1. The provision of marketing literature and/or advertising material;
2. The provision of demonstration articles;
3. The provision of sales training to the subsidiary’s staff;
4. Involvement of the parent company’s employees in the marketing and selling of the infringing article;
5. Research and development of the infringing article being carried out by the parent for the benefit of the subsidiary;
6. The provision of technical and engineering support to the subsidiary’s customers; and/or
7. Replacement parts being ordered directly from the parent.

II. Brazil

A. Introduction
In Brazil, pharmaceuticals are governed by a comprehensive and complex regime of legislation and regulations spanning many different areas of law. The legislative and regulatory landscapes are also very dynamic, as patent laws are constantly under review and government authorities constantly update regulatory processes and policies.

In the Brazilian health regulatory system, introduced by Act No. 6.360/76, any drug may be marketed only if it has been previously registered with the pertinent authority of the Ministry of Health; such competence was attributed to Brazilian Agency of Sanitary Surveillance (ANVISA) by Law No. 9.782/99. The Brazilian patent system is overseen by the Brazilian Patent Office, created by Federal Law No. 5.648/70, and its authority is defined by Brazilian Industrial Property Law No. 9.279/96.

This chapter provides an overview of each element in this complex Brazilian regime together with insights into the issues that might arise and how they might be navigated.

B. Patent Portfolio

1. Patentable Subject Matter in the Pharmaceutical Sector
Article 10, sections VIII and IX of Brazilian Industrial Property Law No. 9.279/96 establishes a prohibition on the patenting of (1) operational or surgical techniques, as well as therapeutic or diagnostic methods for use on the human or animal body; and (2) natural living beings, in whole or in part, biological material including the genome or germ plasm of any
natural living being when found in nature or isolated therefrom, and natural biological processes.

There are three major types of pharmaceutical patents: compound patents, which protect the active ingredient; formulation patents, which cover the drug composition; and process patents, which protect the drug manufacturing process.

When a pharmaceutical patent application is directed toward “strategically important drugs and therapeutic destinations within the Brazilian Universal Healthcare System” as listed by the Ministry of Health, the patent is subject to the prior consent of ANVISA. If this occurs, acceptable patentable matter may be questioned and prior consent may be denied.

In these circumstances, the rejection of a patent application is grounded on an opinion that Swiss-type, second-use, polymorph, and selection patents present a health risk by creating barriers to the entry of generic drugs and thus compromising the Brazilian Universal Healthcare System (SUS).


The granting of patent applications for pharmaceutical processes and products requires prior consent from ANVISA.\(^{28}\)

Resolution RDC 21/2013, which altered Resolution RDC 45/2008, regulates ANVISA’s prior consent of pharmaceutical process and product patent applications. This resolution is the result of a public consultation\(^ {29}\) issued by ANVISA.

As established in Resolution RDC 21/2013, ANVISA will not grant prior consent for pharmaceutical process or product patent applications when the applications contain a prohibited substance.\(^ {30}\) Furthermore, if the subject of the patent application is listed as a strategic drug for the SUS in Ordinances GM/MS No. 978/2008, GM/MS No. 1284/2010, GM/MS 3089/2013, or GM/MS 2531/2014,\(^ {31}\) then ANVISA will review the patentability requirements according to Brazilian Intellectual Property Law.

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28. Article 229-C incorporated into the Brazilian Industrial Property Law by Brazilian Law No. 10,196/01.
29. Public Consultation 66/2012 by ANVISA and a meeting that was held by ANVISA on March 20, 2013.
31. These ordinances may be updated from time to time.
For example, any antiviral or antiretroviral drug will be subjected to a substantive patentability analysis before ANVISA, as antiretrovirals are a general category of drugs considered strategic under Ordinance 3089/2013. In summary, according to ANVISA’s resolution currently in force:

1. The prior consent for pharmaceutical patent applications relating to subject matter (i.e., drug substance) that represents a risk to human health will be denied;
2. Pharmaceutical patent applications related to a substance or a therapeutic destination considered strategic for the SUS will undergo a substantive patent analysis by ANVISA based on the provisions of Brazilian Intellectual Property Law; and
3. Any pharmaceutical patent applications not related to a substance, a prohibited substance, or a strategic therapeutic destination for the SUS will not undergo a substantive examination for patentability requirements by ANVISA.

Despite the fact that ANVISA analyzes patentability requirements when granting prior consent, patent holders who have had their applications denied because of unfavorable opinions from ANVISA on patentability criteria have been successful challenging these decisions before Brazilian courts.

The courts’ decisions are based on the roles of the Brazilian Patent and Trademark Office (BPTO) and ANVISA as stated in the laws that have created them, respectively Law No. 9,279/96 and Law No. 9,782/99. These laws describe very clearly that ANVISA’s goal is to secure the public’s health (e.g., by controlling and preventing diseases, among other similar tasks), while BPTO is assigned to the task of executing the provisions related to the industrial property (IP) rights in Brazil, such that BPTO examines the patentability criteria for all patent applications.

According to Brazilian courts, ANVISA is creating confusion between public health risk and public health policy by deciding to go beyond its assigned activities and starting to perform substantive patentability analysis.

In other words, by misinterpreting Article 229-C of the Brazilian Industrial Property Law (IPL), which foresees that ANVISA shall grant its prior approval before a pharmaceutical patent is granted, ANVISA issued Resolution 45/2008. This allowed ANVISA to analyze patentability

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32. These substances are listed on List F of Ordinance 344/1998 of the Brazilian Ministry of Health.
33. Ordinance 3089/2013, Brazilian Ministry of Health.
34. This analysis is a substantive examination of the requirements of patentability.
criteria rather than examining the application from the perspective of public health, which is illegal according to the most recent decisions issued by Brazilian courts.

C. Clinical Trials

1. Legal Framework

The legal framework concerning clinical trials in Brazil relates mainly, but not restrictively, to Resolution 466/2012 of the National Council of Health (CNS) and Resolution RDC 09/2015 of ANVISA.

Resolution 466/2012 of CNS establishes the guidelines for requiring ethical approval for conducting clinical trials. This legal framework emphasizes the main ethical aspects as well as the attributes of the Institutional Ethics Committee (CEP) and the National Commission for Ethics in Research (CONEP). It also lists the contents of informed consent forms, protocols, and brochures.

Resolution RDC 09/2015 of ANVISA describes the list of documents and procedures required for the regulatory approval of clinical research.

2. Regulatory Pathway for Conducting Clinical Trials in Brazil

Brazilian regulatory approval follows a sequential process in which the first step is the translation of the study and/or its submission into Portuguese.35

The first ethical approval must be released by the CEP of the coordinating site, and is also one of the requirements for submission to CONEP. All trials supported by foreign sponsors require an additional ethical approval from CONEP, whose responsibilities include developing regulations for the protection of subjects in clinical trials.

The coordination of the institutional CEP network by CONEP involves evaluating protocols relating to human genetics and reproduction, new drugs, procedures, devices, vaccines, and research that involves international cooperation. CONEP reviews the documentation from the coordinating site only. Once the approval is issued, it is extended to the other sites participating in the study.

Lastly, all clinical protocols carried out in Brazil must be approved by ANVISA. ANVISA is responsible for issuing the import license and the Special Communicate,36 as well as evaluating protocols with methodological issues and the relevance of data for future submissions.

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35. The documentation refers to the translated dossier, including the protocol, investigator brochure, informed consent form, and sponsor and institutional declarations, which are sent to each site’s Institutional Ethics Committee (CEP) for review.

36. The Special Communicate is the official approval document.
All therapeutic activities requested for the pharmaceutical product to be registered must be supported by clinical trial reports. Such clinical trials must be approved by the health authority of the country where the clinical trial was conducted. The clinical trials must also have been conducted with the finished pharmaceutical product presented for registration.

**D. Regulatory Submission of Drug Application**

In the Brazilian health regulatory system, Act No. 6.360/76 provides that a drug may only be marketed if it has been previously registered with the Ministry of Health:37

Article 12—No product to which this Act refer[s], including those which are imported, may be manufactured, marketed or released before registration with the Ministry of Health.38

The registration, or market approval, issued by ANVISA is the effective authorization for the manufacturing and marketing of a drug in Brazil. ANVISA issues market approval for the following kinds of drugs: (1) nonbiological drugs, which are divided into (a) reference drugs, (b) similar drugs, and (c) generic drugs; and (2) biological products, which are divided into (a) new biological products and (b) biological products; and (3) herbal medicines.

**1. Legal Framework**

There are three categories of market approval for nonbiological drugs: (1) reference drugs, (2) branded generic drugs, and (3) nonbranded generic drugs.

A reference drug39 is defined as an “innovative product registered with the federal authority responsible for health surveillance, and is marketed in the country in which its efficacy, safety, and quality were scientifically proven before the pertinent federal authority by the time of the registration.”40

A branded generic drug is one that “contains the same active ingredient(s), and has the same concentration, dosage form, administration route, dosage administration, and therapeutic recommendation as its equivalent drug registered with the federal authority responsible for the health surveillance. It may differ only in characteristics related to the product size and form, expiration term, packaging, labeling, excipients and vehicles, and it must always be identified by its trade name or brand.”41

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37. This requirement is pursuant to ANVISA Bylaw No. 9.782/99.
38. Act No. 6.360/76.
40. ANVISA Resolution RDC 60/2014.
41. Id.
A nonbranded generic drug is a “drug similar to a reference or innovative product, with which it is intended to be interchangeable, and is usually manufactured after the expiration, or waiver of patent protection or other exclusivity rights with proven efficacy, safety, and quality, and is assigned by DCB [Brazilian Common Denomination] (or INN [international nonproprietary name] when the first one is absent).” The similarity between the generic drug and reference drug is proven by results from pharmaceutical equivalence and bioavailability/bioequivalence studies.

Pharmaceutical equivalents are drugs that contain the same salt or ester of the same therapeutically active molecule in the same quantity and dosage form, which may or may not contain identical excipients. They must comply with the same updated specifications of the Brazilian Pharmacopoeia and, in their absence, with those of other codes authorized by the legislation in force, or with other applicable quality standards related to the identity, dosage, purity, strength, content uniformity, time of decomposition, and dissolution speed.

Bioequivalent drugs are “pharmaceutical equivalents that, when given at the same molar dose and under the same experimental conditions, do not have statistically significant differences in bioavailability.”

2. Nonbiological Drugs
   a. Reference Drugs

The registration of new drugs is regulated by Resolutions RDC 136/2003 and RDC 60/2014. Accordingly, the applicant must submit to ANVISA a dossier containing reports of preclinical and clinical trials in order to prove the quality, safety, and efficacy of such new drug. The dossier must also contain other data related to the company and to the composition of the drug, including technical information regarding the active ingredient, its shelf life, and so on.

The preclinical trials required by RDC 135/2006 are the following: acute, subacute, and chronic toxicity, reproductive toxicity, mutagenic activity, and oncogenic potential. Phases I, II, and III are required clinical trials.

The applicant must also present a copy of the Good Manufacture Process (GMP) certificate issued by ANVISA pertaining to the production line of the site where the drug is manufactured. If the drug is imported and

42. Act No. 9.787/99.
43. ANVISA Resolution RDC 60/2014.
44. ANVISA Resolution RDC 31/2010.
45. ANVISA Resolution RDC 60/2014.
46. According to Law No. 9.787—XXV—bioavailability indicates the velocity and extension of an active ingredient’s absorption in a dosage form from its concentration/time curve in the systemic circulation or its excretion in the urine.
labeled in Brazil, both GMP certificates issued to the manufacturer site and the local labeling site must be submitted.

\[b.\] **Branded and Nonbranded Generics**

The registration of nonbranded and branded generics is regulated by Resolution RDC 60/2014.

It is not necessary to perform clinical trials in order to prove the safety and efficacy of branded or nonbranded generics. The rationale is that clinical trials have already been performed on the reference drug.\[^{47}\] Instead, the applicant must prove that its branded or nonbranded generic drug is bioequivalent to the reference drug. If the applicant can prove bioequivalency, ANVISA will assume that the branded and/or nonbranded generic drug is safe and effective by relying on the clinical data that was evaluated during the registration of the new drug.

In summary, an applicant seeking approval of a generic drug must therefore submit to ANVISA a dossier that includes: information related to the company; details of the drug (its composition, active ingredient, technical information, shelf life, etc.); and reports of relative bioavailability/bioequivalence studies. The applicant must also submit GMP certificates for the manufacturing facility and local labeling site.

### 3. Biological Products

The registration of biological products is regulated by ANVISA Resolution RDC 55/2010. Biological products are defined as drugs that have as their active ingredient: (1) molecules extracted directly from microorganisms, organs, tissues of animal origin, or cells or fluids of human or animal origin ("biological origin"); or (2) molecules produced by the process of genetic modification ("biotechnological origin").\[^{48}\]

Drugs considered to be biological products are (1) vaccines; (2) hyperimmune serum; (3) blood derivatives; (4) biodrugs, including (a) drugs obtained from biological fluids or animal tissues and (b) drugs obtained from biotechnology procedures; (5) monoclonal antibodies; and (6) drugs containing live, attenuated, or dead microorganisms.\[^{49}\]

RDC 55/2010 makes a distinction between “new biological products,” which are biological products that have not previously been registered in Brazil, and “biological products,” which contain a molecule with known biological activity that has previously been registered in Brazil.

For *new biological* drugs, the applicant must submit to ANVISA a dossier containing the same breadth of information as submitted for new biological products.

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\[^{47}\] Law No. 9.787/99 (generic drugs); RDC.
\[^{48}\] ANVISA Resolution RDC 55/2010.
\[^{49}\] Id.
nonbiological drugs (see section 2.1.1). Market approval for follow-on biological products may be obtained by either the individual development route or the comparability route. By the individual development route, the applicant must submit reports of preclinical and clinical trials. The results of the Phase III clinical trial must be comparative (i.e., demonstrate non-inferiority, clinical equivalence, or superiority), whereas Phases I and II clinical trials need not be comparative. By the comparability route, the applicant must present a report proving that its product is comparable to the comparator product. This report must provide a comparative analysis between the two products at all stages of development, including the manufacturing of the molecule as well as a comparison of the products’ stability, purity, impurity profile, and so on. The applicant must also provide nonclinical trial reports designed to detect significant differences between the biological product and the comparator product. The applicant must file reports of (1) pharmacokinetics studies; (2) pharmacodynamic studies; and (3) pivotal studies regarding safety and efficacy. Such studies must also be compared with the comparator product.

In order to obtain market approval in Brazil for both chemical and biological drugs, it is necessary to submit a dossier to ANVISA proving that the product meets the standards for quality, safety, and efficacy as defined by sanitary laws. The basic requirements for obtaining market approvals in Brazil are discussed in a later section.

It is worth highlighting that only nonbiological drugs are interchangeable according to sanitary law—that is, if the physician prescribes it by the reference brand or by its INN, the patient is able to choose whether he or she will acquire the reference, or the branded or nonbranded generic drug.

Biological drugs that have been manufactured in other countries will only be registered in Brazil if the products have market approval in those other countries.

To register a biological product, the applicant must prepare a dossier indicating (1) the name of the manufacturer; (2) the country of manufacture of the active ingredient(s), the bulk biological product, the biological product in its primary package, and the finished biological product; (3) the quality control tests conducted on the active ingredient, the bulk biological product, and the finished biological product batches; (4) the site where the respective quality control tests will be conducted; and (5) the product specifications.

The applicant must also indicate the name of the manufacturer of the active ingredient if the applicant is not the manufacturer. If the active ingredient manufacturer changes, the applicant must request a new registration and may not use the brand name of the previously registered biological product, except when:
1. There is a technology transfer to the new company, which must be duly proven by providing the technology transfer agreement between the companies involved; or

2. The applicant proves through comparative studies that the drug properties of the finished biological product are unchanged after the change of manufacturing facility.

In the same way, if the applicant is not the manufacturer of the biological product in its primary package, the manufacturer must be stated in the application. If the manufacturer of the biological product in its primary package changes, a new product registration must be requested, except when comparative studies can show that the properties of the finished biological product (safety and activity) remain unchanged after the change in manufacturer.

4. Clone Drugs

Since May 2014, with the enactment of Resolution RDC 31/2014, ANVISA established a simplified procedure for the approval, postapproval, and renewal of “clone” drugs comprising (1) branded and nonbranded generic drugs, (2) branded copies of “similar” drugs, (3) specific, dynamised (namely, homeopathic), and herbal drugs, and (4) biological products.

According to the resolution, ANVISA is responsible for simplifying and accelerating the granting of registration of such products through the “clone procedure,” in which a primary clone application for a clone drug is filed before ANVISA. The registration of a clone drug is connected to the registration of a “mother drug,” a product that has been previously registered through the regular registration procedure. The primary clone application is a simplified application that is linked to the technical and clinical reports of a “mother application,” and may only differ from the mother drug in brand name, packaging layout, and the wording of the package insert and labeling.

Under Article 15 of RDC 31/2014, the grant of registration of the primary clone application is subjected to the electronic petitioning and analysis of the following documents by the regulatory agency: (1) receipt of payment of the necessary administrative fees; (2) forms FP1 and PF2 (available on ANVISA’s website); and (3) declaration of the connection to the mother application pursuant to Annex I. When applicable to the category of drug, the package wording and layout, as well as the drug name and differential supplement, are also examined.

50. Annex I is a form submitted for both the mother drug and the clone drug requesting marketing authorization for the clone under the clone procedure.
The enactment of RDC 31/2014 has therefore allowed ANVISA to implement the clone procedure, which has expanded its options to simplify and expedite the granting of registration of clone products.

**E. Strategies**

1. **Patent Enforcement**

   Once a generic or biosimilar drug is granted regulatory approval, and is marketed or manufactured, if the drug infringes a third party’s patent, it is possible to file an ordinary action for infringement under Article 42 of the IPL:

   > Article 42. The patent grants to the holder the right to prevent a third party, without its consent, from producing, using, marketing, selling, or importing for these purposes:
   > I—product subject to patent;
   > II—process or product obtained directly by patented process.

   In addition to preventing the alleged violator from continuing to market and/or manufacture the drug, it is possible for the patent holder to be indemnified for the damages incurred by virtue of the patent infringement.\(^{51}\)

   It is worthwhile to emphasize, however, that the ability to commence an indemnification lawsuit for such damages expires after five years.\(^{52}\)

   In accordance with Article 209, paragraph 1 of the IPL, “the Judge may determine through a preliminary injunction, on the case records of the lawsuit, to stop the act or violation, before the defendant summons, upon deposit in cash or guaranty, as deemed necessary, to avoid irreparable damage or damage of difficult indemnification.” Accordingly, once the requirements necessary for granting a preliminary injunction are met,\(^{53}\) the judge may order that the acts that violate the patent be halted.

2. **Data Protection**

   There is no data protection for pharmaceuticals in Brazil. In practice, ANVISA will not respect any period of nonreliance after the issuance of a market approval to the innovator company. With regard to pharmaceutical products for human use, Brazilian law does not provide for specific registration data exclusivity periods or periods of nonreliance, during which third parties cannot obtain a market approval by referring to the originator’s data. In order to facilitate the issuance of market approvals to unauthorized third parties, a registration dossier should only be presented

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51. Industrial Property Law, art. 209.
52. Industrial Property Law, art. 225.
to ANVISA with a notice that it is secret and should not be used or relied upon.

Moreover, a lawsuit seeking to prevent the issuance of market approval to unauthorized third parties stands a good chance of success in view of (1) section 195.XIV of the IPL,\(^{54}\) (2) the concept of unjust enrichment; and (3) the fact that data protection exists for veterinarian and agrochemical products under Bylaw No. 10,603/02.

3. Linkage Actions
In practical terms, there is no linkage system in Brazil. ANVISA, Brazil’s regulatory agency, will issue market approvals to branded and nonbranded generics even if there are patents in force in Brazil. If the generic product is launched (which, so far, rarely occurs), a patent infringement lawsuit may be initiated. There is no official register in which patents covering a given product are listed and will be checked by ANVISA or third parties.

However, there is at least one court case wherein the market approval of the generic manufacturer had been suspended through a preliminary injunction due to the existence of a patent in force in Brazil. Although it is an agrochemical case, its rationale would apply to pharmaceuticals. Article 43.VII of the IPL states that patent rights do not apply to “acts practiced by unauthorized third parties related to the invention protected by a patent, for the sole purpose of producing test results, information, and data in order to obtain the commercialization registration in Brazil or abroad.” In this case, it was interpreted to relate only to testing aimed at obtaining market approval, however, the issuance of the registration itself amounted to a violation of the patent. As a result, it may be possible to prevent nonauthorized generics from obtaining market approval.

F. Extrajudicial Measures
It may also be possible to solve a patent infringement dispute without the involvement of the judicial system through the use of an extrajudicial notice, which is provided for in Article 867 of the Brazilian Code of Civil Procedure:

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Article 867. Whoever wants to avoid responsibility, to provide conservation and reservation of his/her rights, or formally express any intention, can make his/her complaint in a written petition
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\(^{54}\) Section 195.XIV of the IPL provides that “a crime of unfair competition is committed by he who . . . divulges, exploits or uses, without authorization, the results of tests or other undisclosed data, the determination of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of products.”
addressed to the judge, and request him/her to order the appropriate people.

Extrajudicial notices are used to warn the violator of the infraction without triggering judicial proceedings, and can be equally effective and faster than a patent infringement action.

**G. Possible Patent Term Extension for a Pharmaceutical Product**

The IPL does not provide for extensions of regular patent terms. The term of a regular patent is defined by Article 40 of the IPL as 20 years from its filing date or ten years from its grant, whichever is longer.

Only pipeline (or revalidation) patents, the corresponding applications of which were filed between May 1996 and May 1997 (under the provisions of Article 230 of the IPL), may have their term harmonized with that of the corresponding ground patent. In other words, if a Brazilian pipeline patent is grounded in a foreign patent, the term of the Brazilian patent is extended via a Supplementary Protection Certificate. The term of the pipeline patent may be harmonized with the new extended term in the foreign country, however, a lawsuit is required to implement such a harmonization. Notably, in recent decisions, the Brazilian Superior Court has refused to harmonize a Brazilian pipeline patent with its corresponding foreign patent.

**H. Partnership for Productive Development**

Another important issue in Brazil that must be considered by a patent holder is the Partnership for Productive Development (PDP).

A PDP is part of a measure of the Brazilian Federal Government seeking to promote the competitiveness of the local productive system within the pharmaceutical sector and, consequently, reduce the deficit in the Brazilian trade balance in this sphere.

A PDP is, in essence, a partnership between a public and a private entity, in which a private laboratory undertakes to transfer the technology of a particular drug to a public laboratory, provided that, during the contractual term, the private laboratory is chosen as the exclusive or one of the exclusive suppliers of this product to the Government. In general, a PDP contract must have a duration of up to ten years, but this period may be longer, depending on the nature of technological development to be implemented and upon the approval of the Ministry of Health.

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55. Industrial Property Law, No. 9.279/96.
It is important to mention that, as a rule, a PDP is not preceded by bidding, especially as Article 73 of Law No. 12.715/2012 inserted “contracts for technology transfer related to strategic products for the Unified Health System—SUS,” among bidding dismissal hypotheses set forth in Article 24 of Law 8.666/93.

In any event, due to the lack of solid external oversight and publicity of the PDPs, as well as potential questions related to IP infringement and other administrative and legal concerns, a new regulation for PDPs was implemented last year.

The Ordinance 2531, of November 12, 2014, redefined “the guidelines and criteria for the definition of the list of strategic products for the National Health System (SUS) and the establishment of Partnerships for Productive Development (PDP). It regulates the processes for submission, documentary support, decision, transfer, and absorption of technology, acquisition of strategic products for SUS in the scope of PDPs, and the respective monitoring and evaluation.”

According to the guidelines, following an initial contact between public and private laboratories, together they prepare a PDP project proposal to submit to the Ministry of Health between January 1 and April 30 for one of the listed strategic drugs that will be made available annually on the Ministry of Health website.

The proposal is submitted by the public laboratory for evaluation by the Ministry of Health, which may accept, reject, or make changes to the project. Once the proposal is approved, the public laboratory is called to sign a Commitment Instrument with the Ministry of Health. A statement of agreement signed by the private laboratory must also be attached to this instrument.

The phase referred to as the “PDP project” then commences and involves the implementation of the approved PDP project proposal. During this phase, the public and private laboratories will negotiate the terms of the technology transfer agreement. Upon signing the agreement, the PDP phase starts with the implementation of product development, effective transfer, and absorption of technology, and execution of a strategic product acquisition agreement between the Ministry of Health and the public institution.

Finally, there is an internalization phase, during which the development, transfer and absorption of the technology subject of the PDP is concluded with conditions for production of the product in the country, as well as technological portability in the country by the public institution.

Under the new Regulation 2531/2014, specifically, Article 14, item III, and Article 22, item VII, the execution and implementation of a PDP must
observe the IP rights set out in Law 9279/96. However, the administrative agreement arising from a PDP is mixed, as it involves not only the transfer of technology, but also the supply of the product throughout the duration of the period.

The clear delineation of the implementation phases of a PDP pursuant to Regulation 2531/2014, as well as the mixed nature of the administrative agreement would make the mere execution of the PDP between the public and private partners, in and of itself, an infringement of the related patent in force. However, Article 43 items II and VII state that acts related to scientific or technological research studies, as well as those aimed at obtaining marketing approval before ANVISA, shall not be considered acts of patent infringement.

Although the execution of a PDP involving a patented object does not, in itself, characterize patent infringement, it is the first concrete evidence that the IP rights of the inventor are threatened. Inevitably, at some time in the PDP agreement, the drug subject of the partnership will be offered for sale, manufactured, and, immediately thereafter, marketed directly to the Ministry of Health. These actions would constitute the criminal offense of “offer to sell” referred to in Article 184 and an act of infringement to “place for sale” in accordance with Article 42. Further, according to Brazilian patent law, it is not necessary for the acts to be effectively carried out in order to bring an action for infringement in court. The mere threat to the law authorizes the patent holder to seek recourse from the courts in the form of an inhibitory remedy that, during the patent term, prevents an acquisition from taking place by the Government for the PDP that is under analysis.

III. Canada

A. Introduction

As in the United States, litigation in Canada over the sale of pharmaceuticals is a hybrid area of litigation. It involves the intersection between regulatory law under the Food and Drugs Act (FDA)\(^56\) and the Food and Drugs Regulations, (FDR),\(^57\) which together establish the conditions required for the sale of pharmaceuticals in Canada, and patent law, under the Patent Act\(^58\) that grants market exclusivity to those holding

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56. Food and Drugs Act, R.S.C., c. F-27 (1985) [FDA].
57. Food and Drugs Regulations, C.R.C., c. 870 [FDR].