Brazil

“Penciclovir”

Decision of the Superior Court of Justice of Brazil (Superior Tribunal de Justiça)
5 August 2021 – Case No. 1.543.826 – RJ (2015/0173736-6)

ANVISA Agência Nacional de Vigilância Sanitária
[Brazilian Health Regulatory Agency] v. Novartis
International Pharmaceutical

Law 9.279/1996 (Industrial Property Law), Arts. 18, 229-C; Law 8.080/1990, Arts. 6,19-M; Law 9.782/1999, Art. 7 item XXV

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Keywords Unfavorable opinion · National regulatory agency · Pharmaceutical patent · Patent grant · Public health · ANVISA · Sanitary authorization · Access to medicine · Binding nature of AVISA’s prior consent

1. Under the terms of Art. 229-C of Law 9279/1996, the granting of patents for pharmaceutical products and processes depends on the prior consent of the Brazilian Health Regulatory Agency (ANVISA).

2. This favorable opinion constitutes a prerequisite for the granting of pharmaceutical patents by the Brazilian National Institute of Industrial Property (INPI). This is an inference that arises from the combination of this rule with the provisions of subsec. I of Art. 18 of the same law, which prioritizes the economic and social function of industrial property by considering inventions or utility models contrary to public health, whose protection falls within the regulatory agency’s powers, not to be patentable.

3. The expression “public health” has a broader meaning than “individual health”. It is not limited to treatment or recovery from disease, but comprises a set of preventive measures and control of diseases intended to ensure the physical, mental and social well-being of the community as a whole and each member of it, which includes full therapeutic assistance actions such as pharmaceutical assistance and the formulation of drug policies.

The headnotes correspond to official summary of the decision. Translated from the Portuguese by Ana Letícia Allevato.
4. The amplification of the concept of health – beyond individual health –
derives from its consecration as a right for all to be guaranteed by the
State. It has the duty of formulating and executing economic and social
policies aimed at reducing the risks of diseases and other illnesses and that
ensure universal and equal access to “public health services” and the so-
called “health actions” for the promotion, protection, and recovery of
physical and mental well-being, so as to guarantee human dignity, an
imperative of the Magna Carta of 1988.

5. To enable the implementation of this state duty, the Constitution created
the Unified Health System (SUS), a world reference in the sector, which
covers the aforementioned public actions and services (that are only
complemented by private services) organized in regionalized networks and
hierarchized in order to guarantee comprehensive care for the population,
with priority given to preventive and curative care, without prejudice to
care services (Art. 198).

6. When defining the field of action of SUS, Art. 6 of Law 8.080/1990
(Organic Health Law) reveals that such actions and services of public
relevance are not limited to medical consultations, examinations and
hospitalizations but also include full therapeutic assistance actions,
including pharmaceutical assistance (item I, line “d”) and the formulation
of drug policy (item VI).

7. The so-called full therapeutic assistance consists of the distribution of
drugs – the prescription of which is in accordance with the therapeutic
guidelines defined in a clinical protocol for the disease or illness to be
treated – and the provision of therapeutic procedures on a home,
outpatient, and inpatient basis, listed in tables prepared by the SUS
federal manager (Art. 19-M of Law 8,080/1990, included by Law 12.401/
2011).

8. In this scenario, the relevant role played by ANVISA in the sphere of
economic-social regulation of the drug sector is extracted from the
competence provided in item XXV of Art. 7 of Law 9.782/1999 – aimed at
correcting market failures, by monitoring the evolution of drug prices –
and from the fact that the regulatory agency performs the Executive
Secretariat of the Drug Market Regulation Chamber (SCMED). This is an
interministerial body created by Law 10. 742/2003, which has as objectives
the adoption, implementation and coordination of activities intended to
promote pharmaceutical assistance to the population by means of
mechanisms that stimulate the supply of products and competitiveness
among suppliers.

9. ANVISA’s institutional role in the process of granting pharmaceutical
patents is not to be confused with the sanitary control of medicines, drugs
and pharmaceutical inputs, performed within the scope of the registration
procedure. “Patent granting” and “sanitary authorization” are distinct
things. Interpreting them as synonyms means emptying the legislative
option contained in Art. 229-C of the Industrial Property Law.
10. The difference in ANVISA’s and INPI’s perspectives of analysis of the pharmaceutical patent application eliminates any conflict of attributions. The INPI – currently linked to the Ministry of Economy – has the objective of ensuring the efficient protection of industrial property and, for this purpose, it uses fundamentally technical criteria, supported by all its expertise in the area, to evaluate patent applications. The granting of these is an administrative act of discretion linked to abstract and technological parameters set forth in the governing law and its internal regulations. ANVISA, the holder of specialized knowledge in the health sector in the exercise of the “prior consent” procedure, should enter into any aspects of the pharmaceutical products or processes that allow it to infer whether the granting of the exclusivity right will represent potential harm to SUS public policies aimed at guaranteeing pharmaceutical assistance to the population (even if they are extracted from the patentability requirements i.e. novelty, inventive step and industrial application).

11. Furthermore, there is no conflict between the interpretation herein conferred on Art. 229-C of the Industrial Property Law, and the rules provided for in the TRIPS Agreement, notably due to the mitigations introduced in 2001 with the Doha Declaration, providing that its implementation is consistent with each nation’s right to protect public health and, in particular, to promote access to medicines for all.

12. Recognizing ANVISA’s prior consent as a prerequisite of validity for the grant of a patent for a pharmaceutical product or process, it is therefore certain that in cases in which the contravention of public health policies is demonstrated the respective unfavorable opinion cannot be adopted only as a subsidy for INPI’s decision making. The binding nature of the refusal to consent is, therefore, unquestionable.

[...]

OPINION

The Honorable Justice Luis Felipe Salomão (Rapporteur):

2. The main controversy in the case is in defining whether the prior consent of the Brazilian Health Regulatory Agency (ANVISA), required for the granting of patents for pharmaceutical products and processes, pursuant to the provisions of Art. 229-C of Law 9.279/1996 (Industrial Property Law), is restricted to examining the existence of a potential health risk or can enter the patentability requirements.

The Federal Court of Appeals of the 2nd Region held that it is not ANVISA’s responsibility to examine the patentability requirements […].

At the time of the examination of the appeals filed by ANVISA, the Regional Court, again by majority vote, upheld the winning vote in the appeal, reiterating that it is not “ANVISA’s role to promote the examination of technical criteria proper to patentability (novelty, inventive step and industrial application), and should act, for
purposes of Art. 229-C of Law 9.279/96, according to its institutional attributions, preventing, through sanitary control, the production and marketing of products and services potentially harmful to human health” (pages 11131–11132). […]

4. […] The TRIPS Agreement came into force in Brazil, as is well known in the Superior Court of Justice (STJ), only on 1 January 2000, five years after it was published. That was five years after the publication of Presidential Decree 1.355, of 30 December 1994 which promulgated the final minutes with the results of the Uruguay Round of GATT […].

Nevertheless, even before that date, Law 9.279/1996 was enacted, revoking Law 5.772/1971 and incorporating the trade-related intellectual property rights protection provisions set forth in the TRIPS Agreement.

Some years later, the Executive edited the Provisional Measure 2.006, of 14 December 1999 – later converted into Law 10.196/2001. This introduced Art. 229-C in the Industrial Property Law, conditioning the concession of drug patents to the prior consent of ANVISA. In verbis: “Article 229-C. The granting of patents for pharmaceutical products and processes will depend on the prior consent of the Brazilian Health Surveillance Agency – ANVISA.” […]

In this scenario, there is controversy over the “limits of analysis” to be performed by the regulatory agency for the purposes of prior consent imposed by Art. 229-C of the Industrial Property Law. The question is whether it should be restricted to certifying whether the pharmaceutical products or processes – objects of the patent application – present a potential health risk or not, or is it allowed to consider the patentability requirements – novelty, inventive step and industrial application – whose technical analysis, in principle, is the responsibility of the INPI. […]

[…] [T]he normative orientation, with the purpose of interpreting the legal requirement of “ANVISA’s prior consent for the grant of a pharmaceutical patent”, established two hypotheses: (i) performance of the regulatory agency limited to the verification of potential health risk, conferring a binding character to the negative opinion; and (ii) possibility of the special autonomous government agency to enter the patentability requirements, in the case of pharmaceutical product or process considered of interest for public health policies, stipulating, however, the merely subsidiary character of the refusal of consent, in order to prevail the technical decision of the INPI.

5. However, I do not believe this is the best interpretation to be attributed to Art. 229-C of Law 9.279/1996, which, as transcribed elsewhere, states that “the concession of patents for pharmaceutical products and processes will depend on the prior consent of the Brazilian Health Surveillance Agency (ANVISA)”.

In my opinion, such “prior consent of ANVISA” constitutes a prerequisite for the validity of the granting of pharmaceutical patents by the INPI.

This inference stems from the combination of the aforementioned rule with the provisions of subsection I of Art. 18 of the same law, which prioritizes the economic and social function of industrial property by considering inventions or utility models
that are contrary to public health as unpatentable, the protection of which falls within the jurisdiction of the regulatory agency.

From this perspective, in the case of a drug patent application, it is ANVISA’s responsibility to determine – prior to INPI’s examination – whether the granting of exclusivity rights (for production, use, marketing, importing or licensing) could lead to a situation that is harmful to public health. This is a function that should not be confused with the sanitary control of medicines, drugs and pharmaceutical raw materials, performed in the scope of the registration procedure, in which the special autarchy examines the safety (inexistence of risk to health), efficacy and quality of the product (Arts. 7, item IX, of Law 9.782/1999 and 16 to 24-B of Law 6.360/1976).

Indeed, the expression “public health” has a broader meaning than “individual health”. This is because it is not limited to treatment or recovery from disease, but rather comprises a set of preventive measures and disease control aimed at ensuring the physical, mental, and social well-being of the community as a whole and each member of it.

Given its degree of importance, the right to health has the status of a fundamental social right – translating as a manifestation of the postulate of human dignity – and the Constitution of 1988 reserved an entire section for it in the title on social order (whose objective is social well-being and justice), whose Arts. 196 and 197 state as follows:

Article 196. Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.

Article 197. Health actions and services are of public importance, and it is incumbent upon the Government to provide, in accordance with the law, for their regulation, supervision and control, and they shall be carried out directly or by third parties and also by individuals or private legal entities (emphasis added).

In this context, the expansion of the concept of health – beyond individual health – results from its consecration as a right of all to be guaranteed by the State, which was assigned the duty to formulate and implement economic and social policies aimed at reducing the risks of disease and other hazards and to ensure universal and equal access to “public health services” and the so-called “health actions” for the promotion, protection and recovery of physical and mental well-being, in order to ensure human dignity, an imperative of the Magna Carta of 1988.

With the intention of making this state duty viable, the Constitution created the Unified Health System (SUS), a world reference in the sector, which covers the referred public actions and services – which are only complemented by private services – organized in regionalized and hierarchical networks in order to guarantee integral care to the population, with priority to preventive and curative care, without prejudice to the assistance services (Art. 198).
When defining the field of action of the SUS, Art. 6 of Law 8.080/1990 (Organic Health Law) reveals that these actions and services of public relevance are not limited to the performance of consultations, exams, and hospitalizations, but also include full therapeutic assistance actions, including pharmaceutical assistance (item I, line “d”) and the formulation of drug policies (item VI).

Furthermore, the aforementioned statute, incorporating the directives preconized in Art. 198 of the Constitution, determines that public health policies should observe, among others, the principles of universal access, integral care, and equity (clauses I, II, and IV of Art. 7) [...].

The principle of integral care translates the need to promote, in an articulated and continuous manner, individual and collective preventive and curative health actions and services, including the so-called integral therapeutic care (including pharmaceutical assistance). This consists of the distribution of drugs – the prescription of which is in accordance with the therapeutic guidelines defined in a clinical protocol for the disease or offense to be treated – and the offer of therapeutic procedures, in home, outpatient, and inpatient settings, as listed in tables prepared by the SUS federal manager (Art. 19-M of Law 8.080/1990, included by Law 12.401/2011).

Under the Constitution and the governing law the SUS is also responsible for performing sanitary surveillance actions, understood as a set of actions to eliminate, reduce, or prevent health risks and intervene in sanitary problems, which includes the control of consumer goods that directly or indirectly relate to health, including all stages and processes, from production to consumption (Art. 200, item II, of the 1988 Constitution and Art. 6, item I, line “a” and § 1 of Law 8.080/1990).

In 1999, Law 9.782 created ANVISA and defined the National Sanitary Surveillance System as the set of actions listed in paragraph 1 of Art. 6 of Law 8.080/1990 (referred to above), in addition to those directed to controlling and inspecting procedures, products, and substances of interest to health (Art. 1).

According to Art. 6 of the referred ANVISA Law, its institutional purpose consists of promoting the protection of the population’s health, by means of the sanitary control of the production and sale of products and services subject to the sanitary surveillance, including of the environments, processes, inputs and technologies related thereto, as well as the control of ports, airports and borders.

Among other competencies foreseen in Art. 7 of the law, the one focused on the correction of market failures in the drug sector stands out. This involves monitoring the evolution of drug prices and being the regulatory agency able to request information in order to do this, proceeding with the examination of inventories or summoning the responsible parties to explain conduct indicative of violation to the economic order, such as the imposition of excessive prices or unjustified increases (clause XXV).

The relevant role played by ANVISA in the sphere of economic-social regulation of the sector is also extracted from the fact that it performs the Executive Secretariat of the Drug Market Regulation Chamber (SCMED). This interministerial body was created by Law 10.742/2003 – composed of the Ministers of Health, of the Chief of Staff, of Finance, of Justice, and of Development, Industry, and Foreign Trade – and has as objectives the adoption, implementation, and coordination of activities
intended to promote pharmaceutical assistance to the population, through mechanisms that stimulate product supply and competitiveness among suppliers.

6. Hence, although one cannot neglect the legal attributions of the INPI – especially the execution, at national level, of rules that regulate industrial property, taking into account its social, economic, legal and technical function – I believe that, in relation to drug patents, there is no question of institutional invasion by ANVISA, when the refusal of prior consent is based on any criterion demonstrating the harmful impact of granting the privilege to public health policies, which, as previously demonstrated, include the guarantee of universal access to full pharmaceutical assistance.

This is because, in my opinion, the difference in the perspectives of analysis of the referred federal autonomous bodies about the request for the grant of a pharmaceutical patent eliminates any conflict of attributions.

In effect, it is certain that the INPI, which is currently linked to the Ministry of Economy, has the objective of guaranteeing the efficient protection of industrial property and, in this task, it uses fundamentally technical criteria, supported by all its expertise in the area, to evaluate the patent applications, whose act of granting consubstantiates an administrative act of discretion linked to abstract and technological parameters contained in the governing law and its internal regulations.

On the other hand, ANVISA, holder of specialized knowledge in the health sector, in the exercise of the “act of prior consent”, should enter into any aspects of the pharmaceutical products or processes – even if extracted from the patentability requirements (novelty, inventive step and industrial application) – that allow it to infer whether the granting of the exclusivity right will represent potential harm to the SUS public policies aimed at ensuring pharmaceutical assistance to the population.

The performance of the regulatory agency, in this case, clearly translates into a redistributive function, in which it seeks to reconcile the private interest – the right of exclusivity in the lucrative exploitation of the invention – with the goals and objectives of public interests embedded in health policies.

The thesis proposed here, therefore, derives from the systematic interpretation of the norms contained in item I of Art. 18 of the Industrial Property Law (i.e., prohibition to grant patents to inventions contrary to public health) and in Laws 9.782/1999 and 10.742/2003. These outline the institutional functions and competencies expressly attributed to ANVISA in order to safeguard the viability of health policies considered “of public relevance” by the Constitution of 1988.

From this perspective, the stipulation of the “prior consent” of the special agency as a condition for the grant of a pharmaceutical patent is based on its role of economic-social – or socioeconomic – regulation of the drug sector. This is justified by the commandments extracted from the Constitution, in the sense of the necessary harmonization of the right to industrial property with the principles of social function, free competition and consumer’s defense, as well as the social interest embodied in the State’s duty to give concreteness to the fundamental social right to health (Arts. 5, clauses XXIII, XXIX, 6, 170, clauses III, IV and V, and 196) while observing the reserve of the possible.
In the same way, there is no conflict between the interpretation given to Art. 229-C of the Industrial Property Law and the rules set out in the TRIPS Agreement, which point out the relevance of balancing public and private interests involved in the concession of pharmaceutical patents. […]

Moreover, since the Doha Declaration (2001), the WTO’s members have introduced mitigations to the TRIPS Agreement, providing that its implementation is consistent with the right of each nation to protect public health and, in particular, to promote access to medicines for all. On that occasion the right of each country to grant compulsory licenses ("patent breaks") for medicines as a measure to combat the abuse of the exercise of industrial property was also recognized, given the gravity of public health problems in developing countries and the legitimate concern with the impact of granting patent privileges on the prices of pharmaceutical products.

7. In addition, I reiterate my understanding that, in light of the legal rule exhaustively analyzed (Art. 229-C of Law 9.279/96), the requirement of prior consent from ANVISA constitutes a prerequisite of validity for the concession of a patent for a pharmaceutical product or process – which, obviously, results from the extreme relevance of drugs for the guarantee of universal access to integral health care. Therefore the unfavorable opinion cannot be adopted only as a subsidy for the INPI’s decision making in cases in which the contradiction with public health policies is demonstrated.

The binding nature of the refusal of consent is, therefore, undoubted.

Nevertheless, I consider that any divergence between the agencies on the grounds expressed in the unfavorable opinion to the patent claim should be solved under a dialectic and cooperative view – recommendable in the scope of Public Administration – in which they seek to equate "the purpose of stimulating inventive activity leading to the technological and economic development of the country" and "the social interest of materializing the fundamental right to health, object of SUS public policies".

[…] Consequently, I do not see in this case an unavoidable conflict of attributions that requires the interpretation of the rule inserted in the regulating law, in order to exclude part of its evident content, which is, in my opinion, in total harmony with constitutional principles and norms, besides the international treaty cited many times.

One should not forget, moreover, the submission of the administrative authority of ANVISA – responsible for the opinion (favorable or unfavorable) concerning the privilege of a pharmaceutical product or process – to the provisions of Art. 20 of the Law of Introduction to the Brazilian Law (LINDB), which requires the motivation of the administrative act in light of the "practical consequences of the decision" and the analysis of "possible alternatives".

The exegesis presented also applies to the so-called pipeline patent ("import patent" or "revalidation patent") – which consists of a revalidation, in Brazilian territory, of the protection previously granted abroad – whose concession, under the
terms of paragraph 3 of Art. 230 of Law 9.279/96, must respect item I of Art. 18 of the same statute. […]

9. Returning to the analysis of the concrete case, it can be seen that, after the INPI’s approval of the patentability requirements of the pharmaceutical products indicated by Novartis, ANVISA presented negative opinions […].

[…] [I]t is unequivocal that ANVISA, when exercising the duty provided in Art. 229-C of Law 9.279/96, did not exceed its powers, analyzing all aspects related to patent applications (including patentability requirements) that could cause damage to public health policies of the SUS, especially those related to access to medicines.

As it has been daily reported, SUS, in the last year, has gained notice and praise from jurists and economists, for having represented a crucial tool to minimize, to some extent, the deleterious impacts of the COVID-19 pandemic, a disease that has already claimed the lives of more than 175,000 Brazilians.

In this scenario, I believe it is no longer possible to underestimate the significance of public health policies in everyone’s lives, and therefore it is necessary to rule out any interpretation that may have the power to empty ANVISA’s fundamental role of safeguarding the state actions aimed at guaranteeing universal access to full pharmaceutical assistance (especially for vulnerable social groups), potentially affected by the granting of pharmaceutical patents.

Consequently, it is necessary to amend the appeal court’s decision, which granted the plaintiff’s claim, as it considered that ANVISA had exceeded its legal attributions, which is not the case herein.

10. Once this proposal for dismissal of Novartis’ claim is accepted, the appellant’s assertion based on the violation of Art. 8 of the Industrial Property Law is moot, on the grounds that the pipeline patent must meet the novelty requirement.

[…]

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