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Life Sciences & Pharma IP Litigation 2025

Last Updated January 28, 2025

Brazil

Law and Practice | **Trends and Developments**

Law and Practice

Authors

Ana Paula Affonso Brito (/author/details/153818/QWFsIEFBhdWxhIEFmZm9uc28gQnJpdG8)

Maria Eduarda de O Borrelli (/author/details/153818/TWFyaWEgRWR1YXJkYSBkZSBPIEJvcnJlbGxpIEp1bnF1ZWlyYQ)

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Article 17 of the Brazilian Code of Civil Procedure (the “Brazilian Civil Code” or the “Code”) provides that in order to file a lawsuit, it is necessary to demonstrate legal interest and legitimacy. Thus, an action for patent infringement must be filed by the patentee and in the case of co-ownership, the provisions of the Civil Code will apply.

Since Brazilian law does not provide further details for the co-ownership of patents, other than defining that a patent application may be filed by a group of inventors, most of the rules established between the co-owners are guided by the Brazilian Civil Code. What is not statutorily required, may be required by contract. Contractual dispositions are therefore strongly recommended in Brazil, due to the lack of detailed provisions in the Industrial Property Act.

The Brazilian Civil Code is applied subsidiarily, as the law on co-ownership of a patent is analogous to the law onco-ownership of real estate/property, which sets forth that if two or more people own an undivided thing, each may exercise possessory acts over it, as long as they do not exclude the other co-owners.

Not all joint owners therefore have to join as plaintiffs in patent enforcement actions, and each owner has the right to enforce its property independently. Such provision may not be changed by contract, since this would be an ownership limitation rule. However, other provisions may be altered by contract.

The Brazilian Industrial Property Act

As to licensees, the Brazilian Industrial Property Act (Law #9.279/96) foresees in Articles 61 and 62 that patentees can celebrate exploitation licensing agreements with third parties, and, in this case, the licensee may be invested with all powers to act in defence of the patent. This includes the extraordinary right to figure as a plaintiff in an infringement action, even without joining the patentee as a co-plaintiff.

In the specific scenario in which the patentee does not figure as a co-plaintiff, it will not be necessary to figure as a defendant either – as this position will be solely occupied by the alleged infringer(s). It is important to highlight, however, that the licence agreement must be recorded with the Brazilian Patent and Trademark Office (BPTO) to have an effect on third parties.

Patent nullity actions

As to patent nullity actions, Article 56 of the Brazilian Industrial Property Act foresees that these can be filed before a federal court by the BPTO or by any legitimately interested party, at any time during the patent validity term. Nullity actions are usually filed by those who have been sued in a state court for patent infringement or who have received a cease-and-desist letter from the patentee, to refrain from using the protected technology. This is because an invalidity declaration by the court will have retroactive (ex tunc) effects from the date of the patent application’s filing with the BPTO – which means that should a patent be declared invalid, it will be as if it has never existed, and no infringement condemnation may be declared on a parallel ongoing infringement action.

There are also technologies where protection by patent may put a segment of society at risk, such as pharmaceutical patents, generating greater flexibility for the judge in gauging the legitimate interest of the plaintiff in the nullity action.

In a recent case (REsp No 1332417/RS decision issued on 20 June 2024), the Brazilian Superior Court of Justice (*Superior Tribunal de Justiça*, or STJ) confirmed its understanding that it is possible to argue the nullity of a patent or of a design as a defence against an infringement lawsuit before the state court in Brazil.

The issue had already been analysed by the court in 2020, when the Third Panel of the STJ decided, within the scope of lawsuit REsp No 1.843.507/SP, that although the invalidity claim of a patent has to be addressed to a federal court, the Brazilian IP Act would expressly allow the defendant the possibility to invoke nullity in an infringement action, as a matter of defence, without the need for the BPTO to participate in the lawsuit (Article 56, § 1º of the LPI).

The decision issued on 20 June 2024 standardises the case law and explicitly states that the consequence of a declaration of invalidity of an industrial design or patent as a defence strategy against an infringement lawsuit is limited to parties involved in the lawsuit.

This means that the state court's ruling is confined to the infringement case in which it arises, dealing solely with disputes between private parties without the participation of the BPTO. Thus, such decision does not constitute the formal revocation of the patent or utility model involved and will not cause general effects (erga omnes) or impact on its validity before third parties.

1.2 Defendants/Other Parties to an Action

In life science/pharma cases, the manufacturer is generally sued for infringement, as the supplier of the whole chain, although in the case of pharmaceuticals produced outside Brazil (generally generics), the importer is generally the one who will be sued. Thus, it is seen as more efficient to target the person that started the infringement or the one who has launched the product and given rise to it, as the patentee will be able to seek to cease the infringement at the "roots".

While the infringement action takes place between private parties in the state court, the nullity action may be filed by anyone with a legitimate interest against the patentee and the BPTO, in the federal courts, in accordance with the provision of Article 57 of the Brazilian Industrial Property Act, since the BPTO is the federal agency responsible for the administrative act that granted the targeted patent.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions are available in the Brazilian legal system and are regulated by Article 300 and the following articles of the Brazilian Code of Civil Procedure, as well as Article 209, § 1o of the Brazilian Industrial Property Act, which establishes that the judge may grant an injunction to cease the infringement, aiming to avoid irreparable damages.

Usually requested on an ex parte basis within the initial brief of the infringement or nullity actions, the plaintiff must attest the:

- likelihood of success on the merits; and
- risk of irreparable harm,

and if one such requirement is not fulfilled, the preliminary injunction request will not be granted by the trial court judge.

Although ex parte injunctions are allowed in Brazil for patent infringement cases, in the São Paulo State Court, judges generally allow defendants to submit a short defence within five days of the summoning, before the official deadline for a formal reply, so as

to provide initial inputs to the court. In addition, in 2024 it was apparent that in patent infringement claims in the Rio de Janeiro State Court, judges were also ordering a concise unbiased expert opinion, before the issuance of the preliminary injunction, so as to clarify to the court the main aspects of the infringement.

The Usefulness and Necessity of the Claim

For both patent infringement and patent invalidity actions, the existence of a granted patent is an indispensable prerequisite of the lawsuit, as it attests the procedural interest of the plaintiff. According to a recent decision rendered by the Brazilian Superior Court of Justice on Special Appeal No 2.001.226, the procedural interest requires the confluence of two elements: the usefulness and necessity of the claim submitted to the court. While the former will be attested if the lawsuit can provide the plaintiff with the favourable result sought, the need for the state to act will be attested if it is found that the opposing party resists the claim formulated by the plaintiff.

Thus, it is inferred that the existence of a patent itself should not be used as an exclusive argument to attest to the likelihood of success on the merits, but as an argument to attest the procedural interest of the plaintiff.

Assessing the Pros and Cons

It is also the case that the sooner the patentee adopts the necessary and relevant measures to prevent the ongoing infringement practices, the better the chance that the judge will understand the real urgency of the matter, as well as the risk of irreparable harm. On the other hand, the judge must also weigh the risk of reverse damage to the counterparty, before deciding on the balance whether or not to grant the preliminary injunction.

Judges are used to rendering such decisions on an ex parte basis, but during the past few years, a specific court specialised in IP has been adopting a different practice: the São Paulo State Court – one of the major courts concentrating on IP litigation discussions in Brazil – has been summoning the defendant to present a preliminary response regarding the plaintiff's preliminary injunction request, aiming to promote the least adversarial proceeding so that the judge can better assess the case and render a decision on whether or not to grant the preliminary injunction request.

It is important to highlight that jurisdictional remedies are not only available to the party whose right has been infringed, but also to the party whose right is about to be infringed, aiming to prevent damage from occurring. It is therefore possible for a patentee to file an inhibitory lawsuit combined with a preliminary injunction request, aiming to prevent the defendant from committing the infringement and the material damages arising therefrom. However, such lawsuits are analysed on a case-by-case basis, taking into consideration the background to the discussion, as well as the practices provided by Article 43 of the Brazilian Industrial Property Act, which are considered exemptions of infringement or threat of infringement, such as the Bolar exemption and the market authorisation application.

Should the preliminary injunction be granted on an ex parte basis, the defendant will be summoned via post or by the clerk of the court. As soon as the confirmation receipt is filed in the court's files, both the defence brief and potential interlocutory appeal deadlines will start.

1.4 Structure of Main Proceedings on Infringement/Validity

Bifurcation of Infringement and Validity Proceedings: Legal Provisions and Discussions on the Case Law

Infringement actions must be filed before a state court, while nullity actions must be filed before a federal court, since the participation of the BPTO (a federal autocracy) as a co-defendant is mandatory, as it is responsible for granting the challenged patent, in accordance with Article 57 of the Brazilian Industrial Property Act.

There is currently a discussion in the main Brazilian courts regarding the possibility of arguing the invalidity of a patent in an incidental manner, as a way of defence in an infringement action, based on the provision set forth by Article 56, § 1o of the Brazilian Industrial Property Act ("the nullity of a patent may be argued, at any time, as a matter for defence").

For some judges, it would not be possible to discuss the nullity of a patent during an infringement action, since Article 57 of the Brazilian Industrial Property Act provides that the BPTO must figure as a mandatory co-defendant (and its participation is only possible before the federal courts, due to a competence rule established by the Brazilian Federal Constitution). For this reason, Article 56, § 1o of the Industrial Property Act cannot be interpreted on its own. However, for other judges, it would indeed be possible to discuss the nullity of a patent in an incidental manner in an infringement proceeding, although the decision on the merits rendered in this respect would have inter partes effects but would not affect third parties outside the lawsuit. There is currently no uniformity in Brazilian case law with respect to this subject and each judge can adopt their own position regarding the matter.

Most recently (EREsp 1332417/RS, Motion for Reconsideration in Special Appeal – 2012/0137220-6), the STJ considered whether it is possible to claim the nullity of patents and/or industrial designs as a matter of defence. On 12 June 2024, the Second Panel of the STJ unanimously reaffirmed such understanding by authorising the claim of nullity by the defendant in an infringement lawsuit. The nullity of patents and industrial designs by the state courts is of an incidental nature, operating inter partes effects, and may serve, exclusively, as a guiding basis for deducing the unfoundedness of requests in a related infringement lawsuit.

Staying of the Infringement Proceeding

Article 313, V(a) of the Brazilian Code of Civil Procedure establishes that the staying of a lawsuit may occur where there is a risk of conflicting decisions being rendered by different courts – that is, when the judgment of a certain lawsuit depends on the outcome of another case, or on the declaration of the existence or non-existence of a legal relationship that is the main subject of a parallel discussion.

It is then necessary to assess whether the outcome of the subordinating issue (which, in this case, is the invalidity action) will necessarily influence the decision on the subordinated issue (ie, the infringement action). In this case, the possibility of contradictory decisions being rendered by both the state and federal courts is the main legal basis for suspending the proceedings until the case understood as subordinating is decided, as it can happen that at the same time a patent is declared null by the federal court (producing ex-tunc and retroactive effects), the state court may declare the existence of a patent infringement, meaning that conflicting decisions have been

generated by the two courts. However, if the decision on the patent's invalidity is upheld by the panel of judges in the second instance, the infringement lawsuit in the state court will have no purpose, as the patent will no longer exist in the legal sphere.

This is why it is not unusual for judges to stay infringement actions when there is an ongoing nullity action before another court, based upon the provision of Article 313, V(a) of the Brazilian Code of Civil Procedure. However, it must be mentioned that there are judges who prefer to stay the infringement action only when a relevant development in the nullity action occurs (for instance, a technical report concluding that the the patent is invalid, or a first instance decision on the merits of suspending the effects of the patent or declaring the patent's invalidity), aiming to prevent alleged infringers from filing an invalidity action, with no relevant arguments, simply to delay the infringement action's conclusion.

Exhaustion of the Administrative Sphere

According to Brazilian case law, it is not necessary to wait for the administrative sphere's exhaustion to file a nullity action. As long as the patent is granted by the BPTO in the first instance, an interested party can file a nullity action before a federal court, even if an administrative nullity procedure is pending analysis by the BPTO in the second instance. Should the administrative nullity procedure be granted, and the patent be declared null by the BPTO, the nullity action will lose its purpose and consequently be shelved.

1.5 Timing for Main Proceedings on Infringement/Validity

Judicial Statutory Deadlines

As to an infringement action combined with a request for material and moral damages, the plaintiff must file this within five years from the date of acknowledgement of the infringement, according to Article 225 of the Brazilian Industrial Property Act. If the infringement is continuous, the five-year term will be renewed daily.

As to an invalidity action, the plaintiff may file this at any time during the term of the patent, according to Article 56 of the Brazilian Industrial Property Act. However, if the invalidity action challenges the rejection of a patent application, the action must be filed within five years from the date the BPTO's rejection was released in the Official Gazette.

Estimated Timeframe of Service of an Action and Lawsuit

Defendants are generally served to acknowledge the filing of a lawsuit via post or by the clerk of the court. After confirmation of the defendant's acknowledgement is submitted in the court's files, the defendant has a 15 business-day deadline to present its defence, under penalty of default. After that, the plaintiff will be summoned to submit its response to the defence within the same deadline, and the judge will establish the controversial aspects of the lawsuit to be analysed, appointing the court's expert who will be responsible for analysing the technical aspects of the lawsuit (the patent infringement or the invalidity), and preparing the technical report. Once the technical report is submitted in the court's files, the parties have a common 15 business-day deadline to present their divergent/convergent opinions and the court expert may be summoned to present potential clarifications or amendments to their report. After the conclusion of the technical evidence phase, the judge understands that the lawsuit is sufficiently developed to be judged, but there is no binding deadline for the rendering of the decision on the merits.

Based on recent case law, it is possible to affirm that once the technical evidence phase is concluded, a decision on the merits may take approximately two to six months to be rendered.

1.6 Requirements to Bring Infringement Action

According to a recent decision from the STJ, an infringement action can only be filed once the patent has been granted, since it is the registration itself that guarantees its owner the right to prevent a third party from producing, using, offering for sale or importing the patented product without consent, as set forth in Article 42 of the Brazilian Industrial Property Act. The reason for this is that, before the patent application is granted, it only exists as a mere expectation of rights, as there is no way of ensuring that the patent application will definitely be granted. Thus, although Article 44 of the Brazilian Industrial Property Act sets forth that compensation may be claimed by the patentee, including in the period between the date of publication of the application and the date the patent is granted, the procedural interest will only exist once the BPTO renders an administrative act effectively granting the patent.

1.7 Pre-Action Discovery/Disclosure

The Brazilian Code of Civil Procedure does not foresee pre-action discovery/disclosure.

However, according to Article 396 of the Code, the judge may order the parties to disclose documents and evidence. If a party refuses to comply with the exhibition order without an acceptable reason, a search and seizure order can be issued.

There is no US-style discovery in Brazil. In other words, the parties have no right to seek documents from the other side before trial. The evidentiary phase is judge-oriented, as judges have discretion to order the production of any evidence that they deem appropriate, or deny that which they consider irrelevant to the case.

1.8 Search and Seizure Orders

Search and seizure may be among the requests made by the plaintiff in an infringement action. A patentee can request such order on a preliminary injunction basis, to be corroborated on the merits, with the aim of stopping continuation of the infringing practices by the defendant.

1.9 Declaratory Relief

Declaratory actions are available in the Brazilian legal system, according to Articles 19 and 20 of the Brazilian Code of Civil Procedure. Such proceedings are appropriate whenever the plaintiff aims to dispel doubts and solve disagreements about the existence, non-existence and way of being of a legal relationship. Thus, declarations of infringement or non-infringement may be questioned by plaintiffs and granted by the Brazilian state courts.

1.10 Doctrine of Equivalents

The doctrine of equivalents (DOE) is applicable in Brazil according to Article 186 of the Brazilian Industrial Property Act. Although the law does not set forth any statutory standards to assess DOE, discussions in lawsuits in Brazil tend to rely on the tripartite equivalence test, inspired by the international doctrine.

1.11 Clearing the Way

There is no obligation established by Brazilian regulations to “clear the way” ahead of a new product launch. However, it is strongly advisable to perform a freedom-to-operate (FTO) analysis before starting any developments on a new product. Failure to clear the

way could pose a high risk to the company, since the existence of a patent covering the product intended to be launched could lead to time and financial investment loss, not to mention the potential risk of an infringement lawsuit.

1.12 Experts

According to Article 464 of the Brazilian Code of Civil Procedure, a court expert will be appointed by the judge whenever proof of the facts alleged by the plaintiff depend on special technical knowledge. Thus, given the technical complexity of patent infringement and nullity actions, the production of technical evidence by an unbiased expert appointed by the judge is mandatory, as the judge only has knowledge about legal issues. Such nomination usually happens after the plaintiff's response to the defendant's defence brief, once the judge has established the controversial points of the lawsuit that need to be analysed. The parties then appoint their own technical assistants who will be able to communicate with the court expert, and prepare queries to be answered by the expert during the technical evidence phase/final report.

It is worth mentioning that parties can challenge the nomination of the court expert if there is lack of proof that the professional is a skilled person in the patent's technology field or that the professional has industrial property knowledge. The specialisation of the court expert is therefore a relevant aspect to be double-checked by the parties, since it directly impacts the quality of the technical report that will be issued, and also impacts on the quality and fairness of the trial, as most judges tend to follow the technical report's conclusion, not having sufficient technical knowledge to assess the technology involved themselves. However, it is important to mention that judges are not bound by an expert's conclusion and can adopt a different position from the technical report, as long as such decision is well grounded.

1.13 Use of Experiments

In infringement actions, should a patent cover a method or a process, the burden of proof is on the defendant, according to the terms of Article 42, § 2o of the Brazilian Industrial Property Act. In this sense, it is the defendant (ie, the alleged infringer) who must prove that the method used by them is different from the one patented. Such proof must first be attested in the defence brief, and can be corroborated by a technical assistant hired by the party, or by a specific employee of the defendant's company. Once the defendant provides the court with the necessary proof, the unbiased expert appointed by the court will be responsible for analysing, during the technical evidence phase, the patented method versus the method allegedly used by the defendant. Where necessary, the expert may reproduce, through an experiment in a laboratory, the alleged method used by the counterparty, in order to attest not only to the potential differences between the methods, but also, whether the defendant's method is really effective.

1.14 Discovery/Disclosure

See **1.7 Pre-Action Discovery/Disclosure**.

1.15 Defences and Exceptions to Patent Infringement

Prosecution history estoppel, references from the state of the art, and Bolar exemption, and most recently invalidity arguments (see **1.4 Structure of Main Proceedings on Infringement/Validity**) are common defence strategies used by defendants accused of equivalence infringement or literal infringement. The disclosure-dedication doctrine can also be used as defence to the doctrine of equivalents, although the Brazilian system has not adopted such designations directly in the Brazilian Industrial Property Act.

1.16 Stays and Relevance of Parallel Proceedings

See “Staying of the Infringement Proceeding” in **1.4 Structure of Main Proceedings on Infringement/Validity**.

1.17 Patent Amendment

It is possible for a patent to be declared partially invalid with respect to a specific claim, during litigation. When this happens, the trial court decision should also be considered part of the letter patent, as the BPTO will not issue a new letter patent and there are no provisions binding the BPTO to do so.

As to actions that challenge the rejection of patent applications, seeking for them to be granted in the judicial sphere, recent Brazilian case law has admitted the amendment of a set of claims as long as this is to restrict and limit it, according to Article 32 of the Brazilian Industrial Property Act.

1.18 Court Arbiter

Regarding infringement actions, the São Paulo and Rio de Janeiro state courts are the main courts when it comes to IP matters, as both have specialised judges. However, in order to file this type of action in one of them, the plaintiff must demonstrate that it has its headquarters in one of these cities, or that the infringement practice has occurred in one of these jurisdictions, since this is a prerequisite set forth by Article 53, V of the Brazilian Code of Civil Procedure. Regarding nullity actions, Article 57 of the Brazilian Industrial Property Act requires these to be filed in a federal court – and the Rio de Janeiro court is the major one with specialised judges in IP matters, since the BPTO headquarters are located in the city.

2. Generic Market Entry

2.1 Infringing Acts

The Brazilian IP Law confers the right to prevent third parties that do not have consent from manufacturing, using, offering for sale, selling or importing for such purposes:

- a product that is the subject of a patent; and/or
- a process, or product directly obtained by a patented process.

The patentee is further guaranteed the right to prevent third parties from contributing to other parties’ infringement acts.

Although marketing authorisation applications or grants are usually seen as allowed pre-launch activities, applications for reimbursement, pricing or listing, submissions or awards of tender, and offers to supply after patent term expiry, are subject to an infringement lawsuit.

Special attention is directed to marketing authorisations granted way before the patent expiry, since the regulatory framework requires the renewal of the commercialisation of the object of the authorisation within the final two thirds of the final term.

The parallel importation of a product that is covered by a patent, or that is obtained by means or processes patented in Brazil for commercial purposes, is also subject to an infringement lawsuit, if the product has not been placed on the external market directly by the owner or with the owner’s consent.

As to the skinny label, the rules in Brazil changed in December 2023 when the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, or Anvisa) issued a resolution which allows a patented indication to be carved out of a generic leaflet.

2.2 Regulatory Data and Market Exclusivity

In terms of patent protection, there is no provision for any market exclusivity extension related to orphan, paediatric, new indications, combinations, reclassifications, etc. A patent is valid for 20 years, counted from the filing date, with no possible term adjustment.

However, in view of a Supreme Court decision, which declared the ten-year validity rule of patents unconstitutional, some patentees are filing lawsuits requesting patent term adjustments based on the unjustified delay of the BPTO in the analysis of patent applications, on a case-by-case basis. Said court actions are new and, for now, it is not possible to predict how they are going to evolve and what their outcomes will be, since there is no case law available to support this new legal thesis.

2.3 Acceptable Pre-Launch Preparations

Generics are allowed to request the marketing authorisation of a product and to perform any experimental activities with the aim of having the data required for the marketing authorisation request (Bolar exemption).

The patentee has the right to prevent third parties that do not have consent from producing, using, offering for sale, selling, importing for these purposes, or contributing to such practices, a patented product, process or product obtained directly by a patented process.

However, Article 43, VII of the Brazilian Industrial Property Act expressly provides exceptions to patent protection – among them, acts carried out by unauthorised third parties, related to an invention protected by a patent, which aim to obtain a marketing registration in Brazil, or in another country, for the exploitation and marketing of the product that is the subject of the patent, after the expiry of the patent term. The usefulness of the Bolar exemption is justified by the extensive and excessive bureaucracy of regulatory agencies, including the Brazilian agency Anvisa for medicines in Brazil, which can take years to authorise the marketing of new medicines.

2.4 Publicly Available Drug and Patent Information

There is no Orange Book equivalent in Brazil. Marketing authorisations (MAs) are granted by Anvisa and the grant is noted in the national Official Gazette, which should be monitored, since the holder of the MA for the reference product is not notified of any generic or bio-similar marketing authorisation applications (MAAs) or granted MAs.

On 13 August 2024, the First Panel of the STJ ruled that Anvisa does not have the legal authority to impose restrictions on drug advertising. According to the court, the regulatory agency lacks the authority to create rules that exceed the provisions of Law 9.294/1996, which regulates the advertising of pharmaceutical and related products.

The agency appealed to the STJ, arguing that its regulatory role is legitimate and essential to public health, emphasising that it is responsible for establishing regulations and for proposing, monitoring and implementing policies, guidelines and actions within its scope of competence, in addition to controlling and supervising the advertising of products under this regulatory regime.

According to the STJ decision, although the regulatory agency has general authorisation to issue regulations that ensure the fulfilment of its duties, specifically with regard to the advertising of products under sanitary control, this competence is restricted, as

defined in Article 7, item XXVI of Law 9.782/1999, which stipulates that Anvisa's actions concerning medicines must comply with current legislation.

According to the judges, advertising restrictions for medicines are established by Law 9.294/1996, supplemented by Decree 2.018/1996, and have immediate application, being mandatory for all, including public administration. However, the ruling stated that RDC 96/2008 contains several provisions that exceed the limits set by Law 9.294/1996. Among them are the prohibition of indirect advertising at events and in movies; restrictions on advertisements showing people using medicines, especially if suggesting pleasant qualities such as taste; the requirement for warnings about substances that may cause sedation or drowsiness; and restriction of the use of certain expressions in the advertising of over-the-counter medicines.

Thus, it was considered that Anvisa had exceeded its regulatory authority, creating obligations for private parties, which exceeds its role of merely overseeing, monitoring and controlling advertising practices. With this understanding, the STJ suspended Anvisa's resolution on advertising and denied the special appeal.

Despite the above decision, which emphasised that Anvisa does not have the authority to create rules that exceed the provisions of Law 9.294/1996, medicines and pharmaceutical products are health-related goods, not merely consumer products. Therefore, their advertising remains subject to all other applicable regulations in Brazil.

Among these regulations is self-regulation conducted by CONAR – the National Council for Advertising Self-Regulation. Unlike Anvisa's rules and the previously mentioned laws, CONAR establishes ethical guidelines of a consultative nature and, when called upon, issues decisions that lack coercive force, but which are usually followed by advertisers. It has a significant impact on corporate behaviour and advertising regulation in Brazil, ensuring that information in advertisements is truthful and honest, and does not mislead consumers.

In Brazil, it is still Anvisa's duty, however, to ensure that medical and pharmaceutical products available on the Brazilian market comply with public health standards, are safe and effective, and contribute to the health and well-being of the population.

2.5 Reimbursement and Pricing/Linkage Markets

The Medicines Market Regulation Chamber (*Câmara de Regulação do Mercado de Medicamentos*, or CMED) acts as an inter-ministerial body overseeing the economic regulation of Brazil's pharmaceutical market, with Anvisa serving as the executive secretariat of said chamber.

CMED sets price limits for drugs, implements rules that maintain a competitive field, monitors sales, and enforces penalties for rule violations.

The primary regulatory framework governing medicine pricing is CMED Resolution No 02/2004. This resolution categorises medicines into six pricing categories, in addition to omitted cases not foreseen by the regulations, which are resolved by the CMED Executive Technical Committee (CTE).

For generic medicines, pricing adheres to the guidelines outlined in Article 3, VI, combined with Article 12 of CMED Resolution No 02/2004. These generic medicines fall under Category VI, which specifies that their price cannot exceed the maximum limit of 65% of the corresponding reference medicine's price.

3. Biosimilar Market Entry

3.1 Infringing Acts

Litigation concerning biologics or bio-similar patents remains the same as in **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

For data and regulatory exclusivity concerning biologics and bio-similars, see **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-Launch Preparations

Litigation concerning biologics or bio-similars remains the same as in **2.3 Acceptable Pre-Launch Preparations**.

3.4 Publicly Available Drug and Patent Information

Litigation concerning biologics or bio-similars remains the same as in **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets

Litigation concerning biologics or bio-similars remains the same as in **2.5 Reimbursement and Pricing/Linkage Markets**.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Initially, it is important to highlight that patent term adjustments (PTAs) or supplementary protection certificates (SPCs) are not available in Brazil, nor are they the subject of any formal legal provision.

However, in view of a Supreme Court decision issued in May 2021 (lawsuit ADI No 5529/DF), stating the unconstitutionality of the sole paragraph of Article 40 of the Industrial Property Act and abolishing the ten-year minimum validity term for patents for inventions and the seven-year minimum validity term for utility models, patentees are filing lawsuits in Brazil requesting PTAs based on the unjustified delay of the BPTO in the analysis of patent applications, on a case-by-case basis. Therefore, it is not up to the BPTO to decide a possible patent term adjustment. Rather, this discussion is being addressed in the federal courts, with the BPTO figuring as a defendant.

Such lawsuits are new and, for now, it is not possible to predict how they are going to evolve, what their outcome will be, and how long it will take to reach a final decision. It is also not possible to answer questions regarding eligibility criteria and/or provide information regarding the calculation of the duration of adjustments.

At present, there are approximately 60 lawsuits requesting a PTA before the Brasília Federal Court, and most of these have the same goal: seeking a PTA, based on an excerpt from a decision by the Honourable Judge Dias Toffoli, who quoted the PTA expression as an institute of other countries, which, in theory, allows the extension of the patent validity term.

Most of the decisions already issued are preliminary injunction decisions that do not have the purpose of effectively extending the patent term in a definitive way, but rather, that have the purpose of suspending the patent expiry date, until a decision is made on the merits of the matter (all of them still pending).

The movement to file lawsuits seeking patent validity adjustment began in the second half of 2021. All patents subject to these lawsuits refer to technologies in the pharmaceutical area. Up until April 2024, a total of 62 lawsuits had been filed seeking compensation for the term, due to unjustified delays on the part of the BPTO. These lawsuits have been filed before the federal courts, in the court of the Judicial Section of Brasília, the federal capital.

The unanimous choice of the Brasília court implies a significant impact on case law regarding PTAs, since all first-instance decisions will emanate from the Brasília court and the respective appeals will be heard by the Federal Regional Court of the First Circuit (TRF-1). By concentrating such lawsuits in a single court, the expected effect is the consolidation of the TRF-1 as a paradigmatic instance in which Brazilian precedents on the subject will be issued, at least for now.

Among the 62 actions filed, several bring claims for preliminary relief in the first instance (either with the initial brief or incidentally), that is, it is requested that the final provision (compensation for the patent term) be granted provisionally, based on Article 300, caput, of the current Code of Civil Procedure.

Among the 24 preliminary injunction claims, there are more rejections than grants of preliminary relief when analysing the decisions handed down with regard to requests for preliminary injunctions.

Regarding the merits of these lawsuits, all the judgments handed down in 2024 have dismissed requests for a patent adjustment term. The reasons behind such conclusions are similar to the arguments accepted for the denial of the preliminary injunctions. In particular, four key points have grounded the dismissal of the requests:

- the adjustment of the deadline would go against the unconstitutionality decision handed down by the STF in ADI 5529;
- the adjustment of the patent term depends on there being prior legislative activity expressly authorising this;
- by virtue of Article 44 of the LPI, companies could benefit from the lengthy patent examination; and
- social interest should guide the patent protection system and society would be harmed by the prolonged validity of pharmaceutical patents.

The only judgment that does not mention such arguments (Case No 1074941-83.2021.4.01.3400) is based exclusively on the application of the statute of limitations of the claim filed.

Therefore, it is clear that judges are hesitant to address the issue without clearer instructions from the higher courts on the admissibility of the case-by-case adjustment in view of the understanding established at the time of ADI 5529.

As a direct result of the decisions of dismissal in the first instance, appeals have been filed and it is expected that the position of the TRF-1 in the appeals stage will shape the near future of PTA actions in Brazil.

4.2 Paediatric Extensions

In Brazil, there is no division in PTA lawsuits based on a certain field of medical specialisation, nor any provision of extension based on special groups of patients or diseases.

4.3 Paediatric-Use Marketing Authorisations

See **4.2 Paediatric Extensions**.

4.4 Orphan Medicines Extensions

See **4.2 Paediatric Extensions**.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

The Brazilian legal system does not differentiate between injunctions in the area of life sciences from others aimed at other technologies, as they are treated as a whole within the industrial property law and also by the Brazilian Code of Civil Procedure. The general rules for granting injunctions in patent matters are set out in Article 209, §1 of the Industrial Property Law.

Provisional Order of Suspension

According to Article 209, Section 1o of the Brazilian Industrial Property Act, the judge may, during the course of proceedings and in order to avoid damage that is irreparable or difficult to repair, provisionally order the suspension of the violation, or of the act that gives rise to it, prior to summoning the defendant, and where necessary, order the posting of a cash bond or a bank guarantee.

In other words, the judge may request a guarantee from the patentee for granting an injunction based on the judge's sole discretion. There are many situations in which this payment is not required from the patentee, as the conditions for granting injunctions are the following: (i) likelihood of the plaintiff arguments; and (ii) risk of irreparable harm.

If the guaranteed bond is ordered by the court, however, it must remain in effect until the conclusion of the lawsuit, at least until the judgment on the merits is issued. If the plaintiff's arguments are accepted in the final decision, the security deposit can be claimed by the plaintiff.

In Brazil, there are no regulatory authorities that participate in this guarantee which, when due, will be charged solely to the patentee.

Preliminary Injunction

A preliminary injunction is enforceable from the day the defendant is informed about it by service. The parameters and enforceability terms of preliminary injunctions may vary, however, depending on the judge's decision. The timing for service will depend on the court's office backlog, as a writ of summons needs to be issued and addressed by registered mail to the defendant or handed in by the clerk of the court, which are the two possibilities of service, according to the Brazilian Code of Civil Procedure.

Preliminary injunctions remain in effect while the lawsuit is pending but may be revoked or modified at any time. Except for very specific situations, a preliminary injunction remains in effect during the period in which proceedings are stayed (Section 296 of the Brazilian Code of Civil Procedure).

The judge may order the measures deemed necessary to enforce a preliminary injunction and such parameters may vary depending on the case (Section 297 of the Brazilian Code of Civil Procedure).

If requested by the judge, the patentee may have to pay a bond before the preliminary injunction is enforceable and such amount will depend on the amount in dispute, to be set at the judge's sole discretion.

A preliminary injunction is also called a “provisional remedy” and may be based on urgency or evidence. A provisional remedy based on urgency, of a preventative nature or as a preliminary satisfaction of judgment, may be granted prior to the filing of the claim, or incidentally.

Most preliminary injunctions claimed in patent infringement cases are requested with the infringement or nullity lawsuits, and are therefore part of the claims and not part of another lawsuit.

An interlocutory appeal may be filed against the decision granting the preliminary injunction/provisional remedy within 15 days from the confirmation of the defendant’s summoning. It must be addressed to the Court of Appeals.

5.2 Final Injunctive Relief

Confirmation or Revocation of Preliminary Injunction

After the issuance of a final decision on the merits, the preliminary injunction can be confirmed or revoked. Where it is confirmed, it will be transformed from a preliminary injunction to a definite injunction or relief. From the publication of the decision on the day of service, the parties can file an appeal addressed to the Court of Appeals within 15 business days. The appeal filed against the final judgment will suspend the proceedings and the effects of the decision. However, a judgment will be enforced immediately after its publication when it confirms, grants or revokes a preliminary injunction, according to Article 1012, § 1o. V of the Brazilian Code of Civil Procedure.

There are two possibilities of enforcement: final, when the decision is no longer appealable; or definite or provisional, when the decision is being discussed on the appeal level.

Patent Infringement – Cease or Pay

Regarding patent infringement cases, there are generally two provisions in the decision to be enforced – the obligation to cease the infringement and to pay losses and damages. Regarding the cease-of-use order, the enforcement of the decision will be established by the judge, who will set the measures required for the accomplishment of the obligation, in order to fulfil the specific remedy or to obtain relief from the equivalent result. Among the measures established for enforcement, the judge may set a daily fine, search and seizure, and if necessary, request the support of police authorities. When it comes to losses and damages, these are assessed during the quantification phase and a professional accountant will be appointed to calculate the final amount due, as explained in **5.4 Damages**.

Appeal Process

A patentee does not need to pay a bond before a final injunction is enforceable, but where the plaintiff chooses to have provisional enforcement of the judgment (while it is subject to appeal), it will be the plaintiff’s responsibility to compensate any losses incurred by the judgment debtor should the judgment be reversed, according to Article 510, I of the Brazilian Code of Civil Procedure.

In Brazil, all appeals will stay the final injunction, unless the preliminary injunction is confirmed in the decision by the trial court judge. In this case, the effects are immediate. However, it is possible to ask for an injunction in the appeal requesting the suspension of the final ruling, as long as the appellant proves the probability of the appeal being granted, or if there are considerable grounds to believe there is a risk of

serious damage or harm that cannot be overcome. The possibilities of obtaining such stay will depend on the evidence the appellant provides in filing a precautionary measure at the Court of Appeals.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The court has the discretion to revert any obligation into losses and damages in Brazil. For instance, if the defendant is ordered to cease an infringement under a daily penalty and does not comply with the order, the judge can increase the daily penalty or even order the pledging of an asset or of a current account. Judges can reduce the final amount due based on the reasonability and proportionality of the matter discussed.

5.4 Damages

The Lawsuit

Under Brazilian law, the injured party in a patent infringement lawsuit can request compensatory damages in addition to obtaining a court order that the infringing practice be ceased. Such damages can be divided into two main categories: (i) moral damages; and (ii) material damages, which include actual damages and the loss of profit.

For moral damages, the courts will assess the amount to be granted to the injured party on a case-by-case basis, depending on the financial situation of each party, and reasonableness and proportionality in relation to the injury.

In terms of material damages, compensation has the purpose of restoring the status of the injured party to what it was prior to the violation. Brazilian law does not provide for punitive damages.

Under Section 210 of the Brazilian Industrial Property Act, a patentee or exclusive licensee can file a civil complaint to cease the infringement and request compensation for its losses.

The damages (ie, loss of profits) will be calculated based on criteria most favourable to the injured party, considering the following:

- the benefits that would have been gained by the injured party if the violation had not occurred;
- the benefits gained by the infringer of the rights; and
- the remuneration that the infringer would have paid to the right's holder for the granting of a licence that would have legally permitted the infringer to exploit the subject's rights.

The Quantification Phase

It is important to keep in mind, however, that the quantification phase in Brazil is a separate proceeding, started only after the trial court has already rendered a merits decision on the infringement and generally, after the decision is no longer appealable. Moral damages (if applicable) will be fixed in the trial court decision.

After the quantification phase is started by the plaintiff, the judge will appoint an unbiased expert accountant with the task of examining the accounting information provided by the parties, in order to decide on the final figures of material damages. Thereafter, the parties can nominate their own accounting assistants, and each will submit queries to the expert.

The expert analysis is comprised of a report with the answers to the queries, and the final amount of damages due on the grounds of the merits decision. The parties can challenge both the report and the trial court decision confirming the expert's assessments, through an interlocutory appeal.

This means that the quantification phase can take significant time, but by having the constitutional right to challenge the arguments/evidence of all the parties involved in the dispute, the parties are guaranteed that the due process of law is being applied at all stages of the dispute.

Decisions of the São Paulo State Court

Common questions relate to how much is recoverable in damages, under which parameters, and how long it will take to receive the amount related to a damages award. Based on case law analysis, the decisions rendered by the São Paulo Court of Appeals have been setting the tone.

Infringement lawsuits need to be filed with the state courts. The São Paulo State Court receives many disputes, since most major companies are established in the State of São Paulo, which has IP-specialised judges and chambers that frequently address the applicability of Section 210 of the Brazilian Industrial Property Act.

On the grounds of the parameters established in Section 210, the expert will calculate the damages, using the criteria most favourable to the injured party. In this sense, the São Paulo Court of Appeals considers that, for the purpose of quantification, the net value of the infringing products will guide the expert in determining the damages.

Although the quantification phase can be quite lengthy, the IP holder can expect that, in Brazil, material damages related to infringement of industrial property rights are due regardless of proof of actual loss, and that once the infringement is attested, damages will follow.

5.5 Legal Costs

The applicable law for legal costs recovery is the Brazilian Code of Civil Procedure.

According to Section 82 of the Code, the losing party must reimburse the legal and procedural fees which were paid in advance on the lawsuit. With the exception of free legal aid, parties are responsible for bearing the expenses of the acts they perform or request in the proceedings, paying them in advance, from the start until the final judgment or, during its enforcement, until there is full satisfaction of the right recognised in the instrument.

Section 1 – The plaintiff must advance the expenses relative to the act which the judge determines, ex officio or at the request of the public prosecutor's office, when the latter intervenes as guardian of the law.

Section 2 – The decision on the merits will require the losing party to reimburse the successful party for the expenses advanced.

The legal fees are the expenses with court fees (such as those which must be paid when the lawsuit is filed, as well as some types of appeal) and the procedural fees include the amount expended by the successful party on technical assistance, travel expenses, witness travel allowance, and court expert fees, all in accordance with Section 84 of the Code.

The losing party must pay the counterparty's (successful litigant's) attorney's fees, which may vary from 10% up to 20% of the value of the claim, as per Section 85 of the Code, which sets forth that the decision on the merits will order the losing party to pay the fees of the successful party's counsel.

However, attorney's fees set by the judge to be reimbursed are unrelated to the attorney's fees paid by the parties during the lawsuit. This amount set by the judge is based upon a percentage over the value of the claim, and goes strictly to the successful party's attorneys, as a type of "award" for the victory.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

Shame litigation can be addressed to the Brazilian Economic Defence Council (*Conselho Administrativo de Defesa Econômica*, or CADE) through a very specific proceeding, and judges can also apply bad-faith litigation fines, based on a percentage of the amount in dispute.

6. Other IP Rights

6.1 Trade Marks

Trade mark and trade dress disputes in the life sciences and pharma sector are common before the Brazilian courts, either in infringement or nullity actions. When it comes to trade marks, in the administrative sphere, Anvisa exercises an additional barrier to registration, specifically aimed at analysis of the graphic and phonetic distinctiveness regarding other pharma products, regardless of the examination process by the BPTO. The reason for this is the public agency's concern about preventing confusion among consumers between products/drugs aimed at different treatments. In this sense, Anvisa has established some resolutions, in addition to Law 6.360/76, to prevent the adoption of names, designations, labels or packages that may cause error, confusion or undue association among consumers.

For instance, Orientation No 43/2017 of Anvisa establishes the complementary details to guide the agency when evaluating and deciding on third party's requests to register the name of a certain drug. Among other things, an analysis to decide on the approval of the name of a drug product must include research of Anvisa's and the BPTO's databases, evaluation of graphic and phonetic resemblances, assessment of potential errors, assessment of the safety of the proposed name, based on assumptions of risk of error in cases of prescriptions, dispensing and/or administration or use.

In the pharma and life sciences field, the judges tend to be extra-careful in court discussions about trade marks and trade dress which are possibly confusingly similar to a third party's prior-registered trade marks or trade dress, as the case concerns human health.

6.2 Copyright

Copyright disputes in the life sciences and pharma sector are not common in Brazil.

6.3 Trade Secrets

In Brazil, life sciences and pharma cases fall under the data package discussion on the grounds of unfair competition practices.

According to Article 195, XIV of the Brazilian Industrial Property Act, a crime of unfair competition is perpetrated by anyone who divulges, exploits or utilises, without authorisation, results of tests or other undisclosed data, the preparation of which

involved considerable effort and was submitted to government agencies as a condition for obtaining approval to commercialise products.

7. Appeal

7.1 Timeframe to Appeal Decision

Regarding the Preliminary Injunction

After the trial court decision is published, the parties that do not agree with it can file a motion for clarification within five days in order to challenge omissions, contradictions, obscurities and oversights. From the motion for clarification decision, the parties will have 15 days to file an interlocutory appeal and it is possible to claim an injunction to suspend the preliminary injunction decision. The interlocutory appeal will be addressed to a rapporteur judge who will analyse the injunction claim and serve the counterparty to respond to the appeal within 15 days. Generally, it will take a couple of months to have the judgment session, which is not a hearing, but the attorneys will be able to present oral arguments before the panel as a preliminary injunction discussion allows such oral debates. It is possible to re-analyse the trial court decision and for the matter to be considered de novo. Once the panel has issued the vote, the decision will be published and the parties can file motions for clarification within five days of the publication and/or file special appeals to the Superior Court of Justice questioning the applicability of the federal law. If constitutional matters are involved, it is possible to offer an extraordinary appeal to the Supreme Court. However, this is unusual for patent matters.

First Instance Main Action Decision for Infringement and Nullity Actions

The timing to file an appeal against a first instance main action decision is 15 days from date of publication onwards. It is also possible to question the decision by filing a motion for clarification. The timing in a main action appeal judgment session will depend on the court's backlog, but it can take one to two years for a final judgment. Once the Court of Appeals schedules the judgment session, the parties prepare summary briefs to be personally discussed with the judges designated for the judgment and to present oral arguments in the judgment session. The judgment session will be before a panel of three judges.

The decision can be unanimous, or not. In the case of 2:1 votes, an extended session will be scheduled and two other judges will join the panel, so that there is a casting vote.

Once the panel has issued the vote, the decision will be published and the parties can file a motion for clarification within five days of the publication and/or file a special appeal to the Superior Court of Justice questioning the applicability of the federal law. In the case of constitutional matters, it is possible to offer an extraordinary appeal to the Supreme Court. However, for patent matters, this would be quite unusual.

If a preliminary injunction or final injunction decision is overturned on appeal or the patent is revoked, the preliminary injunction will not automatically be lifted and the interested party must submit a brief asking for it to be lifted/revoked. An interested party might evaluate the best strategic moment to submit a brief, but this can be done at any time before the judge who first issued the injunction.

7.2 Appeal Court(s) Arbiter

Infringement matters are discussed in state courts and the final decision is appealable to the correspondent State Court of Appeals. Nullity lawsuits are discussed in federal courts and the final decision is appealable to the Federal Circuit of Appeal, which can cover more than one state. In both cases, the appeal is addressed to a panel of three judges but a rapporteur judge will be in charge of receiving the appeal, analysing a potential injunction claim and re-preparing the main vote that will be presented in the judgment session. The decision can be unanimous, or not. In the case of 2:1 votes, an extended session will be scheduled and two other judges will join the panel, so that there is a casting vote.

7.3 Special Provisions

IP lawsuits, including those for life sciences and pharma, are subject to civil and criminal proceedings that are guided by the Civil and Criminal Proceeding Codes. There are some specific rules in the Industrial Property Act, Federal Law No 9279/96, that discuss injunctions, bonds and damages criteria, but such provisions are all grounded on the general legal system applied to all types of lawsuits.

8. Other Relevant Forums/Procedures

8.1 The UPC or Other Forums

Officials using anti-counterfeiting measures at customs in ports and airports in Brazil will generally contact the patentee to take suitable legal measures when there is a notice of infringement.

9. Alternative Dispute Resolution

9.1 ADR Options

Arbitration, conciliation and mediation are all available in Brazil. However, patentees in life sciences disputes do not use these ADR options, preferring to address the discussion in a lawsuit where the ordinary provisions of injunction and damages will apply.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

Settlements are available and are used by the parties in both judicial and ADR options, especially in cases where the trial is slow and/or the costs of litigating are high.

11. Collective Redress

11.1 Group Claims

Both collective redress and group claims are available in Brazil for life sciences-related actions. They are mostly used in cases involving consumer protection, public health issues, defective medical products, or environmental harm caused by the life sciences industry. The Brazilian legal system allows for these collective legal actions to be pursued by public entities, consumer organisations and other representatives to protect the rights of affected individuals or groups.

Collective Redress in Life Sciences Legal Actions

In Brazil, public civil actions are a key tool for collective redress and can be used in life sciences cases. For example, public health-related lawsuits, such as those involving defective medical products, dangerous pharmaceuticals, or environmental harm caused

by the pharmaceutical or biotechnology industries, can be pursued under this legal framework.

These actions can be initiated by public entities like the public prosecutor's office, regulatory agencies (eg, Anvisa), or accredited civil society organisations. Public civil actions aim to protect collective rights, such as consumer rights, public health, or the environment.

Examples in the life sciences sector:

- claims related to the harmful side effects of drugs or medical devices;
- actions against healthcare providers for negligence or failure to provide appropriate care; and
- cases involving misleading advertising of health products or treatments.

Group Claims in Life Sciences Legal Actions

Group claims are also possible in Brazilian life sciences legal actions, typically when a group of individuals with similar legal interests are affected by the same or related issues.

Under the Consumer Protection Code (Law No 8,078/1990), collective actions can be filed by consumer protection organisations, public entities, or other representative bodies, particularly in cases where large groups of consumers or patients are harmed by defective products or services.

In the life sciences field, group claims could involve:

- patients who are harmed by unsafe or defective drugs or medical devices;
- large groups of consumers affected by misleading health claims or illegal marketing practices in the healthcare sector; or
- actions to protect the right to access healthcare services or medications that may be limited by discriminatory practices or failures by healthcare providers.

Specific Life Sciences-Related Laws and Protections

The Consumer Protection Code (Law No 8,078/1990) plays a significant role in group claims related to life sciences, as it ensures the protection of consumers' rights, including access to safe and effective medical products and services.

Anvisa also has a key role in regulating medical products, and regulatory failures or violations could trigger collective legal actions.

Other related legal frameworks, such as laws regarding environmental protection, data protection and public health, can also provide avenues for collective or group claims in life sciences cases.

Montaury Pimenta, Machado & Vieira de Mello

Av. Almirante Barroso, 139-7th Floor
Rio de Janeiro
ZIP 20.031-005
Brazil

+55 21 2524 0510

montaury@montaury.com.br
(mailto:montaury@montaury.com.br) www.montaury.com.br