar Jahja & Partners
- K&K Advocates
- PRAWIRANEGARA International Patent & Trademark Law Office
- Rouse & Co
- SKC Law

Japan

- Abe, Ikubo & Katayama
- ASAMURA IP P.C.
- Hiroe and Associates
- ITOH International Patent Office
- Nakamura & Partners
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Jurisdictional Briefing, US: subject matter eligibility no longer just for software and biotechechnology practitioners

Dave S. Christensen and Maggie Russell of Cantor Colburn review the changes for subject matter eligibility as a result of the *American Axle & Mfg. v. Neapco Holdings LLC* case.

For a number of years, subject matter eligibility rejections have been a thorn in the side of patent practitioners in the software and biotechnology arts. When the US Supreme Court denied cert in *American Axle & Mfg. v. Neapco Holdings LLC*, the lives of drafters of mechanical patents became much harder.

While it has long been held that Congress intended patentable subject matter to "include anything under the sun made by man,"[1] in order to obtain such a patent, the invention must have subject matter eligibility, as specified by §101 and analyzed through the *Alice/Mayo* framework.[2] Under the *Alice/Mayo* framework, there are three judicially recognized exceptions, including: laws of nature, natural phenomenon, and abstract ideas.[3] It has been reasoned such exceptions "are basic tools of scientific and technological work" and monopolizing these tools would deter innovation.[4] An invention is determined to be patent eligible either because it is not directed towards an exception or the claimed invention as a whole includes aspects that amount to "significantly more than the exception."[5]

The invention at issue in *American Axle* relates to a method for reducing vibration in vehicle driveshafts through the application of a liner, which was "tuned" to the mass and stiffness and designed to attenuate the vibrations in response to varying frequencies.[6] During litigation Neapco's expert stated, "the phrase 'tuning a mass and a stiffness of at least one liner' claims Hooke's law." Further, one of the named inventors and American Axle's engineering manager admitted mass and stiffness are directly implicated.[7]

Dave S. Christensen

Maggie Russell

In the case of *American Axle*, what may have originally been an indefiniteness issue (would one of ordinary skill have known how to "tune" a liner) turned into a subject matter eligibility debate. Both the District Court and the Court of Appeals for the Federal Circuit (CAFC) determined the claims were directed towards a law of nature, specifically Hooke's Law, as a way of achieving the desired result without any aspects that amount to significantly more.[8] The CAFC elaborated "...the claims' instruction to tune a liner essentially amounts to the sort of directive prohibited by the Supreme Court in *Mayo* – i.e. "simply stat[ing] a law of nature while adding the words 'apply it.'"[9]

For those interested in claiming a mechanical invention that utilizes a law of nature, a way to avoid such an issue comes in changes to both the specification and the claims. Ensuring the claims are written to include specific mechanisms, physical structures, or steps that utilizes a law of nature, can demonstrate the invention amounts to more than the judicial exception. There have been a number of recent decisions citing *American Axle* that elaborate on the importance of including such claim language.[10]

If such language is not used, the specification can be used to elaborate on the language used in the claim, such as providing examples or alternative methods for carrying out a step. Often in litigation, clarity and indefiniteness issues can be overcome through the use of experts; however, as seen here, such a strategy may create a fatal §101 issue when the only method of carrying out a claimed element is through a law of nature. The court employed the suggested use provided by the patentee's expert to demonstrate the claims lacked descriptions of the mechanism.[11] In order to appropriately patent mechanical inventions that utilize a law of nature, the claims and the specification should enable the application to overcome potential subject matter eligibility issues.

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Résumés

Dave S. Christensen, Partner
Dave co-chairs the firm's Mechanical Engineering Patent Practice Group and chairs the Additive Manufacturing Practice Group, leading teams dedicated to responsive, client-focused services. He focuses his practice on assisting clients in using patents and trade secrets to protect their products in both US and foreign jurisdictions in a variety of technical fields, including consumer products, electrical power distribution and transmission, renewable energy, and optical measurement systems. A significant part of his practice includes assisting clients in developing cost-effective strategies for managing risk and building their brand in new product development, and in building and managing their intellectual property portfolios.

Maggie Russell, Associate
Maggie focuses her practice on drafting and prosecuting patent applications for chemical and material science technologies. Maggie has experience in a wide range of fields including chemistry, chemical engineering, semiconductor devices, mechanical engineering, and material science. Prior to joining Cantor Colburn, she worked as a semiconductor engineer at BAE Systems and authored multiple publications in the *Journal of the Electrochemical Society.*

1 *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (noting that congress intended patentable subject matter "to include anything under the sun that is made by man," indicating the intention to cover a large amount of subject matter limited only by what is man-made).
2 *See* 35 U.S.C §101.
3 *See* 35 U.S.C §101. *See also* Mayo Collaborative Services v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012) (detailing how judicial exceptions include laws of nature, abstract ideas, and natural phenomena). *See also* Alice Corp. Pty. Ltd v. CLS Bank Int'l, 573 U.S. 208, 217–18.
4 *See* Mayo, *supra* note 3, at 71.
5 *See generally* MPEP §2106 (9th ed. Rev. 8, Aug. 2017). *See also* Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1334 (Fed. Cir. 2016).
6 *See* Am. Axle & Mfg. v. Neapco Holdings LLC, 967 F.3d 1285, 1289-1293.
7 *See* Id at 1294 "For example, Neapco's expert, Dr. Becker, stated that "the phrase 'tuning a mass and a stiffness of at least one liner' claims Hooke's law." J.A. 1604.", "AAM's engineering manager likewise admitted that "if [one] do[es] something to control the stiffness [or mass]" of a liner—the variables directly implicated by Hooke's law—that person is "directly controlling tuning." J.A. 2547 (20:23-21:1).".
8 *See Id.; See also Id.* at 1304.
9 *See* American Axle & Mfg. v. Neapco Holdings LLC, 939 F.3d 1355, 1362 (Fed. Cir. 2019).
10 *See* Barry v. SeaSpine Holdings Corp., 2022 U.S. Dist. LEXIS 14060; *See Also* Xodus Med., Inc. v. Prime Med., LLC, 2021 U.S. Dist. LEXIS 244222; *See Also* Northwestern Univ. v. Kuka AG, 2021 U.S. Dist. LEXIS 194914.
11 *See* Am. Axle & Mfg. v. Neapco Holdings LLC, 967 F.3d 1285, 1362.

How to choose an IPMS

Sam Nicholson, Managing Director at Equinox IPMS, provides key insight into choosing the correct intellectual Property Management System for your way of working so you can hit the ground running and be confident from day one.

Intellectual property attorneys have countless dates and processes to follow to fulfill client needs. Adopting an Intellectual Property Management System (IPMS) can be incredibly effective for keeping on top of cases and working as efficiently as possible.

An intellectual property management system is software designed specifically for intellectual property professionals. It helps keep processes moving by keeping track of key dates, payments, and correspondence to ensure everything is accounted for and ready on time.

To adopt an IPMS or switch to a new service is a huge decision for a firm. It can be a big investment, and it can be difficult to know whether the chosen software will fulfill all a firm's requirements. Additionally, adopting an IPMS could mean entrusting sensitive data to an external organization, and ensuring this is done securely is paramount.

But how does a firm choose which IPMS to adopt? Sam Nicholson, Managing Director at Equinox, has been at the forefront of IPMS development since 2006. Here, he offers a range of key features to look for when seeking out a new intellectual property management system for your firm.

Getting started and seeking support

It can be daunting to adopt a new system. Your firm has spent years refining its processes into a well-oiled machine, and introducing a new system risks new complexity and issues. The best software providers will guide you through the onboarding process with minimum hassle and choosing a supplier that makes adoption as simple as possible will go a long way when you are getting started.

An IPMS supplier should be responsive to your needs and take care to cater to your firm's specific requirements. When meeting with the provider, consider how well they have accounted for your needs and the extent to which they can tailor the system to fit your processes. The best suppliers will explain how their software can adapt to how you already operate and perhaps more importantly how it can enhance your practices.

When the time comes to onboard your firm onto your chosen system, the IPMS provider should make the process as clear and easy to follow as possible. This also extends to training; you should expect comprehensive training on the system before you go live so that you and your team feel confident in how to get the most from the software.

Sam Nicholson

> **Consider how the provider will store your data and assess the level of support specifically driven towards data management and security.**

Well maintained system

Some software companies go years without releasing an update, leaving their users with a system that is slow and does not provide a desirable standard of performance. Updates iron out bugs and keep your software running smoothly. Without them, you will have issues.

When exploring the range of IPMS solutions on the market, consider how often their service is updated and determine the quality of their development teams. A good development team will keep users on the latest version of their software as promptly as possible and clearly communicate how these changes will benefit your firm.

Data security

Security is a priority. When your firm stores any data within an IPMS, it should feel 100% confident that everything in that system is protected. Whether that data is stored with the software provider or on your firm's own server, it should be safe with maximum visibility for the user.

Any valuable IPMS will have a thorough data security system in place. Consider how the provider will store your data and assess the level of support specifically driven towards data management and security. Availability is incredibly important, so ask about uptime too.

For example, at Equinox we have a dedicated Data Services team that takes responsibility for the transfer and management of subscriber data and a meticulous Operations team who ensure the best software security measures are in place. Having teams with specific expertise allows the appropriate level of attention towards ensuring your system and data is kept secure and available when you need it.

Strong support team

If you find yourself needing help using the system or troubleshooting an issue you are having, your firm needs to be confident that it can get effective, prompt support. The legal industry is very time-sensitive so requires quick action, and if there is an issue at an inopportune moment, its users should be confident that it can be resolved quickly to keep their cases on track.

Take care to consider the quality of an IPMS provider's support team. Is support available when you might need it? How quickly can they respond to your queries? The strongest software companies have a dedicated help desk that can respond to you and help with your issue as fast as possible.

Strong development that grows with you

Responsive intellectual property law updates

The global intellectual property landscape is ever-changing, and an IPMS needs to keep on top of these developments to ensure it can support its subscribers and their clients through legislative updates.

An IPMS relies on pre-sets, which are sometimes known as law files. These are pre-prepared processes for a jurisdiction that align with a firm's cases and processes to provide prompts and automation where necessary to maximize efficient operation. These pre-sets need to be regularly reviewed and updated in line with legislative developments to ensure that cases are handled properly within the system.

A stronger IPMS supplier will monitor legislative developments and issue updates to users as soon as possible. This demonstrates that their system is being maintained regularly and offers users a vital global law resource.

Equinox operates a devoted IP Services team that keeps its finger on the pulse of international intellectual property law. When a country changes its rules, our subscribers have their pre-sets updated when they come into effect so they can keep their cases in line with the law. This service is supported by weekly news updates that ensure subscribers are kept aware of incoming changes.

Innovative development

A forward-thinking development team will anticipate its users' needs ahead of time. When new laws or practices come into action, your software should have anticipated this change and been pre-emptively updated to account for change and avoid delays.

With the long-awaited Unitary Patent system anticipated to come into effect soon, Equinox has already implemented development to be ready in advance of the legislation coming into effect. When the time comes, subscribers will be able to hit the ground running without any delay.

When choosing your IPMS, consider how they react to changes in the industry. Will the provider anticipate your needs? Look for strong development experience and an innovative approach to ensure confidence in the longevity of your software.

> **When choosing your IPMS, consider how they react to changes in the industry.**

Scalability

When a firm grows and takes on more clients, its IPMS should scale with the organization to meet its new requirements. Some software providers limit the number of users or clients a subscriber can maintain on the system, resulting in additional costs when the business grows. As a result, firms should take care to choose a supplier that scales with rather than against

Résumé

Sam Nicholson, Managing Director at Equinox IPMS, has been at the forefront of intellectual property management system development since 2006. He has overseen the company as it has grown from a small business to having a global impact on the intellectual property industry.

Equinox provides its leading IPMS to 240+ organizations across the world. In the UK alone, around one-fifth of all IP attorneys use Equinox IPMS daily to provide their services to clients. With a unique tech-first approach, the IPMS developer is on the cutting edge of legal technology.

> Choose a provider that gives you confidence in its service from day one.

their growth; an IPMS should be willing and capable to help a firm grow.

Equinox IPMS is designed to be scalable: when your firm grows, our IPMS not only keeps up with you but actually helps you continue that growth. Many of our subscribers have seen a seamless transition as they take on new employees and win new clients, as Equinox has offered intelligent optimization opportunities that support their expansion. It is fantastic to watch firms grow with Equinox IPMS.

Adaptability and accessibility

Strong configuration options

No two IP firms are the same. One firm will operate differently from the next, with variations as granular as the terminology used in their processes and as broad as how they communicate with clients. When adopting an IPMS, it is wise to choose one that fits into and enhances your existing processes rather than forcing your team to adapt.

Equinox IPMS is designed to enhance the processes a subscriber already uses. When new subscribers come to Equinox, we take time to consider how they already operate and explore how we can configure Equinox IPMS to enhance their processes. This is done by helping select and upload pre-sets from our extensive catalogue and can extend to details as small as changing the terminology used in the system interface. Your IPMS should make as many changes as possible to fit in with and enhance your practices.

Integrating with other services

IP professionals often rely on a range of services to do their job. Be it Microsoft Office or financial services that track payments, an IPMS should integrate seamlessly to make handling a case as simple as possible. Increasingly, software across a range of industries is adapting to a more integrated approach that allows software services to work together, and your IPMS should be no different.

Adopting an IPMS that offers integrations with other useful services is the best way to streamline internal processes. Firms should aim to establish a connected network of the services they rely on. Consider whether your chosen IPMS can integrate with your billing software to make tracking the full process of your cases as straightforward as is feasible.

Forward-thinking IPMS providers are always looking to extend integrations further. At Equinox, we listen to our subscribers to discover what other complimentary services they use and work to make them integrate into our IPMS for a seamless user experience.

Accessibility and availability

An IPMS should be easy to use and available from anywhere. A web-based system is the best option as it can be accessed from a variety of devices and does not require a time-consuming software download. This helps your team access the system more quickly and stay responsive when needed.

The interface of the software should be easy to understand and clear to follow. A modern, clear, crisp design for your software may not seem like a major priority compared to other factors, but when you and your colleagues will be using the IPMS daily, ensuring the software is simple to operate is a must.

Key things to remember when choosing an IPMS

It is better to adopt an IPMS that can be configured and shaped to fit the way you work. Your firm has spent years honing its practices and your method and approach are why your clients trust you. Your IPMS should enhance how you work and not force your team into a one-size fits all system.

When you grow, the IPMS you choose should grow with you. Consider the longevity of your time with the software, if you take on new staff or clients, you should be confident that the software you rely on is ready and willing to support and accelerate your success.

Your IPMS should have its finger on the pulse of the industry and anticipate your needs. You should be confident that your software is kept in line with every jurisdiction you operate in with regular updates to the system and its pre-sets. With legal technology developing to be increasingly integrated, your IPMS needs to follow this trajectory and include as many integrations as possible with other services you use.

Overall, the best way to choose an IPMS is to consider the quality of your experience with the software from your first exposure to the system right through to when you need support. Choose a provider that gives you confidence in its service from day one.

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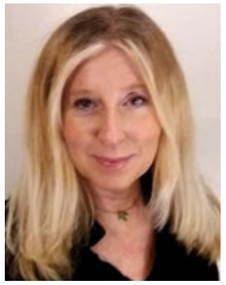
Claiming preliminary and *ex parte* injunctions – what is needed to succeed?

Maria Zamkova, CEO at Fenix Legal, evaluates two recent cases to offer advice for claiming preliminary and *ex parte* injunction for successfully protecting a patent even before the patent is granted.

When you realize that someone is trying to infringe your protected patents it is necessary to act quickly to minimize the damages. But when is the right time to act, and what is needed to reach quick decisions from the court? The Swedish Patent and Market Court of Appeal have made a couple of indicative rulings that may assist in planning the court actions.



Maria Zamkova

Case PMÖ 5185-22 (decision date May 19, 2022)

The three affiliated pharmaceutical companies Novartis AG (Switzerland), Novartis Pharma AG (Switzerland), and Novartis Sweden Aktiebolag (Sweden) sought a preliminary injunction, a final injunction, and a declaration of liability *per se* against two generics companies based on a patent expected to be granted soon. The Patent and Market Court dismissed the claim on the grounds that no patent had yet been granted.

Novartis appealed the decision to the Patent and Market Court of Appeal (PMÖD), and requested the PMÖD to set aside the appealed decision and refer the case back to the Patent and Market Court for further proceedings. Novartis argued that the decision (on the patent) in written form from the Board of Appeal of the European Patent Office (EPO) that a patent should be granted was expected to be dispatched only at the end of June 2022. The patent was therefore estimated to be granted in August 2022. Even with such an adjusted schedule, the patent will be granted well before that a final decision in the case before the Swedish PMD can be counted.

The Patent and Market Court of Appeal noted that it is sufficient for admissibility based on the performance when the court rules on the merits of the claim. If it appears from the information provided by the claimant that performance has not taken place at the time of filing, the court must make an assessment as to whether the presented claim expires before the case is decided. The PMÖD further noted that the Technical Board of Appeal had ordered the Examining Division to grant the patent with the patent claim on which the claimants had based their infringement assertion. PMÖD held that, at the present stage, it had to accept the Novartis assertion as to when patent grant was to be expected and that it was unlikely that the PMD would rule on the merits of the claim before that. PMÖD also observed that the record did not suggest that the conditions for advancing the case before patent grant were lacking. PMÖD thus found the claim for injunctive relief admissible.

The Patent and Market Court of Appeal has not allowed an appeal against the decision.

Case PMÖ 9563-22 (decision date August 6, 2022).

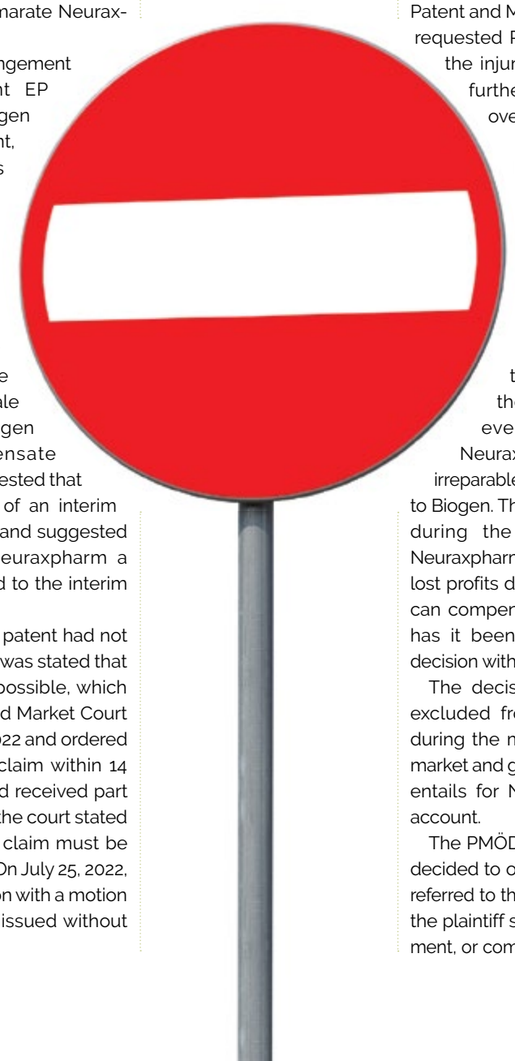
The question in the case was if there have been conditions to decide on an interim injunction under the Swedish Patent Act without hearing the other party (*ex parte* injunction).

Biogen International GmbH (Biogen) filed a lawsuit at the Swedish Patent and Market Court (PMD) against Neuraxpharm Sweden AB (Neuraxpharm) on July 19, 2022 and then presented, among other things, a request that Neuraxpharm be temporarily prohibited from disposing of the medicinal product Dimethyl fumarate Neuraxpharm in a certain way.

The claims were based on infringement of Biogen's European patent EP 2653873 B1. In the lawsuit, Biogen stated that the matter was urgent, i.e., because Neuraxpharm's product had been designated by the Tandvårds- och läkemedelsförmånsverket (Dental and Pharmaceutical Benefits Agency), TLV as the product of the period for August 2022, and because Neuraxpharm had already built up a stock of the product and acted for a full-scale launch that would cause Biogen great and hard-to-compensate damage. Biogen, therefore, requested that the court deal with the issue of an interim injunction as quickly as possible and suggested that the court should give Neuraxpharm a maximum of 14 days to respond to the interim request.

At the time of the lawsuit, the patent had not been validated in Sweden, but it was stated that this would happen as soon as possible, which was July 21, 2022. The Patent and Market Court issued a subpoena on July 20, 2022 and ordered Neuraxpharm to file a counterclaim within 14 days from that the company had received part of the lawsuit. At the same time, the court stated that any opinion on the interim claim must be submitted within the same time. On July 25, 2022, Biogen supplemented their action with a motion for the interim injunction to be issued without hearing Neuraxpharm.

> **"PMÖD thus found the claim for injunctive relief admissible."**



On July 29, 2022, Neuraxpharm confirmed that the subpoena had been received. Later that day, the Patent and Market Court granted Biogen's motion and issued an interim injunction – which went into effect immediately - without hearing Neuraxpharm.

The Patent and Market Court stated that the reason for the decision was that it was likely that the patent was valid and that the alleged infringement product infringed the patent. The reason for not hearing Neuraxpharm was that Neuraxpharm was delayed in confirming receipt of the subpoena even though they should have been aware that Biogen was planning to file the action, that it was likely that Biogen would lose basically all of its sales from August 1, 2022, if the alleged infringement product remained on the market, and – as Neuraxpharm was a start-up company with an unclear financial position - it was uncertain whether Neuraxpharm would be able to compensate the Biogen's damage if no injunction was issued.

Neuraxpharm appealed the decision to the Patent and Market Court of Appeal (PMÖD), and requested PMÖD to immediately decide that the injunction should be suspended until further notice and that PMÖD should overturn PMD's decision.

In support of the appeal, Neuraxpharm stated that: There have not been conditions for announcing a decision on an interim injunction without hearing Neuraxpharm. The fact that it took some time from the time the summons was issued to the time Neuraxpharm confirmed receipt of the summons does not mean that the requirement of danger in the event of delay has been met. Neuraxpharm's hearing could not cause irreparable damage of appreciable magnitude to Biogen. The damage that Biogen could suffer during the time it would take to allow Neuraxpharm to come forward consists solely of lost profits due to reduced sales. Neuraxpharm can compensate Biogen for any damage. Nor has it been propor-tionate to announce the decision without hearing Neuraxpharm.

The decision means that Neuraxpharm is excluded from practically the entire market during the month of August. Furthermore, the market and goodwill damage that an interim ban entails for Neuraxpharm must be taken into account.

The PMÖD upheld the suspension claim and decided to overturn the PMD's decision. PMÖD referred to the Swedish Patents Act stating that if the plaintiff shows probable cause that infringement, or complicity in infringement, occurs and if

Résumé

Maria Zamkova is CEO at Fenix Legal, has a Master of Industrial Design, and is a patent attorney and registered EUIPO trademark and design attorney. Maria is an expert in European Patents, assisting national and international clients in IPDD, and is a frequent lecturer in "IP and business strategies". She a is a Member of the Board of the Association of Swedish Patent Attorneys (SPOF). Maria has been awarded the Client Choice Awards by the International Law Office and Lexology (ILO) as the best expert on Intellectual Property - Patent - in Sweden.

that, diminishes the value of the exclusive right to the patent, the court may issue a ban on fines for the time until the case has been finally decided or something else has been decided. Before such a ban is announced, the defendant must have been given the opportunity to make a statement, unless a delay would entail a risk of damage.

PMÖD noted that in the present case, at the time the lawsuit was brought, the patent had admittedly not taken effect in Sweden and was prohibited and therefore could not be announced at that time. However, Biogen stated that the patent would be validated as soon as possible, or more precisely on July 21, 2022. Despite this, Biogen suggested in the lawsuit that Neuraxpharm would be given a response time of up to 14 days. Neither when the lawsuit was brought nor when the patent became effective in Sweden two days later, did Biogen thus express any need for an immediate decision. The question is whether the circumstances that Biogen subsequently adduced constitute a basis for a prohibition order without hearing the other party. These additional stated circumstances are essential for the patent to become effective in Sweden, that Neuraxpharm took the time to confirm receipt of the summons, that Neuraxpharm took certain additional administrative measures to be able to definitively launch its product in August 2022 and that Neuraxpharm is a relatively new company with unclear finances. According to the Patents and Markets Court of Appeal, these circumstances, neither individually nor together with other circumstances, can sufficiently justify an exception to the main rule regarding the hearing of the other party.

> **The Patent and Market Court of Appeal has not allowed an appeal against the decision.**

The Patent and Market Court of Appeal has not allowed an appeal against the decision.

So, what to learn from these decisions?

Case 1, PMÖ 5185-22, is important as it shows the possibility of pre-grant litigation. It also clearly indicates what evidence is needed in order to convince the court that the patent is soon to be granted – at least before the Patent and Market Court has made its final decision. Look at each status of your pending applications – it may well be possible to stop infringement even if your patent is not granted yet in Sweden.

Case 2, PMÖ 9563-22, is also a clear example on the importance to act quickly – raise your claims from the start, especially as *ex parte* injunction can mainly only be accepted if you can show the legal and financial risks for further delays.

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There are always two sides of the same coin – a brief polemic on the unitary patent system from a Polish perspective

Tomasz Gawliczek, PhD, Polish patent attorney and attorney-at-law, and Piotr Godlewski, Polish and European patent attorney, of JWP Patent & Trademark Attorneys express their differing opinions on the implementation of the UPC and Poland's decision to opt-out.

In 2022 works related to the launch of the unitary patent system accelerated sharply. The institution of the European patent with unitary effect and the activity of the Unified Patent Court will affect not only those European Union Member States which undertook to construct the new system from scratch. Looking at the bigger picture, there is no doubt that changes introduced by entry into force of the UPCA will actually affect (to a greater or lesser degree) all in Europe.

In this situation, Hamlet's question - "to be (inside new patent system) or not to be?" – takes on a slightly different meaning, especially from a perspective of Poland which acceded to the EU enhanced cooperation in creating unitary patent protection system, but to this day did not sign the UPCA. Two Polish patent attorneys who work in the same patent law firm see the answer to this question in a slightly different way. This two-voice discussion is part of a broader debate which has been ongoing for many years and which concerns even more fundamental question: does Europe actually needs the newly created patent system?

Does being absent in the UPCA system mean that one is non-existent? – comments of Piotr Godlewski

The Agreement of 19 February 2013 which established the Preparatory Committee in relation to the European patent with unitary effect and the Unified Patent Court (UPC) was signed by 24 European Union Member States. Among 27 current members of the European Union (as of 2020 the United Kingdom is no longer part of the community) three countries did not accede to this Agreement: Croatia, Spain and Poland.

> **Assuming that all the EU Member States will speak in one voice should be described as far-reaching naivety.**

What is interesting, new regulations constituting the European patent with unitary effect and the Unified Patent Court – the entry into force of which is scheduled for 2023 – shall be binding in only 17 of the 24 countries that are mentioned above. Cyprus, Czech Republic, Greece, Hungary, Ireland, Romania and Slovakia have not yet ratified the UPCA (the question is: is it on purpose?).

This short numerical analysis is intended to show that there is no unanimity as to new institutions in the world of European patents. Assuming that all the EU Member States will speak in one voice should be described as far-reaching naivety.

Taking these numbers into consideration, one may ask if the decision of Poland on staying in the shadow should be regarded as a loss of an opportunity in shaping the new system? The answer may be yes, to some extent, since not being part of the new order right from the start of its functioning one may lose its influence on shaping it. This is included in the following opinion of Tomasz Gawliczek who considers the absence of Poland in the new system as a potential "loss".

Résumés

Tomasz Gawliczek, PhD works as a patent attorney and attorney-at-law at JWP Patent & Trademark Attorneys. He specializes in intellectual property litigation, in particular patents, industrial designs and trademarks. He has extensive experience in contentious cases, including proceedings before the General Court of the European Union in Luxembourg. As one of the first Polish lawyers, he completed postgraduate studies at the University of Strasbourg in France in the field of conducting cross-border patent litigation in Europe. He holds a PhD in Law from the University of Wrocław. Additionally, he completed postgraduate studies in intellectual property law at Jagiellonian University in Cracow. Tomasz is fluent in English and Spanish.

Piotr Godlewski, National and European Patent Attorney at JWP Patent & Trademark Attorneys. Former Head of Patent Department and longtime Head of Life Science Division. He specializes in patent prosecution for the Life Science industry as well as patent litigation cases before Polish Patent Office, European Patent Office and national court and was the first qualified European patent attorney at JWP. He advises on matters related to patents strategy to Big Pharma, universities, institutes supported by government as well as SMEs. He conducts numerous trainings and workshops on intellectual property issues. Piotr is fluent in English.

However, in my view we should not talk about a loss in the first place, but rather about an opportunity created by a current situation. The absence of Poland in the UPCA system does not mean that the European patents with unitary effect will not finally – within a certain time framework – be binding on our territory.

Although Poland did not sign the Agreement on a Unified Patent Court, it neither withdrew from enhanced cooperation mechanism (which, apart from UPCA, is composed of Union legal acts: Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection and Council Regulation (EU) No 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection). What is enhanced cooperation? It is a mechanism, envisaged in the European Union procedures, which enables states to choose to integrate to a larger extent in specific areas. Referring to the European patent with unitary effect and to the unified system of patent protection, Poland had the opportunity to take a position and influence the final shape of adopted regulations.

While remaining on the sidelines – even to a greater extent than the seven states already mentioned which still have not ratified the UPCA – Poland is not, however, as firm with its position as Spain which has not participated in enhanced cooperation from the beginning and has distanced itself from new institutions completely.

Tomasz Gawliczek

Piotr Godlewski

At this stage, no one knows if a stance taken by Poland may bring more positive results or more negative ones. Certainly, the stance taken by Poland is safe in that sense that it is always possible to accede to the UPCA system. Surely, a multitude of factors will influence the exact time of this accession.

A lot has already been written about doubts concerning the new system as well as the positive aspects of new institutions which have been awaited by some for decades. However, only the actual numbers of pending revocation proceedings, "opt-out" motions submitted, lawsuits filed, translations submitted etc., will allow assessing if the interests of all interested parties have been taken into account.

It is known that rulings issued at the beginning may determine further actions of the UPC and being absent in the system from the beginning, which is the case of Poland that excluded itself from the system, will deprive us of an influence on law making. However, it seems that there is no such jurisdiction in the world in which there is no evolution in adjudication and in my view, accordingly, this will also be the case of the UPC. The tenth, hundredth, and thousandth case shall influence the jurisprudence and at the same time guarantees, liberties and finally concerns of all those who act pursuant to patented technical solutions. The pending proceedings shall enable the evaluation of what, from the commercial point of view, will be the influence on the functioning of particular industry sectors and what will be the true effects of the proceedings concerning local (national) entities. Finally, it is the number of European patents with unitary effect being granted and in force that will show how big the influence of the new system on local economies is and if it brings more opportunities (by imposing more competition) or more risks (by reducing freedom of activity of SMEs which are less innovative and more of reproducible character).

Each Member State of the European Union (apart from our common regulations and in some cases common currency) has its own history and experiences which also influence political decisions. This geopolitical factor – in particular taking into account the latest events beyond the Polish eastern border – may prove to be crucial. Regarding the evolving reality, Poland, which is a border country of the European Union, must decide, in a flexible manner, if and what instruments to use in order to gain as much as possible and lose as little as possible.

Almost a decade has passed since the last analysis was made which determined the position of businesses, politicians and the whole industrial property community in Poland. It is a long period of time during which a lot has changed. Therefore, a majority of concerns which were valid in relation to views presented in 2012/2013 now have lost their importance.

In my view, close and flexible observation of the functioning of the new system from the beginning, as well as learning from the experience of neighboring countries will enable Poland to undertake the right decision. Obviously, if right from the beginning of the new system all 24 states that signed the preparatory agreement and participated in it actively (rather than just 17 states), if the United Kingdom had not left the European Union, and finally if Poland had been the only EU country excluded from the enhanced cooperation and completely boycotted the constitution of the new system, my opinion would surely have been different. Defining such an approach as an opportunity would not have been justified.

However, in the current situation, I treat the position of Poland as an opportunity and it depends on smart political decisions and close and thorough analysis, as well as on data evaluation, whether we, as a country, seize this opportunity.

Do latecomers who are about to join UPCA may only gain? – responds Tomasz Gawliczek, PhD

Legal changes (especially those of systemic character) always bring questions about the associated consequences. Some outcomes may be anticipated, but the real evaluation in this regard may be done only after some period of time. Thus, is it worth waiting for further development of events related to implementing the UPCA in order to be sure how this system will function in practice? Such a suggestion is made hereinabove by Piotr Godlewski. However, one cannot forget that the discussion which has taken place so far in Poland focused only on the issue of whether to join the new system or not.

> **“However, one cannot forget that the discussion which has taken place so far in Poland focused only on the issue of whether to join the new system or not.”**

In this context, it is worth remembering that participation in the European Union enhanced cooperation mechanism is of voluntary nature. Therefore, by acceding to it, Poland - in a similar way as these other countries which had already signed the UPCA but still did not ratified this agreement - has undertaken obligations related to achieving goals of this cooperation. Thus, the participation of Poland in this project has already been decided. Furthermore, the question asked today of whether the accession of Poland to this new system should be finalised shall be replaced by the one on when exactly this accession should be finalised.

There is no doubt that the best solutions are frequently those that have already proven to be working. If the unitary patent system proves to be efficient and reliable in a longer term perspective (first revision of the UPCA regulations is to be made after seven years of entry into force of this agreement), then certainly the number of participants

therein will be growing gradually. However, it must be taken into account that states acceding late to the UPCA will have to accept not only the already existing jurisprudence of the UPC but also the established ways of functioning of the Court. These are going to evolve constantly during the process of applying regulations of the whole unitary patent package, including implementing legal acts adopted in the meantime.

Moreover, states which will join the new system at a later date shall be covered by the "unitary effect" to a lesser extent than the incumbent participants. This results from an assumption made that there are different generations of the European patent with unitary effect. In this regard, it may be expected that in these countries the role of national patent courts shall still be greater than the one of the UPC. Especially taking into account the form of transitional provisions and the fact that, given the circumstances, a relatively greater part of technical solutions will be protected on the territories of new Contracting Member States with classic European patents.

At the same time, it must be underlined that the absence of Poland in the system will not result in that the solutions adopted in the unitary patent package will have no influence on Polish entrepreneurs who conduct businesses in other countries of the European Union. In case of an infringement of a European patent with unitary effect by them, instead of being sued in Poland – which would be the case if this country signed and ratified UPCA – they will be sued by the entitled entities before local divisions of the UPC in other countries of the European Union and this obviously increases the cost of conducting such litigation. Moreover, when the same patent is to be validated in Poland the litigation may be duplicated. Then, such a dispute will take place simultaneously before the patent court in Warsaw and before the foreign local division of the UPC.

Among the arguments presented during the discussion concerning the accession of Poland to the UPCA, especially these were underlined which pointed to multiplying the number of European patents valid in this country after the accession to the new system. However, one cannot forget that the nature of patent law can be reduced to the fact of stimulating the innovation factor and the investments related thereto. It seems that the role and meaning of patent protection is regarded in this way by states which are at the forefront of the peloton leading the functioning of the new system. Lithuania, Latvia or Bulgaria – taking into account EPO statistics on, for example, the number of European patents granted in 2021 for entities coming from these countries – could have more doubts concerning this issue than Poland although they do not articulate them.

> **This constitutes a good example and confirms that it is the right moment to restart discussions on this subject in states that are still undecided.**

Finally, the strategy of "expectation" which consists in observing how the new patent system works in practice and in acceding to this system at the later stage brings also some risk of a political nature. Sometimes it happens that postponement of taking decision leads to diminishing the importance of the matter which decision relates to or (in extreme cases) to completely marginalizing thereof in public debate. When seeing the dynamic progress of works related to the launching of the UPC now, Ireland wishes to come back to the discussion on ratifying the UPCA. This constitutes a good example and confirms that it is the right moment to restart discussions on this subject in states that are still undecided.

Works on creating a unitary patent system in Europe took almost 50 years. The expectation that a completely alternative system will emerge next to this one based on the unitary patent package seems to be an idealistic approach, at least to some extent. We are all aware that the UPCA is not an exemplary solution, but it allows us to realize at least some of the postulates that were presented for quite some time in the context of a need to increase European economy competitiveness with respect to other world economies. Thus, is it really the case that only observing the process of consolidation of Europe in relation to patent protection issues may bring greater benefits to the system outsiders than to its creators? Taking the above arguments into account it appears to me that the answer is for now unequivocal.

Do these different opinions exclude each other?

Moderate scepticism and limited enthusiasm – these expressions provide the best description of the two positions in this general polemic related to solutions included in the unitary patent package. Although it is a subject for much longer discussion, we both agree on two important issues. Firstly, Europe is in need of a patent system reform. Secondly, only a substantial discussion in which different views are presented constitutes a good starting point to develop efficient solutions. Therefore we wish Europe, Poland and our readers exactly such substantial discussions on this issue.

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Argentina: "right to be forgotten"

Santiago R. O'Conor, Managing Partner of O'Conor & Power, reviews a person's rights to have their information deindexed from Google, calling in to question the protection of personal information over information for public interest.

I. Introduction

In a unanimous decision, the Argentine Supreme Court overturned the judgment of the Civil Chamber that granted Natalia Denegri's claim, which -invoking the "right to be forgotten" admitted by the Court of Justice of the European Union in the "Costeja" case- requested that Google be ordered to remove the contents in the results of such search engine that made reference to her name and to the facts related to the famous "Coppola Case", which took place more than two decades ago.

Santiago R. O'Conor

II. Facts from the case and prior decisions

In this case, Natalia Denegri filed before the Argentine courts a lawsuit against Google Inc. in which she requested the suppression and elimination from the search engines of all the links and sites that led to information or images of her as well as those associated with the so called "Coppola Case" that took place at the end of the 1990s, case in which the plaintiff was accidentally involved. She admitted that the information found in the search engines were true to the events in which she was involved concerning a criminal case that obtained a large media coverage, but that the information belonged to a past that she wished to forget and that it was already old, irrelevant, unnecessary and obsolete, lacking of all informative and media importance, currently being of no public and general interest.

The judge in the First Instance partially upheld the action, establishing that, instead of suppressing, the defendant had to deindex, the Google and YouTube platform of any link or association between the words 'Natalia Denegri', 'Natalia Ruth Denegri' or 'Natalia Denegri caso Cóppola' and any image or video which content could include physical or verbal aggression, insults, discussions, signing and/or dancing scenes, as well as videos of possible interviews in which the plaintiff would have given information of her personal life, since, in those cases, it was about scenes whose relevance was linked more to be "grotesque than to the informative" and it lacked any general interest. Consequently, the Civil National Chamber of Appeals confirmed the decision arrived by the First Instance Court detailing that it resulted assertive because it restricted the access to news that specifically reproduced scenes of a sensible matter in which the plaintiff was involved, taking into consideration that they

> **Therefore the exercise of the "right to be forgotten" in this case should be balanced with the right to the free flow of information and the freedom of speech.**

Résumé

Santiago R. O'Conor, Managing Partner

Santiago R. O'Conor was born in Buenos Aires, Argentina. He is an attorney and graduate of the Faculty of Law of the State University of Buenos Aires. He has undertaken postgraduate studies at Harvard Law School and the Fordham IP Institute of New York, and has been a professor of international private law. Santiago is a patent and trademark agent specialized in intellectual and industrial property fields, advising domestic and foreign companies on local and international IP law, prosecution, and litigation in Argentina and throughout Latin America with more than 35 years of practice and experience and is the managing partner of O'Conor & Power. He is an active participant in many IP International Associations, with a main focus at INTA, CITMA, ECTA, PTMG, AIPPI and ASIPI, among others.

were events of undeniable public interest that demanded their dissemination for the acknowledgement from the society since they were related to a criminal case that ended in the dismissal and conviction of a federal judge, a secretary and former police officers, and that therefore the exercise of the "right to be forgotten" in this case should be balanced with the right to the free flow of information and the freedom of speech.

Against this decision, Google Inc. deducted an extraordinary federal appeal which was denied because it was considered as arbitrary, so in turn, they filed a complaint before the National Supreme Court of Justice, where it claimed that the sentence issued by the Civil Chamber violated the right to the freedom of speech recognized in the Argentine National Constitution, in international human rights treaties with constitutional hierarchy and in the jurisprudence of the Supreme Court on the matter, and that it imposed an unreasonable limitation on its activity and an indiscriminate censorship of legal content linked to a public figure and on a matter of public interest based on a "right to be forgotten" of imprecise reach and without legal basis.

III. The Supreme Court ruling

Finally, the Supreme Court gave way to the complaint submitted because of the extraordinary federal appeal and rejected the lawsuit through a decision issued on June 28th, 2022.

A. "The freedom of speech and its vast constitutional protection"

Among the arguments put forward by the Court in its ruling, it is possible to highlight the importance of the constitutional protection of freedom of speech. The judges of the Court detailed that the circulation of information through the Internet is included in the protection provided by freedom of speech, and that this is also recognized by the Congress through Article Nº 1 of Law Nº 26.032 related to the service of internet.

The Supreme Court set forth two interpretative criteria according to the jurisprudence concerning the responsibility of the search engines:

In first place, the Supreme Court affirmed that, given the importance of freedom of speech in the Argentine Constitutional System, its limitations must be understood in a restrictive manner. Consequently, it also established that the assumptions of prior censorship should be presumed unconstitutional, and that this implies – in addition to the reversal of the burden of proof referred to above – that the Supreme Court interprets in a restrictive manner the assumptions in which it could be appropriate to make an exception, if conceded, then the adopted measure must be strictly essential to satisfy the purpose.

In this case, it is considered that a judicial ruling that stipulates the deindexation of results in certain search engines would censor communication and imply a strong restriction on the circulation of information of public interest, especially since the activity of search engines plays a decisive role in the global dissemination of data. Therefore, such a claim would constitute an extreme measure in which a strong presumption of unconstitutionality.

> **A judicial ruling that stipulates the deindexation of results in certain search engines would censor communication and imply a strong restriction on the circulation of information of public interest.**

B. Lawfulness of the Content and Public Interest

The Supreme Court, in a certain manner also recognizes the existence of a right to be forgotten by establishing that, in matters of restriction requests, an assumption of preventive protection could be accepted, on an exceptional basis, based on the illegality of the content provided and the damage suffered, which continues to be generated at the present time. However, this was not appropriate for this particular case, since such requirements were not fulfilled: the plaintiff herself admitted that the information appearing on the internet sites are true, but it is due to the time that has passed that she alleges that the news currently lacks any informative or media importance for society in general, even though it embarrasses and seriously affects current personal, professional, work and family life.

In this sense, the Supreme Court mentions that the passage of time of a piece of news or information that was part of a broad public debate does not justify its suppression, since this implicates a serious risk to history, which is fed by different facts of culture, even when the past is unacceptable and offensive by the standards of the present. In turn, it is established that, for a democratic society, the true information referring to a public person and an event of relevant public interest requires its permanence and free access by the individuals that compose it, since it is part of history, whose knowledge cannot deprive the members – both current and future – of a society.

In turn, the Supreme Court highlighted the difference compared to previous Supreme Court precedents such as "Rodríguez, María Belén", "Gimbutas" and "Paquez" cases, since in those cases the claim was the deindexation of the links based on the illegality of such information, while in the present it was not argued that the information was illegal, but rather that the maintenance of the availability of true information would have generated a "future and possible illegality". The Supreme Court concludes that this situation was not proven in this case.

C. Affectation of personal rights

The Supreme Court also studied the possible affectation of the personal rights of the plaintiff, especially her right to honor and her right to privacy. The latter held that it is not possible for an illicit affectation of the right to honor to occur through the dissemination of truthful information related to a matter of public interest and referring to a public person, such that the authorization to the restriction on the exercise of another fundamental right, as the freedom of speech. The Supreme Court also considered that the "tacky" character that the lower courts assigned to the scenes in which the plaintiff participated, did not constitute a reason to support the ruling, since these verdicts cannot depend on the subjectivity of the judges involved in this case.

Finally, with regards to privacy, the Supreme Court recognized that it is a right that enjoys strong constitutional protection, but this protection does not extend to those aspects of the personal life that the owner consents to reveal to the public. In turn, it reiterated that there were not enough elements in the case to consider that the consent of the plaintiff had been invalidated when the events occurred, in addition to the fact that it was not a grievance raised in the lawsuit.

IV. Closing comments

The Supreme Court concluded that, in the circumstances described, no legal or constitutional basis was found in the plaintiffs demand, since no sufficient arguments were provided to evidence that a person who was and is a public figure has the right to limit access to truthful and public interest information that circulates on the internet about them and is accessible to the public according to his own discretion and preferences, thus restricting that information to the aspects that she herself considers relevant or, on the contrary, inappropriate to the self-perception of her current identity.

> **No sufficient arguments were provided to evidence that a person who was and is a public figure has the right to limit access to truthful and public interest information.**

The Supreme Court ruling in this case constitutes a valuable precedent for future cases where alleged infringement to the freedom of speech on the Internet collides with personal rights. Through the ruling, the Supreme Court once again reaffirms the protection that this right has in the Argentine legal system, and at the same time gives rise to the possibility that if the right to be forgotten is applied in situations that warrant the exercise of such a mechanism.

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New state standard for patent research

Vladimir Bashkirov, Head of Patent Search Department, and Alexander Budkin, Patent Search Expert, of Gorodissky & Partners evaluate the new methodology and reporting for the new Russian State Standard on Patent Studies.

For more than 25 years, a State Standard on Patent Studies (GOST R 15.011-96) has been acting in Russia. This State Standard has established unified requirements on the scope of and procedure for patent studies in Russia, required for implementation by all business entities.

On 19 September 2022, a new edition of this State Standard, issued as GOST R 15.011-2022 enters into force, replacing the old one, mainly due to a need to update a number of old terms, introduce new concepts, adjust the forms of reporting documents, and set modern patent studies approaches and methodologies.

One of the strong points of the new Standard is clearly dividing patent studies into types. In particular, the Standard determines specific types of patent studies by correlating its conduct with the development stages and technological life cycle phases. Thus, prior art patent studies are supposed to be conducted at the initial R&D stage, at defining the development areas, when the results of the studies can themselves become the R&D basis for further developing the identified prior art by creating new technical solutions. Patentability patent studies are associated with the development stage of a specific technical solution when the results of studies can be used for preliminarily evaluating prospects of obtaining patent protection for such a solution. Freedom-to-operate patent studies are linked to products that are about to be launched into manufacturing. The studies identify risks of infringement of third-party patent rights in manufacturing and (or) sale of a manufactured product or developed technical solution in a particular country.

Another type of patent studies are contained in a separate section, which is named Target Patent Studies.

Among the target patent studies are:

- Analysing a strategy for protecting results of intellectual activity;
- Analysing a developer's intellectual property portfolio (scope and content of exclusive rights);
- Analysing a unique nature of a solution of an item appearance in an industrial design or artisan industry and its patentability as an industrial design;
- Analysing means of individualization for distinctiveness and registrability;
- Analysing a complex item to identify elements capable of legal protection; etc.

Vladimir Bashkirov

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Résumés

Vladimir Bashkirov

Vladimir is a Head of Patent Search Department, Russian Patent Attorney and Eurasian Design Attorney. He graduated from Tver State University as an economist in 1999 and later in 2007 qualified as a lawyer in Russian State Academy of Intellectual Property.

Vladimir joined Gorodissky & Partners in 2003. Among his specialties are patent searches, statistic searches in technical fields, searches covering scientific-technical publications, industrial design searches in Russia and abroad; consulting on patent-related issues.

Alexander Budkin

Alexander is a Patent Search Expert at Gorodissky & Partners. He graduated from The Bauman Moscow State Technical University in 1997 as an engineer.

Alexander joined Gorodissky & Partners in 2015. Among his specialties are patent searches, statistic searches in technical fields, and searches covering scientific-technical publications in Russia and abroad.

The list of objectives for the target patent studies is non-exhaustive, thereby allowing other studies, e.g., searching and analysing information for challenging patent validity, to be conducted based on methodology and with reporting forms provided by the Standard.

Requirements for reporting results of patent studies are contained in a special section of the Standard, with samples provided in appendixes of the Standard, thereby suggesting use of unified forms for reporting results of particular types of patent studies.

The new edition of the Standard introduces long-waited clear definitions of what, in the sense of the patent studies, the prior art and technical level are. Introducing those two specific definitions, clearly distinct from alike by wording, but different in essence statutory definitions of prior art and technical level for patentability conditions of inventions is indeed an outstanding feature of the new Standard. Provisions of the old Standard being silent on both definitions resulted in vagueness and confusion. Now, the Standard clearly defines that prior art is information that has become known in the world before the start date of patent studies, and technical level is a characteristic of the technological item, studied by comparing the parameters describing its technical advantage with the corresponding parameters of its peers.

Another new feature of the Standard is recognizing "patent landscape" as a type of patent study. The new Standard defines patent landscape as the results of an analytical information study of patent documentation, which reflects a patent situation in a specific technology or a patent activity of innovators as a function of time and geographical spread, based on statistics and graphically presented. Introducing such a tool in the State Standard demonstrates general recommendation to use it as one of the studies, certainly not instead of the first mentioned above three main studies, but more as visually understandable map-looking document showing general tendencies.

> **The new edition of the Standard introduces long-waited clear definitions of what, in the sense of the patent studies, the prior art and technical level are.**

Finally, the new Standard gives a special interpretation of the concept of information search, as a search other than patent and based on solely non-patent literature.

Undisputedly, the developers of the new Standard made it much clearer than the old Standard, which was very important in the situation when local Russian businesses started active filling in the gaps for the local manufacturing of many goods previously imported. Following the methodologies set forth in the new Standard definitely allows avoidanceof patent infringement and properly defining a task for parent studies with the expectation of clearly provided results by utilizing reporting forms provided by the Standard. Our own long-term experience in the Patent Studies Department of Gorodissky and Partners Law firm shows that the methodology and reporting forms as set forth by the Standard are quite good, accepted not only by local but also by foreign companies interested in local and worldwide patent studies.

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Update on divisional applications in Mexico

Sergio L. Olivares, Daniel Sánchez, and Mauricio Sámano of OLIVARES explain the relationship between the new law applied in 2020 and divisional applications from parent applications.

I. Introduction:

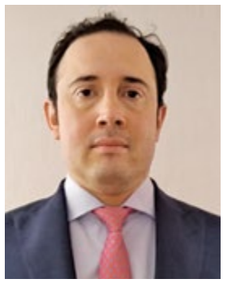
Divisional practice is important for almost any company interested in obtaining patent protection in certain regions. In Mexico, divisional applications have been filed throughout the years, both voluntarily and resulting from a lack of unity objection, and they are an excellent venue for strengthening patent protection.

On November 5, 2020, a new IP law entered into force. This new law has changed the practice for filing divisional applications in Mexico, as we will further discuss. In the previous law, voluntary divisionals were not specifically contemplated, and the legal support for filing voluntary divisionals was found in article 4-G(2) of the Paris Convention, in which the applicant would have the opportunity of voluntarily filing a divisional application, as long as the parent case was pending. The new law specifically covers the possibility of filing voluntary divisionals and establishes a specific deadline for filing them. However, there are significant changes that will require applicants to develop new strategies for filing divisionals.

The new law applies to any patent application filed from November 5, 2020, and onwards, and the new law does not apply to divisionals that derive from a parent application filed prior to November 5, 2020.

Sergio L. Olivares

Daniel Sánchez



Mauricio Sámano

II. Current scenario for filing divisional applications in Mexico

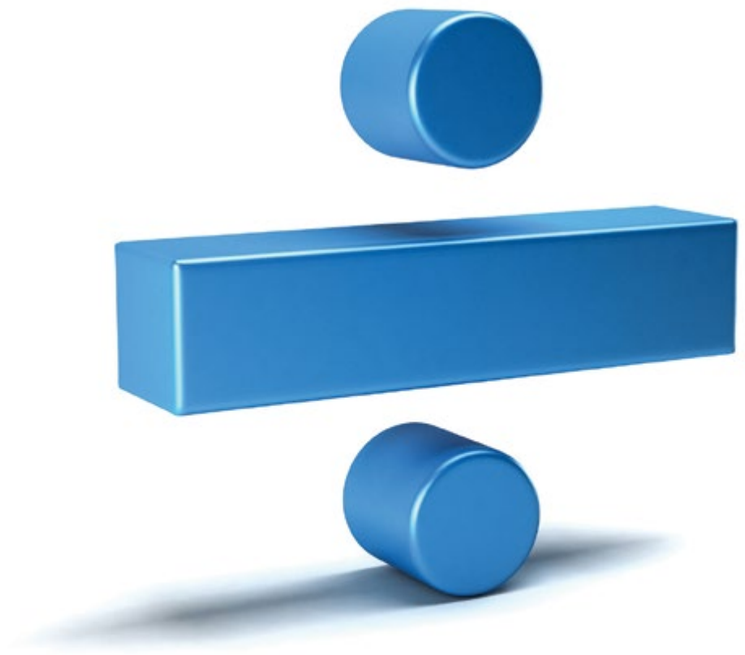
Article 100 of our new IP law, which entered into force on November 5, 2020, reads as follows:

> *Article 100.- In the case of divisional applications filed voluntarily or at the request of the Institute, the applicant shall comply with the following requirements:*
>
> *I.- Submit the descriptions, claims, and drawings necessary for each application, except for the documentation relating to the priority claimed and its translation that already are in the initial application and, if applicable, the assignment of rights and power of attorney. The drawings and descriptions exhibited shall not suffer alterations that modify the invention contemplated in the initial application;*
>
> *II.- To claim an invention different from the one claimed in the initial application and other divisional applications, without containing additional subject matter or that gives greater scope to the one initially filed.*
>
> ***When an invention or a group of inventions have not been claimed due to the division, these cannot be claimed again in the initial application or in the application that gave rise to the division and***
>
> *III.- To file the divisional application within the term referred to in Article 111 of this Law or, when the division is voluntary, under the terms of Article 102 of this Law.*
>
> ***The divisional application cannot consist of the division of other divisional applications unless this is appropriate in the opinion of the Institute or is required of the applicant, under the terms of Article 113 of this Law.***
>
> *If the divisional application does not comply with the requirements outlined in this article, it shall not benefit from the date of filing of the initial application from which it is intended to derive, considering it is filed on the date it was received if it complies with Article 105 of this Law.*

After analyzing the above article, we can see that the new IP law has formalized the divisional practice that existed previously, and in the case of a lack of unity objection, any divisional needs to be filed at the same time or before the response to the office action (in which unity was objected) is filed. In the case of voluntary divisionals, the time limit for filing any voluntary divisional is before the payment of the grant fees.

One major change in divisional practice is that now, when unity of invention is objected, any invention or group of inventions that are not included in the initial application or in the application that originated the division, cannot be included again in any of said applications. Therefore, when receiving a unity objection, the applicant needs to consider this when deciding the scope of protection that is of commercial interest for them. If this is not yet clear, it is important to not let go of any matter when dividing the application.

Another major change in divisional practice is that it will no longer be possible to voluntarily file divisionals that derive from another divisional application. "Cascade divisionals" (2nd, 3rd, etc. generation divisionals) can now only be filed when the Examiner specifically requests the division through the issuance of a lack of unity objection. In view of this major change, applicants will now have to be creative in developing strategies to secure the possibility of being able to file future cascade divisionals. For example, applicants could file in the first divisional, a set of claims that do not comply with unity of invention, to assure that the Examiner issues a lack of unity objection, thus giving the applicant the opportunity to file further divisional applications in the future.



"The new law applies to any patent application filed from November 5, 2020, and onwards, and the new law does not apply to divisionals that derive from a parent application filed prior to November 5, 2020."

III. Challenges for cascade divisionals after the new IP Law

Mexico's new IP law is clear on how divisional applications should be handled going forward. However, applicants have faced challenges from Mexican PTO's (hereinafter referred to as IMPI) interpretation of the applicability of the new IP Law.

A few months after the new IP Law entered into force on November 5, 2020, applicants started to receive formal office actions from the IMPI , in which Examiners started objecting divisional applications that were filed voluntarily and that derived from another divisional (cascade divisionals). Examiners did not consider these applications as divisionals, rather considering them as independent new applications, using the legal filing date of the divisional as the date of its submission before IMPI, instead of the legal filing date of the parent case. This meant that these divisionals were doomed from the beginning because the publications of the parent case would affect novelty, and they would never be granted.

Résumés

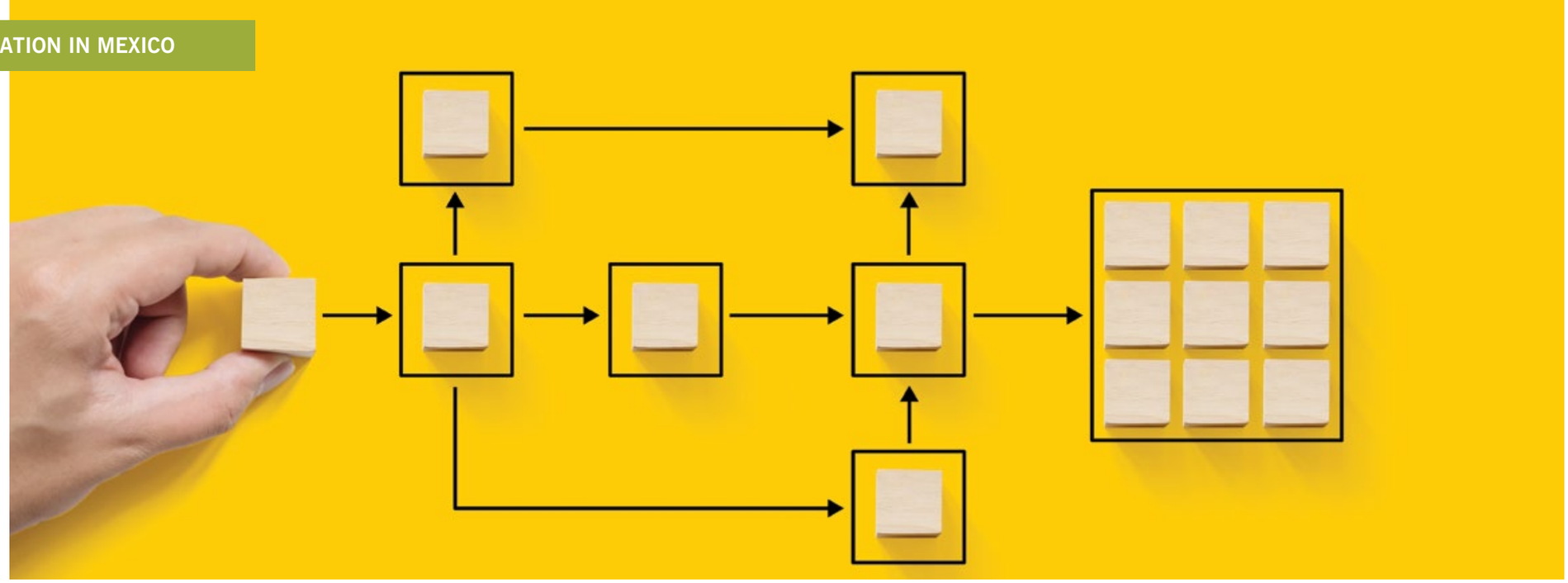
Sergio Olivares, Jr. joined OLIVARES in 1987 and today leads the firm with strength and a commitment to transparency, client satisfaction, and personal service. He has been a partner since 1994 and Chairman of the Management Committee since 2009.

Daniel Sanchez joined OLIVARES in 2000 and became a partner in 2011. He is one of the leading intellectual property (IP) and administrative litigators in Mexico and is recognized by industry rankings and publications.

Mauricio Samano works in the patent department of our firm. His work in 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.

DIVISIONAL APPLICATION IN MEXICO

"We can see that the new IP law has formalized the divisional practice that existed previously."



IMPI based these formal office actions on Article 100 of the New IP Law, which as we have already mentioned, states that cascade divisional applications are now restricted to only those required by IMPI due to a unity of invention objection. However, IMPI's reasoning was simply incorrect because these divisionals derived from a parent case that was filed before November 5, 2020. Thus, they should have been examined according to the provisions of the previous IP Law, which did not have this limitation on divisional applications. IMPI's justification for examining these cascade divisionals under the provisions of the new law that entered into force on November 5, 2020, was simply that the cascade divisionals were filed after November 5, 2020.

Transitory provisions of the new law, clearly provide that any application filed before November 5, 2020, should continue its prosecution under the provisions of the former law. Furthermore, Mexico's Constitution prohibits the retroactive application of any law.

In many cases, after the issuance of two formal office actions (the maximum number of formal office actions that can be issued in Mexico), which were timely replied, with legal arguments rebutting IMPI's inexplicable criteria, there would be a rejection of the cascade divisionals. These rejections, in turn, were challenged through appeals that were filed before IMPI itself.

These were difficult times in which unfortunately applicants did not have certainty, and Mexican law firms did their best to explain this odd situation to their clients, along with making lobbying efforts through associations and independently to try to overturn these baffling criteria.

Fortunately, these lobbying efforts were successful, and in May of 2022, IMPI overturned their criteria and now recognize cascade divisional applications that derived from applications prosecuted under the former law as divisional applications sharing the legal date of the parent case. Because of this, the appeals that were filed with IMPI were all resolved in favor of the applicant, and in the cases in which the first or second formal office action was responded, an additional office action was issued stating that all formal requirements were met.

IV. Unexpected resolution from the Circuit Court

On July 15, 2022, the Mexican Circuit Court en banc issued a decision on the time limit for filing divisional applications for patents prosecuted under the rules of the former Industrial Property Law (abrogated in 2020).

In this decision, the Court determined that divisional applications must be requested prior to the conclusion of the substantive examination. However, the decision was reluctant in pronouncing whether the two, two-month terms (that is four at the most) for the payment of fees after the issuance of the Notice of Allowance, would be considered part of this examination. So, it remained unclear for many practitioners if the time limit for filing a divisional had now changed to the date that the Notice of Allowance is issued.

This criterion was issued because the former Industrial Property Law was ambiguous regarding divisional applications, including the timeframe for requesting them, and several litigation actions were filed as a consequence. However, the new Industrial Property Law states that the time limit for requesting a divisional application is prior to the payment of the grant fees.

With respect to this new criterion, there are relevant points that must be considered:

- It applies only to patents prosecuted under the rules of the former Industrial Property Law.

- Judicial decisions are not mandatory for IMPI to follow but can be highly persuasive.

- The conflicts of applicability of law in time, in case of doubt, Courts should also apply the most favorable law in benefit of citizens.

It is important to clarify that for applications prosecuted under the previous law, IMPI's criteria has always been to accept divisional applications at any time during the prosecution of the parent case and before the payment of the grant fees. It is difficult to think that this Court decision would change this criterion, particularly because it is contradictory with the timelines for filing divisionals that are established in the New IP Law that entered in force on November 5, 2020.

Conclusions

Considering that for some time the previous law and the new IP law will coexist, it is necessary to develop strategies that assure the most robust protection possible in view of the current scenario for filing divisional applications.

While the new IP Law sets a stricter framework, divisional applications are still available in Mexico. In the case of applications filed prior to November 5, 2020, cascade divisional applications can still be filed, and there is still value in going this route.

Now, the Court's resolution does not change the past landscape. As such, and as has been the case, divisional applications filed before November 2020 need to be requested before paying the final fees of the parent or the one from which the division is made. It remains important to be attentive to future resolutions clarifying whether there is an exact moment between the issuance and service of the fourth official action and the payment of the final fees for this.

As to applications filed after November 2020, those are with the new IP Law, and there is an exact provision for the right time, and the Court resolution does not affect this.

The challenge for IP practitioners in Mexico is to assure that this happens through lobbying efforts and through litigation, when necessary. However, the priority is to stop inaccurate information and misunderstandings of the current landscape. In sum, divisional applications are still available but new rules need to be considered.

"IMPI's criteria has always been to accept divisional applications at any time during the prosecution of the parent case and before the payment of the grant fees."

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ADAPT: the light to a diverse future in the patent field

The Patent Lawyer sits down with a panel of ADAPT's members, including Judy Yee, Assistant General Counsel at Microsoft, Micheal Binns, Global Head of Patent Portfolio Strategy for Meta's Family of Apps, and Ken Seddon, CEO of LOT Network, to discuss their DEI mission and how patent professionals can get involved.

Can you each start by introducing yourselves and your role in IP?

Judy: I went to law school at night while working as an engineer. I did not go to law school with the intent of becoming an attorney, much less a patent attorney, but rather I went to make friends after moving across the country. Looking back, I wasn't aware of the requirements to become a patent attorney or what a career in IP would entail. For me, it was something I stumbled upon – and learned that I had the background needed to be considered.

Today, I serve as an Assistant General Counsel in Microsoft's IP Group where I am responsible for leading a team of attorneys and patent professionals that provide IP support to Microsoft's Cloud and AI business.

Through the work I do, and now through the ADAPT initiative, my goal is to help others along their careers. I have always been passionate about STEM programming and DEI platforms, and now I am excited to see not only colleagues of mine in the IP industry excel at their companies, but also become a resource for students and future IP leaders.

> **We aim to create a community of companies who support each other and regularly discuss and innovate on diversity programs, including tracking success and impact over time.**

Micheal: As an immigrant and first generation college student, I can attest to the life-changing benefits of the legal profession, particularly patent law. However, I was not aware of patent law until my second year of law school. Fortunately, I already had the prerequisite undergraduate degree, but for many, this is too late. I hope to make a change in the industry alongside the amazing people and organizations that have started ADAPT.

Ken: I am CEO of LOT Network, a non-profit community of companies committed to protecting its members from costly patent troll litigation.

LOT Network is committed to bringing companies together to address issues facing the IP industry — and we are happy to be partnering with ADAPT to address the issue of DEI.

Can you introduce ADAPT?

Judy: ADAPT, which stands for Advancing Diversity Across Patent Teams, is on a mission to help solve the issue of DEI within patent teams. As a collaborative effort, this collective of IP and patent legal professionals and teams are coming together to drive more awareness for DEI within the industry, as well as make accessible and scale DEI programs within individual companies and throughout the patent and intellectual property industries.

All of the thought leaders of ADAPT are current and long standing members of LOT Network, so not only are they working together to solve the patent assertion entity (PAE) issue, but now expanding their collaboration to solve the lack of diversity and inclusion within our industry.

What are your perceptions on how DEI exists in the patent field today?

Micheal: It is no surprise that the practice of law is one of the least diverse professions. Sadly, the diversity numbers within the patent profession paint a far bleaker picture. For example, the American Bar Association reported that only 5% of attorneys in the U.S. are Black, but only 1.7% practice intellectual property law according to a survey by the American Intellectual Property Law Association. Women are also missing from the practice. Sadly, there are more Mikes admitted to the patent bar than there are racially diverse women. While I love my name, this is an upsetting statistic.

To be clear, many companies are doing a variety of DEI work, including Meta's Patent Pipeline Program, which provides free patent prosecution training to women and underrepresented minorities with technical degrees, and then connects them with law firms looking to hire diverse

Meet the Panel

Judy Yee is an Assistant General Counsel in Microsoft's IP Group where she is responsible for leading a team of attorneys and patent professionals that provide IP support to Microsoft's Cloud and AI business. She has dedicated 15+ years of her career to IP law with an emphasis on delivering business value and protection through intellectual property. Ms. Yee holds a BS in computer science from the University of Michigan and a JD from Seattle University. She practiced at Perkins Coie before going in-house and, prior to entering the practice of law, she was a software engineer at Intel Corporation. Ms. Yee is passionate about advancing women in technology, law and policy.

Micheal Binns is Global Head of Patent Portfolio Strategy for Meta's Family of Apps and an Associate General Counsel on the Patent, Licensing, and Open Source team at Meta, formerly Facebook. At Meta, Micheal is a subcommittee co-chair within the Black@Legal group, focused on ensuring an equitable experience for diverse employees in the Legal department. He also promotes diversity, equity, and inclusion in the legal field by providing opportunities for lawyers within tech, mentoring future and current law students, and working to increase the diversity pipeline for college and law school students looking to enter the intellectual property field.

Ken Seddon is CEO of LOT Network, Inc., a non-profit community of companies committed to protecting its members from costly patent troll litigation. Ken has been an executive at some of the largest patent holders in the world including Apple, Micron, Motorola, Intel and ARM. He has developed product IP strategies, and acquired and defended patents from PAE assertions. LOT Network currently protects its members from litigation involving over 3.5 million worldwide patents. Network members include market leaders such as Disney, Meta, Amazon and Google, as well as startups across industries. Please visit http://www.lotnet.com to learn more.

technical specialists. This program is making a real difference, as earlier this year, three of our Pipeline Scholars commenced full-time employment at our partner law firms. But to scale this type of program takes more than one organization to make lasting change. If we come together on a unified DEI mission, we can make meaningful change and ADAPT is that unification.

Judy: According to a USPTO study, only 22% of registered patent attorneys and agents are women. 6.5% of the registered patent attorneys and agents are racially diverse and 1.7% of the registered patent attorneys and agents are racially diverse women.

There is still much work to be done in our fields.

What is ADAPT's core mission?

Judy: ADAPT's core mission includes three pillars:

(1) Accessibility: Provide a database of how-to guides on running DEI programs and a directory of volunteer and sponsorship activities for DEI organizations to accelerate adoption of DEI programs.

(2) Mentorship: Provide a mentorship program to support diverse patent professionals through law school and in the early stages of their career.

(3) Technology: Share industry DEI statistics.

Why do you think that ADAPT is important for the patent community?

Micheal: As a patent attorney, inventor, and business owner, I am constantly reminded that I have beaten the odds. Systemic inequality rears its ugly head in all aspects of the innovation ecosystem, and most people who look like me, never have a chance to obtain legal rights to their own creations or enter the profession. This is why ADAPT's mission is so important. If we can create meaningful change in the profession, we will create opportunities for women and underrepresented groups to see real participation in the patent industry, which in turn leads to greater representation in the inventor community, because they can see themselves in the lawyers they choose to engage or hope to become.

Ken: The founding companies of ADAPT have done the due diligence of researching and understanding what the needs were for the DEI pipeline. Together, they have identified and generated a set of best-in-class tools and solutions for solving the pipeline issue. These thought leaders realize that not every company is as well resourced, so ADAPT was formed to inventory all solutions that have been done, and then scale these solutions to offer something for every IP department regardless of their size or industry.

Judy: As mentioned previously, the percentage of diverse leadership in IP Is staggering. With so few women registered as patent attorneys and agents and then add to that the low numbers of racially diverse women, we know more work needs to be done.

ADAPT resources will be available for anyone to use them, and we hope that those using them will share their experience. We also are looking for companies of all sizes and across industries to share their DEI programs by contributing to the database of how-to guides. We aim to create a community of companies who support each other and regularly discuss and innovate on diversity programs, including tracking success and impact over time.

Why is LOT Network the place to build this initiative?

Ken: Since it was founded, LOT Network was always community and collaboration-minded. We set out to be a place where the fiercest competitors could come together to agree to help solve the PAE problem. Now, with more than 2,400 members and counting, we want to bring IP and patent leaders together to help solve one of the industry's toughest challenges – the expansion of DEI in our field. As a non-profit organization committed to building stronger relationships together, we felt that being the catalyst for ADAPT was aligned with our mission and values and look forward to supporting the initiative in years to come.

Micheal: Since it was founded, LOT Network was always community and collaboration-minded. And with more than 2,300 members and counting, they are a great resource to unify our existing industry goals, which includes DEI.

> **Systemic inequality rears its ugly head in all aspects of the innovation ecosystem, and most people who look like me, never have a chance to obtain legal rights to their own creations or enter the profession. This is why ADAPT's mission is so important.**

Judy: LOT Network was the ideal platform for launching ADAPT. In an environment where our companies might be competitors, we've all agreed that together – through LOT – we're committed to protecting our innovations and patents in a collaborative environment. Therefore, it made sense for LOT to be the place where we can build an even stronger community of patent leadership – especially one focused on DEI awareness.

How do you foresee ADAPT impacting the patent community?

Ken: A survey[1] conducted by the American Bar Association found that, "The practice of law remains one of the least diverse professions in America." The survey highlights how only 22% of registered patent attorneys and patent agents are women and that only 6.5% of registered patent attorneys and patent agents are racially diverse. These numbers are staggering. Our hope is that through the efforts of some of the world's leading companies – like the founding members of ADAPT – we will begin to shift the industry's perception around diversity and inclusion within our patent teams.

The survey also noted that, "Accordingly, it will be difficult for firms that practice in the areas of computer science, electrical engineering, and mechanical engineering to improve their diversity efforts, particularly at the partnership level, given that the diversity numbers are dismal at the start." By working to support current and future patent leaders, as well as engineers and computer science professionals, we can hopefully remove many of the barriers that individuals may face when it comes to pursuing a career path in the IP industry. We know that more diverse teams deliver stronger results, and we want to see those benefits trickle over to our sector as well.

Micheal: With its three core missions - accessibility, mentorship and technology - every company can have the resources and support to further DEI in the patent community. In addition, the knowledge of companies coming together on this can make for greater impact than a single company doing this alone.

Who can become involved in ADAPT? And how?

Judy: ADAPT welcomes participation from individuals, companies and law firms of all sizes and in any part of their DEI journey to share their DEI experience, contribute to others' programs or build their own. And while we are focused on patent professionals at the moment, we aspire to expand to other areas of IP in the future.

ADAPT resources, however, will be available for anyone to use and we hope that those using them will share their experiences with the greater IP community. We also are looking for companies of all sizes and across industries to share their DEI programs by contributing to our database of 'how-to' guides, volunteering for existing DEI programs or partnering with nonprofits in the space.

Anyone who wants to learn more, or become involved, can visit www.adapt.legal or email info@adapt.legal.

Where do you hope ADAPT will be in five years?

Micheal: In addition to potentially expanding into other areas of intellectual property, we hope that we can increase the number of companies and organizations pledging to get involved with DEI programs and initiatives that will create a profession that matches with the broader legal landscape and our communities. We also want to learn from other companies who will add and share new and creative ways to address ADAPT's mission.

ADAPT.legal

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> **By working to support current and future patent leaders, as well as engineers and computer science professionals, we can hopefully remove many of the barriers that individuals may face when it comes to pursuing a career path in the IP industry.**

[1] https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2020-21/september-october/diversity-patent-law-data-analysis-diversity-patent-practice-technology-background-region/

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