The Patent Lawyer

GLOBAL REACH, LOCAL KNOWLEDGE

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July / August 2023

# A new dawn for patent law in Europe – can the UPC place European patent litigation on par with US patent litigation?

Launch interactive document

SOUTH AMERICA Law firm RANKINGS

Rachel Fetches, Partner & Head of Law at HGF, provides a first glimpse into the new UPC system, with summary of the unfolding patent actions that will influence the development of case law, to predict the success of the new system.

IPISC: IP infringement insurance
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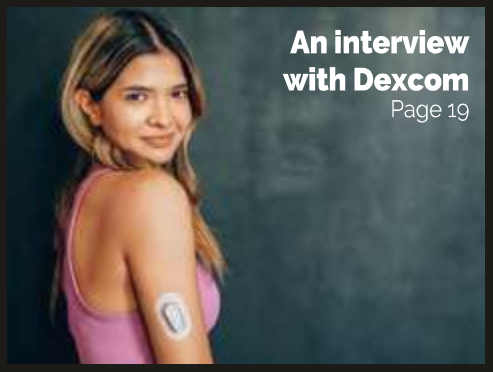

An interview with Dexcom
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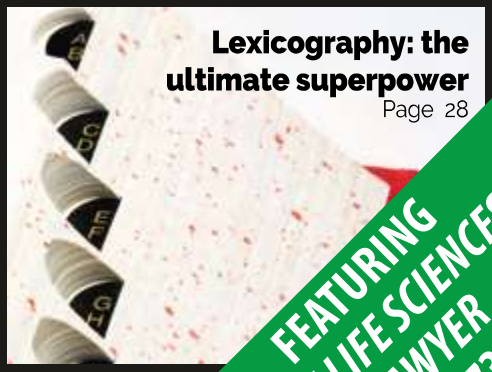

Lexicography: the ultimate superpower
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CTC Legal Media

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Throughout the next few pages, you will view a comprehensive list of the 10 most well-respected law firms from South America, 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.

## Argentina

Berton Moreno IP
G. Breuer
Hausheer Belgrano & Fernandez
Marval, O'Farrell & Mairal
Moeller IP
Noetinger & Armando
O'Conor & Power
Ojam Bullrich Flanzbaum
Palacio & Asociados
Pérez Alati, Grondona, Benites & Arntsen (PAGBAM)





## Bolivia

Bolet & Terrero
Bufete Aguirre, Quintanilla, Soria & Nishizawa (BAQSN)
Cervieri Monsuarez
C.R. & F. Rojas Abogados
DAK Intellectual Property
Escobar & Escobar
Guevara & Gutierrez (Dentons)
Indacochea & Asociados
Landivar & Landivar
Moreno Baldivieso

## Brazil

Barbosa Müssnich Aragão (BMA)
Bhering Advogados
Daniel Law
Dannemann Siemsen Advogados
Guerra IP
Gusmão & Labrunie
Licks Attorneys
Montaury Pimenta, Machado & Vieira de Mello
Trench Rossi Watanabe
Vaz e Dias Advogados & Associados

### Wednesday 25 October

*AIPPI Café 10* will begin at **09:00** so you can grab your morning coffee and warm up for the day with a roundtable discussion. *Panel Session XIII - Use, Re-use, Recycle* will also be taking place, focusing on the impact increased sustainability initiatives are having on trademark protection while addressing concerns over recycling and upcycling products bearing trademarks.

Simultaneously, *Panel Session XIV - NFTs in Practice* will address the burning questions NFTs continue to raise around copyright, trademarks and design laws. Expect advice on how IP practitioners can best advise their clients on IP protection for NFTs.

*AIPPI Café 11, 12 and 13* will run between **09:30-11:00** for more riveting discussions, with the morning's Networking Coffee Break between **10:30-11:00**.

At **10:00** the much-anticipated session *UPC Mock Trial; UPC Now* will take place, which will review the first few months of the long-awaited Unitary Patent Court with experience and insights from experts.

At **11:00**, the traditional panel session *Panel Session XV - IP Law Global Update* will be presented by leading practitioners from the US, Japan and EU and will include the most pertinent topics from the past year. Alternatively, *Panel Session XVI - Subject Matter Matters* will look at the ever-changing issues regarding patent specification and the scope of claims from both the prosecution and litigation viewpoints. The panel will consider recent case law and IP Office requirements in various jurisdictions throughout the session.

*AIPPI Café 14, 15 and 16* will run between **11:00 and 12:30** before *IP Lunch 3 - IP for Games is Not a Game*, which will focus on innovation and creativity in the gaming industry and the presented challenges in IP protection. Networking Lunch will also take place between **12:30-14:00**.

*Women in AIPPI* will be hosted upon the elegant boat GRIT between **17:00-18:00** for a scenic cruise down the Bosphorus waterway - an opportunity for female IP professionals to network with like-minded individuals.

AIPPI's closing dinner will deliver the splendor and richness of Ottoman culture at the Hilton Istanbul Bomonti Hotel and Conference Center from **19:30**. Guests are encouraged to 'bring their own culture' for this black-tie event. The dinner will be the perfect end to a fantastic event full of educational opportunities and reconnection.

> **The much-anticipated session *UPC Mock Trial; UPC Now* will take place, which will review the first few months of the long-awaited Unitary Patent Court with experience and insights from experts.**

**Head to www.aippicongress.org to book your place at the 2023 AIPPI World Congress, 22-25 October 2023 in Istanbul, which is sure to be a knowledge-rich few days enlightened by the company of IP colleagues!**





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# Telemedicine in Portugal: navigating legal challenges and liability risks

Ricardo Costa Macedo, João Bertholo Meireles, and Rafael Cunha Jóia of Caiado Guerreiro evaluate the impact digital evolution is having on legal risk in the health industry.

**Pharmaceutical patent litigation**
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remote healthcare services, many believe that healthcare professionals are still eager to meet their patients in a clinic, hospital, or even at home, mainly to prevent possible liability issues.

Frequently, healthcare professionals may decide not to make a diagnosis based on the information collected from the patient, considering it insufficient to determine with absolute clarity the problem in question.

Indeed, healthcare professionals are not obliged, at any time, to issue medical opinions when they have insufficient knowledge or information on a patient to render a solid and reasoned opinion. With that said, despite this discretion and autonomy to decide whether there is enough information, when a healthcare professional communicates a certain decision or recommendation to their patient, then they are liable and legally responsible for it, as per the Medical Deontology Regulation of the Portuguese Medical Association.

Such provisions should be reconciled as soon as possible and effectively with article 284 of the Portuguese Criminal Code, which states, *a contrario*, that medical professionals have a duty to assist and aid their patients in cases of dangers posed to their lives or physical integrity.

> **A possible way to tackle these legal challenges and liability risks is to inform the patient of the eventual outcomes of telemedicine.**

In this scenario, healthcare practitioners may encounter a challenging dilemma or find themselves in a difficult predicament. Therefore, a possible way to tackle these legal challenges and liability risks is to inform the patient of the eventual outcomes of telemedicine, allowing the beneficiary to choose whether or not to undergo a specific treatment or undertake the prescribed medicine.

Hence, it should be emphasized that, in the case of telemedicine, many medical practitioners are nowadays strongly advocating for their colleagues to convey extra information and be as detailed as possible about the remote healthcare services they are about to provide, as opposed to when they are meeting the patients in person. This comes as a consequence of attempting to fully inform the patient, who is about to receive healthcare, in an effort to obtain the required voluntary and informed consent and avoid possible liability issues.

For everything that was stated above, despite society entering into a digital era, that would theoretically drive healthcare professionals to embrace telemedicine and all its advantages, there are obstacles and barriers standing in the way of delivering such healthcare services.

Issues, such as the possible increase in medical errors and mainly the medical liability deriving thereof, will persist in the minds of many medical professionals until a clear and more define legal framework emerges. Perhaps the medicine of the near future will be able to gradually tackle such issues, so as to eliminate all of the dis-advantages when providing healthcare services remotely.

In conclusion, the fact that telemedicine remains largely unregulated in Portugal and the associated difficulties in assessing the liability stemming from telemedical acts may be the biggest obstacle faced by the healthcare sector and by medical practitioners when providing remote healthcare services, the latter not being able to take full advantage of the many benefits of telemedicine. As such, one highly encourages the legislator to, step by step, begin addressing this phenomenon and lay down the legal framework for telemedicine.


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of a medicament for the treatment of Y, wherein X is a compound or composition and Y is a disease or disorder.

The second use claims acceptable by Mexican Examiners are compound for use claims, such as the EPC2000 second medical use format style claims under the drafting of X for use in the treatment of Y, wherein X is a compound or composition and Y is a disease or disorder.

Until today, the Mexican Institute of Industrial Property did not include patents with EPC2000 claims in the *Linkage Gazette*, as such claims are considered not to fall within the provisions of Article 162 of FLPIP and are being interpreted to be directed to use and not to a product *per se*.

Additionally, an official Gazette citing the patents that do not comply with the provisions of Article 162 of FLPIP is also published twice a year, again in February and August.

The decision of the Mexican Authority to exclude a patent in the official *Linkage Gazette* can be combated by filing an Amparo Appeal before a District Court.

In conclusion, our firm has successfully requested the inclusion of medicaments in the *Linkage Gazette* without having regulatory approval. Thus, based on our practice, it should be noted that it is possible to request the petition once the patent is granted as an action to alert possible competitors.

It is recommended to enter the petition shortly after the Patent is obtained, however, there is no specific or fatal deadline for filing a writ requesting the publication of the granted patent in the official Gazette.

It is important to consider that a rejection for including a patent in the official *Linkage Gazette* does not invalidate a patent.

> **It is important to consider that a rejection for including a patent in the official *Linkage Gazette* does not invalidate a patent.**


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# Life Sciences patent practice: a comparison between Brazil and the United States

**Gabriela Neves Salerno of Montaury Pimenta Machado & Vieira de Mello and Jeffrey D. Morton of Procopio, Cory, Hargreaves & Savitch LLP provide a comparative review of the patenting system in Brazil and the US for new medical use and antibodies.**

The Brazilian Patent and Trademark Office (BRPTO) has, in recent years, improved in terms of providing clear and detailed guidelines for examination of patent applications in the Life Sciences. In parallel, and in light of a significant effort to tackle a pre-existing examination backlog, the timeframe for substantive examination has decreased considerably. However, Brazil still has certain unique rules when it comes to life sciences patent practice, which sometimes renders prosecution in the country a challenge for foreign applicants, such as those from the United States.

As discussed further in this article, the relevant patent law in the United States is generally viewed as being more flexible than Brazil's. Accordingly, the objective of this chapter is to provide a comparison between the patent practice in both countries, particularly considering important life sciences issues, namely new medical uses, and antibodies.

Gabriela Neves Salerno

Jeffrey D. Morton

## New medical uses

**Brazil**

New medical uses generally refer to patent claims that focus on novel, non-obvious uses of a known compound. In Brazil, new medical uses have been a controversial issue in view of strict rules adopted by the BRPTO. Non-exhaustive examples of restrictions imposed on claims related to new medical uses that differ from many countries are as follows:

1) *Features related to the use of the compound, such as dosage, administration/ application form, dosage interval, and/or group of patients do not impart novelty to the known use of the compound*[1].

Given that many new medical use inventions are based on the above-mentioned features, the non-acceptance thereof needs to be carefully considered when drafting a claim set for entry into the Brazilian national phase.

Another important limitation imposed by the BRPTO is as follows:

2) *"In vitro" test results may show evidence of the new therapeutic use; however, they are often not confirmed "in vivo" due to pharmacokinetic aspects, among others related to the behavior of the drug within the organism. Thus, it is not always possible to extrapolate the results of "in vitro" tests for an actual therapeutic application, unless additional complementary information be presented proving this equivalence. In case of studies performed in animals, the models adopted should present the possibility of extrapolation for humans or animals to be treated.*[2]

Based on the above-recited restriction, it is almost mandatory to submit *in vivo* tests to prove

## Résumés

**Gabriela Salerno** is a partner of Montaury Pimenta, Machado & Vieira de Mello and head of the technical team of Montaury's patent department.
She is the chair of the Patent Committee of the Brazilian Association of Intellectual Property (ABPI), vice-chair of the IPO- Intellectual Property Owners' Association Committee on Intellectual Property Practice in Latin America and a member of the firm's Diversity and Inclusion Committee. She has 17 years of experience in counseling clients on patent matters especially related to the life science field.

**Jeff Morton** is a partner at Procopio, Cory, Hargreaves & Savitch LLP, headquartered in San Diego, California. He provides strategic intellectual property advice, including patent prosecution, and related transactional support for emerging and mature companies in a wide variety of industries, with a particular focus on life sciences and medical technologies. A PhD immunologist, Jeff has extensive patent experience in technologies including genomics, immunology, and gene editing technologies, and advises on complex freedom-to-operate life sciences issues. Jeff also maintains an active trademark practice and provides cross-border legal advice with Canadian clients, being admitted in both the US and Canada. He has been recognized by the World Intellectual Property Review as a US Patent Leader and Trademark Leader and as an IAM Strategy 300 world-leading IP strategist.

the efficacy of new medical uses. However, this provision only applies to new medical uses, which raises a discussion on a distinct (and stricter) treatment to this specific subject matter as compared to other patentable matters for which there is no such rule.

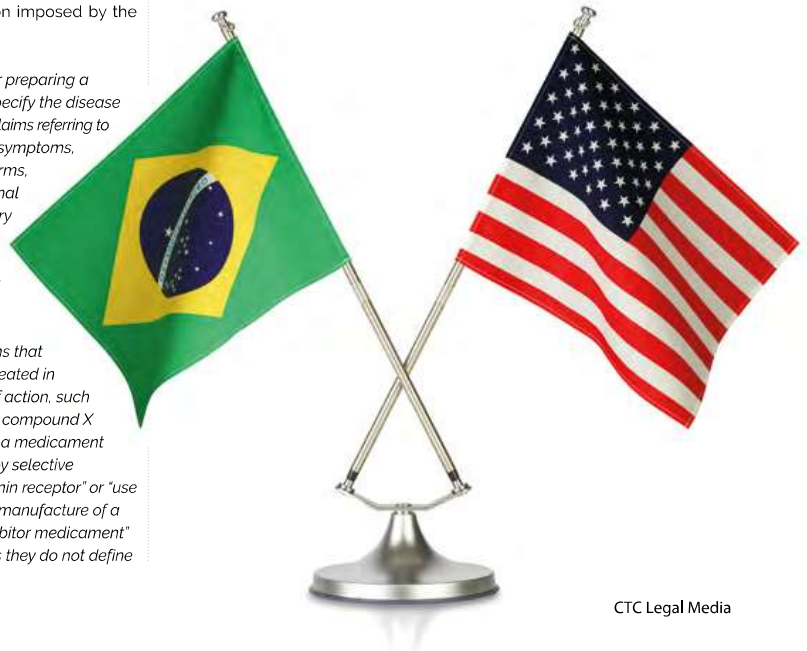
A third important limitation imposed by the BRPTO follows:

3) *The new use claims for preparing a medicament should specify the disease to be treated. New use claims referring to disorders, syndromes, symptoms, or any other generic terms, such as "gastro-intestinal disorders" or "respiratory syndromes", will not be accepted because they render the subject matter to be protected undefined.*
*New medical use claims that refer to the condition treated in terms of mechanism of action, such as for example, "use of compound X for the manufacture of a medicament for treating a disease by selective occupation of a serotonin receptor" or "use of compound X for the manufacture of a serotonin reuptake inhibitor medicament" will not be accepted as they do not define the disease in a clear and precise manner. Excerpts contained in the new medical use claims related to the therapeutic scheme and group of patients also do not define the use of a compound to prepare a medicament and, thus, are not accepted for rendering the subject matter undefined*[3].

Once again, and different from many other jurisdictions, the clarity requirements are strictly defined in the BRPTO guide-lines for the examination of patent applications.

**United States**

Like Brazil, the United States permits claims that focus on new medical uses to known compounds. However, unlike Brazil and many other international jurisdictions, these claims are typically drafted as methods of medical treatment, which constitute patent-eligible subject matter in the United States. As noted in the US Patent Office's Manual of Patent Examining Procedure (§2173.05(q)): "attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness ..." Moreover, claims drafted in the method of medical treatment format do not generally contain the various limitations identified above with respect to practice in front of the BRPTO. Rather, US-style method of medical treatment claims are examined principally for novelty (35 U.S.C. 102), non-obviousness (35 U.S.C. 103), and indefinite-ness (35 U.S.C. 112).





### Antibodies

**Brazil**

The term "antibodies" includes both polyclonal and monoclonal antibodies. Polyclonal antibodies are biological products isolated from the nature, and therefore, according to the Brazilian IP Law, are not considered to be inventions, even if isolated. Monoclonal antibodies, on the other hand, may be obtained by human intervention and thus are entitled to protection in Brazil, provided they comply with the patentability requirements and are drafted in one of the accepted formats.

According to the current Guidelines, claims directed to antibodies are considered properly drafted when they define the antibody by (i) the hybridoma from which it is produced, or (ii) its specific amino acid sequence. The definition of an antibody by the protein to which it binds and/or by its affinity is not considered clear and precise.

In cases wherein the antibody is defined by the hybridoma, it is mandatory to have the deposit of the hybridoma in an institution authorized by BRPTO or recommended in an international agreement by the filing date or priority date of the patent application, and the submission of the deposit number in the patent application. In cases wherein the antibody is defined by its amino acid sequence, the BRPTO does not accept the language "at least X% of sequence identity".

The above-mentioned considerations also apply to fragments of antibodies, which are only considered to be an invention if they are not fragments originating from natural antibodies. Modifications in antibody fragments, as well as chimeric/humanized antibodies, may also be protected in Brazil if the patentability requirements are met and the claims are properly drafted.

When it comes to processes of obtaining an antibody, the process of producing monoclonal antibodies is not considered a natural biological process, since it comprises the obtainment of a hybridoma or genetic engineering techniques. Furthermore, although the process for obtaining a polyclonal antibody is considered a natural biological process and, therefore, it is not considered to be an invention, there is an exception. BRPTO considers there is significant human intervention in cases wherein non-trivial technical steps involving the determination of the epitope or modification of the antigen to elicit the immunological response. Accordingly, said processes are entitled to protection.

**United States**

Again, the United States patent law tends to be more liberal in terms of patentability of antibodies. Both polyclonal and monoclonal antibodies are potentially patentable and there is no strict view on polyclonal antibodies not constituting an invention.

> **"Although the process for obtaining a polyclonal antibody is considered a natural biological process and, therefore, it is not considered to be an invention, there is an exception."**

Historically, antibodies in the United States could be claimed either by function – for example, based on an antibody's functional binding with its cognate antigen – or by structure – for example using the antibody's amino acid sequence. However, there has been a trend, over the past decade, away from allowing broad functional claims for antibodies; specifically, the 2017 Federal Circuit decision in *Amgen v. Sanofi*[4] did away with the newly characterized antigen test, which had previously permitted broad patent claim coverage where the antibody was characterized in reference to its antigen.

Moreover, in 2023 the US Supreme Court will be deciding on the legal concept of enablement in *Amgen v. Sanofi*[5w] in the context of monoclonal antibodies. At issue before the US Supreme Court is a determination of the appropriate legal standard to be applied between whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation – i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "'time and effort.'" Regardless of the ultimate decision rendered by the United States' highest court, the trend in claiming antibodies is clearly towards increased structure, instead of relying solely on functional claim language.

### Conclusions on new medical uses and antibodies

The United States and Brazil are the world's third and sixth largest countries by population, respectively. As major economies, the importance of protecting valuable life science inventions is paramount. In particular, it is critically important for patent applicants to be able to secure patent rights for new medical uses and antibodies in these key jurisdictions. As outlined above, each jurisdiction contains nuanced law that can make or break patent protection. Consulting early and often with experts in each jurisdiction is highly recommended for life science clients looking to protect their life science inventions in Brazil and the United States.

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1 BPTO's Guidelines for Examination of Patent Applications in the Chemistry Area, Section 9.1.1
2 BPTO's Guidelines for Examination of Patent Applications in the Chemistry Area, Section 9.1.3
3 BPTO's Guidelines for Examination of Patent Applications in the Chemistry Area, Section 9.1.4
4 872 F.3d 1367 (Fed Cir 2017).
5 Case number: 21-757.