

**BRAZIL'S ANUENCIA PREVIA: HOW BRAZIL'S UNIQUE
PHARMACEUTICAL PATENT LAW ILLUSTRATES THAT THE
UNITED STATES AND BRAZIL CONTINUE TO DISAGREE ON
TRIPS' FLEXIBILITIES TO PROTECT ACCESS TO ESSENTIAL
MEDICATIONS**

**By Bryan Murphy
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I. Introduction

In recent years, the debate over the effects of pharmaceutical patents on public health and access to medicines in developing nations has become entrenched at the forefront of the issue of globalization. Brazil has taken center stage in the developing world's efforts to find a balance between obligations to protect intellectual property rights (IPRS) under TRIPS and the pressing need to ensure their populations have access to essential medications. The focus on Brazil is attributable to the nation's aggressive efforts to provide access to medications for its HIV positive citizens. Their program is heralded as a model for the developing world¹, but it is not without its critics. The program relies on access to low-cost pharmaceuticals², and to guarantee this access the government has been innovative in its government policies towards pharmaceutical patent rights. The developing world governments and pharmaceutical multinationals have been less than thrilled at what they portray as Brazil's cavalier attitude towards pharmaceutical patents.

Since 2001, the discussion on how to interpret TRIPS in light of member nation's commitment to protect public health has evolved. This shift is marked most poignantly by the 2001 Doha Declaration on the TRIPS Agreement and Public Health and the Paragraph 6 Decision of August 30, 2003, that further clarified a provision of that declaration. These negotiated understandings clearly affirmed that TRIPS can accommodate the developing world's need to promote public health, but a shared interpretation of TRIPS between the developed and developing world still remains elusive.

¹ Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUMAN RIGHTS AND DEVELOPMENT LAW JOURNAL 103 (2003), at 131.

² *Id.* at 130.

This paper is an examination of Brazil's latest domestic innovation for the treatment of pharmaceutical patents, *anuencia previa* (prior approval). The paper begins by explaining this rather clandestine law and then proceeds to examine the current debate over its implementation. By examining the positions of actors within Brazil and the world, the paper will attempt to use the debate over *anuencia previa* to identify where current disagreements over the correct interpretation of TRIPS exist. The interests at stake, and how they affect interpretation of TRIPS, will also be examined. Additionally, the paper examines *anuencia previa*'s legitimacy under TRIPS. Lastly, the paper will present an argument as to why Brazil should abandon *anuencia previa* in order to adopt a program of compulsory licensing to protect access to medicines, and why the United States and the developing world should endorse such a move.

II. Patent Protection of Pharmaceuticals in Brazil

Like many developing nations, Brazil did not offer patent protection to pharmaceuticals until joining the WTO in 1994.³ In accordance with its obligations under the WTO, Brazil implemented a new industrial property law, Law 9.279, in 1996 meant to bring the country into compliance with TRIPS obligations for the protection of intellectual property.⁴ Brazil's industrial property law is widely viewed as offering strong protection of intellectual property rights adequate to satisfy TRIPS obligations, including those for patent protection of pharmaceuticals.⁵ However, Brazil's enforcement of its own patent law remains an issue for observers in the developing

³ Lazzarini, *supra* note 1, at 129.

⁴ *Id.*

⁵ PhRMA, 2004 Special 301 Submission, at 93, at www.phrma.org/international/americas/brazil.cfm

world.⁶ Brazil has been particularly hard pressed to cope with the tremendous increase in patent applications that has corresponded with its adoption of increased protection of IPRs under Law 9.279/96.⁷ Brazil is estimated to currently have a backlog of 60,000 patent applications, of which 18,000 are for pharmaceutical patents.⁸ Even more distressing to pharmaceutical multinationals is that Brazil has to date only issued 428 non-pipeline patents for pharmaceuticals.⁹

Brazil's industrial property law has also been a work in progress, especially in regards to patent protection. The original draft of the law included a provision that required patents to be "worked," or produced in Brazil.¹⁰ If a country chose to import the product instead of producing at least some of it within Brazil, the government reserved the right to issue a compulsory license for domestic production.¹¹ The law raised particular concern among multinational pharmaceutical companies as they feared Brazil would use the law to issue compulsory licenses of pharmaceuticals.¹² The United States affirmed how serious it saw the issue by filing a complaint over the law with the WTO.¹³ The United States terminated the dispute without prejudice in 2001 when Brazil agreed to notify the United States if it intended to issue a compulsory license under the law.¹⁴ The law remains on the books in Brazil.¹⁵

⁶ Id.

⁷ For a discussion of the increase in patent applications after 1996 see Daniela Christovão, *O Acordo TRIPS: Relações entre o Comércio Internacional e o Sistema de Propriedade Intelectual Brasileiro*, University of Sao Paulo, School of Law (2003).

⁸ USTR, 2005 National Trade Estimate Report on Foreign Trade Barriers, at 34, at www.ustr.gov/Document_Library/Reports_Publications/2005/Section_Index.html.

⁹ PhRMA, supra note 5, at 95.

¹⁰ Id. at 33

¹¹ Id.

¹² Christovão, supra note 7, at 92-97.

¹³ Id.

¹⁴ Id.

¹⁵ Id.

A situation in Brazil that must be addressed in any discussion of pharmaceutical patents is the nation's proactive program to combat the HIV/AIDS epidemic that once threatened to devastate the country, but that now appears largely under control.¹⁶ The essential element to Brazil's program, which is administered by the Ministry of Health, has been to make available free anti-retroviral medications to the entire HIV positive population.¹⁷ Brazil's program has been heralded the world over as a model to aspire to in the treatment of HIV/AIDS,¹⁸ and now provides free medication to over 100,000 people.¹⁹ The majority of the drugs it provides are under patents owned by multinational pharmaceutical companies.²⁰ Brazil's ability to realize lower prices for the anti-retroviral drugs through manufacturing generic versions and negotiating lower prices has therefore been essential to the programs viability.²¹ As drug prices for the HIV cocktail of medications provided by the government has increased over the years, Brazil has become more aggressive in negotiating for lower prices with the pharmaceutical industry.²² Brazil has increasingly used the threat of compulsory licensing to compel patent owners to offer lower prices for the anti-retroviral medications.²³ Brazil's program to offer free HIV medications to its population is a priority of the Brazilian government,²⁴ and ensuring its viability through access to low cost medications has become one of the primary forces shaping Brazilian policy towards the treatment pharmaceutical patents.

¹⁶ See Lazzarini, supra note 1, at 128-132.

¹⁷ Id.

¹⁸ Id. at 131-32.

¹⁹ Id.

²⁰ See *Brazil Requests Voluntary Licensing for AIDS Drugs to Treat More Patients, Reduce Costs of Importing Patented Drugs*, Medical News Today, March 17, 2005, at www.cptech.org/ip/health/c/brazil/.

²¹ Lazzarini, supra note 1, at 128-29.

²² See Cptech website, Brazil page, at <http://www.cptech.org/ip/health/c/brazil/>.

²³ Id.

²⁴ Lazzarini, supra note 1, at 128-29.

III. What is Anuencia Previa?

Brazil's Article 229-C of Law 9.279/96, or *anuencia previa* as it is popularly known, is a statutory requirement that was implemented in Brazil in the late 1999 as a part of Brazil's continuing efforts to deal with its newly self imposed obligations to protect pharmaceutical IPRs.²⁵ The statute divides the examination of patent applications for pharmaceutical products and processes between the Brazilian patent office and the Ministry of Health.²⁶ Since the adoption of Law 9.279/96, the Brazilian government has consistently taken a position in favor of public health in trying to negotiate a balance between pharmaceutical IPRs and access to medicines. *Anuencia previa* was adopted by the Brazilian government as part of this commitment to an agenda in support of public health.²⁷

Anuencia previa is a program that was instituted on the premise that patents for pharmaceuticals are different than patents on other technologies because of their unique and important implications for society.²⁸ The law was created by the Brazilian legislature to make sure that applications for pharmaceutical patents would receive special examination in recognition of their special relationship with society.²⁹ Under Brazilian law, the National Institute for Intellectual Property (INPI) is vested with the responsibility of examining all patent applications and the power to grant or deny patent protection to any invention submitted for review.³⁰ *Anuencia previa* modifies the

²⁵ See Eduardo Colonna Rosman, *O Limite Normativo de Agência Nacional de Vigilância Sanitária – ANVISA*, REVISTA DA ABPI, No. 71, Jul-Aug 2004, at 32-33.

²⁶ Art. 229 – C of Law 9.279/96.

²⁷ Edson Beas Rodrigues Junior, *Anuencia Prévia: Integração do Direito à saúde aos Direitos de Propriedade Intelectual*, at 2.

²⁸ Alyne Silva, *Anuência Prévia de Patentes e a ANVISA*, Comunidade Virtual em Vigilância Sanitária, at cvirtual-anvisa.bireme.br/tiki-read_article.php?articleId=80.

²⁹ Id.

³⁰ Law 9.279/96.

jurisdiction of INPI by requiring that it share its power for the examination of patent applications for pharmaceuticals with another governmental agency, the National Health Surveillance Agency (ANVISA).³¹ The law that created anuencia previa reads, in its relevant part:

“The concession of patents for pharmaceutical products and processes will depend on the prior approval of ANVISA”³²

Anuencia previa creates a unique program for the examination of patent applications for pharmaceutical products and processes. However, the legislative act that authorizes anuencia previa is of little guidance to understanding the law’s role in Brazil. An analysis how of the program is implemented by ANVISA is therefore needed to understand it.

IV. Why Examine Anuencia Previa?

The examination of anuencia previa is relevant to the discussion of divergent views of the present interpretation of TRIPS as it applies to health and access to medicines for several reasons. The first is that it is a program being instituted in Brazil, a developing world country that has been at the forefront of the debate of over TRIPS and its effects on access to medicines.³³ Second, anuencia previa is a program directed solely at patent protection of pharmaceuticals, so it is uniquely focused on the issue of access to medicines. Third, anuencia previa is a new and completely original development in the

³¹ Article 229-C of Law 10.196/01.

³² Id.

³³ See Generally Cptech, supra note 22.

treatment of pharmaceutical IPRs.³⁴ Its genesis has coincided with recent developments in the understanding of TRIPS, most notably the Doha Declaration on the TRIPS Agreement and Public Health, and is therefore particularly relevant to the discussion on present interpretations of the agreement. And partly because it is a new and unique way to treat pharmaceutical IPRs, *anuencia previa* has generated vigorous debate over its legality, policy, and its effects on the pharmaceutical market and access to medicines. This debate has occurred between diverse actors in both Brazil and the international community. An examination of *anuencia previa* and the debate that surrounds it, is therefore instructive on the debate over what is permissible for the treatment of pharmaceutical IPRs under the developing, yet fragmented, understanding of how TRIPS is to be interpreted. And lastly, and most importantly, ANVISA is actually denying patent protection to some applications for pharmaceutical products and processes under the power of *anuencia previa*.³⁵

V. How does it Work?

Anuencia previa is a recent development in Brazil. It was born during Brazil's legislative efforts to deal with the fact that the country began offering patent protection to pharmaceuticals for the first time in 1996.³⁶ On December 14, 1999, the Brazilian legislature created *anuencia previa* by passing Provisional Measure No. 2.006/99.³⁷ The Brazilian legislature later acted to make *anuencia previa* a permanent element of Brazil's

³⁴ European Federation of Pharmaceutical Industries and Associations, *Position Paper: Brazil*, November 2004, at www.efpia.org/4_pos/Brazil2004.pdf.

³⁵ ANVISA, Propriedade Intelectual de Produtos e Processos Farmacêuticos: Situação de Processos, at http://www.anvisa.gov.br/medicamentos/intelectual/situacao_processos.pdf.

³⁶ Rosman, *supra* note 25, at 32-33.

³⁷ Maristela Basso, *A ANVISA e a Concessão de Patentes Farmacêuticas*, VALOR ECONÔMICO, October 20, 2004; Rosman, *supra* note 25, at 33.

Industrial Property Law by passing Law 10.196/01 on February 14, 2001. Law 10.196/2001 amended Article 229-C of Law 9.279/96 to include the stipulation that the grant of all patents for pharmaceutical products and processes was subject to ANVISA's prior approval.³⁸

It is interesting to note that the creation of the *anuencia previa* program, which gave ANVISA veto power over the granting of pharmaceutical patents, coincided with the creation of ANVISA itself. ANVISA was created in 1999 as part of the government's efforts to adopt new measures to reorganize the monitoring and surveillance of medicines within Brazil.³⁹ The creation of *anuencia previa* seems to have been part of this government effort to reform the regulation of medicines within Brazil that was the government aim behind the creation of ANVISA.⁴⁰

The remarkable thing about the legislation creating *anuencia previa* is that it is so simple and singular. Article 229-C reads in its entirety "the concession of patents for pharmaceutical products and processes will depend on the prior approval of ANVISA."⁴¹ There is no further legislative act or regulation that clarifies how this power of prior approval should be exercised.⁴² The creation of *anuencia previa* is a shotgun wedding which requires that two distinct government agencies, INPI and ANVISA, work together in the examination and granting of pharmaceutical patents.⁴³ However, the legislature has left it to the two agencies to decide how this relationship will function.

³⁸ Id.

³⁹ Silva, *supra* note 28.

⁴⁰ Id.

⁴¹ Art. 229-C of Law. 9.279/96

⁴² Rodrigues, *supra* note 25, at 4.

⁴³ Gabriel Tannus, *A Aprovação de Patentes na Contramão do Mundo*, Centro de Vigilância Sanitaria, at intranet.ensp.fiocruz.br/visa/opiniao_integra.cfm?opiniao=141.

The lack of further legislative guidance on *anuência prévia* has led to tension between ANVISA and INPI as they each have their own ideas about the proper criteria for the concession of pharmaceutical patents.⁴⁴ Activists claim that INPI often ignores their legal obligation to grant pharmaceutical patents only with ANVISA's prior approval.⁴⁵ Carlos André Passarelli, a coordinator of two NGOs dedicated to increasing access to medicines for AIDS patients, asserts that the agencies are not working in harmony, as would be hoped.⁴⁶ According to Passarelli, INPI attempts to disrupt the work of ANVISA in relation to approving pharmaceutical patents by issuing opinions contrary to those that ANVISA has published.⁴⁷ Nonetheless, relations have seemed to improve somewhat between ANVISA and INPI since the recent appointment of a new director of INPI.⁴⁸

INPI and ANVISA are independent agencies within different ministries of Brazil's federal government.⁴⁹ They have different mandates and responsibilities, and perhaps it was predictable that there would be conflict when asking them to share responsibility for the granting of pharmaceutical patents.

INPI was created in 1970 to control the granting of industrial property in Brazil,⁵⁰ and it shares a role similar to that played by the United States Patent and Trademark

⁴⁴ Rodrigues, *supra* note 25, at 4.

⁴⁵ Adriana Marcolini, *Presidente Lula Precisa Cumprir Promessa de Quebrar Patentes*, Agência de Notícias de AIDS, at www.agenciaaids.com.br/noticias-resultado.asp?Codigo=1947; ABIA and GTPI/REBRIP, Carta ao INPI, at www.aids.gov.br/final/novidades/carta_ao_inpi.asp.

⁴⁶ Marcolini, *supra* note 45.

⁴⁷ *Id.*

⁴⁸ Instituto de Direito do Comércio Internacional e Desenvolvimento (IDCID), *Nota Informativa – Assunto: Anuência Prévia da ANVISA*.

⁴⁹ INPI is part of the Ministry of Development, Industry, and Foreign Commerce while ANVISA is part of the Ministry of Health. See www.anvisa.gov.br; www.inpi.gov.br.

⁵⁰ Industrial property refers to non-copyright intellectual property, most notably patents, trademarks, and industrial designs.

Office in the United States.⁵¹ INPI's primary goal is to apply the norms of Brazil's Industrial Property Law to regulate industrial property, which includes all patentable subject matter.⁵² Law 9.279/96 establishes that inventions, including pharmaceutical inventions, are worthy of patent protection if they possess novelty, inventive step, and industrial application.⁵³ These are the general requirements applied under TRIPS for patentability, as well as in the United States. However, INPI claims that it must also always keep in mind the social, economic, legal, and technical function of intellectual property when applying Law 9.279/96.⁵⁴ The Industrial Property Law applied by INPI also accommodates the standard prohibitions on patenting any device that is against morals, good customs, security, order, or public health.⁵⁵

ANVISA has a markedly different mandate than INPI. The agency defines its mission as "to protect and promote health, ensuring the hygiene and safety of products and services and taking part in developing access to it."⁵⁶ The agency is relatively young, having been created by Law 9.782 of 1999, and can be considered analogous to the United States Food and Drug Administration in many of its duties.⁵⁷ The statutorily prescribed institutional purpose of ANVISA, which is even narrower than the agency's stated mission, reads "to promote the protection of the population's health by exercising control over the health aspects of the production and marketing of products and services subject to health surveillance."⁵⁸ Examination of pharmaceutical patents is a minor

⁵¹ Apresentação – Conheça o INPI, at www.inpi.gov.br.

⁵² Apresentação – Conheça o INPI, at www.inpi.gov.br; INPI - Legislação, at www.inpi.gov.br.

⁵³ Art. 8 of Law 9.279/96.

⁵⁴ Apresentação – Conheça o INPI, at www.inpi.gov.br.

⁵⁵ Article 18 of Law 9.279/96.

⁵⁶ ANVISA website, at www.anvisa.gov.br/eng/institution/introduction.htm.

⁵⁷ Id.

⁵⁸ Art. 6 of Law 9.782/1999. Art. 6 reads in its entirety "The institutional purpose of the agency is to promote the protection of the population's health by exercising control over the health aspects of the

responsibility of ANVISA and any mention of patent examination is noticeably absent from the agency's regulatory defined competencies.⁵⁹

The disagreement that exists between INPI and ANVISA over *anuencia previa* is founded in the fact that both agencies were created to serve Brazilian society, but by promoting different means to serve the public. INPI's mandate is to serve society by granting and regulating intellectual property rights, which are individual rights that are granted because of their ability to serve the public interest by promoting investment and innovation. In contrast, ANVISA is charged with the duty of protecting public health and promoting access to medicines, a public good in itself.

The conflict is even more diagnosable than having different government mandates, explains Edson Beas Rodrigues Junior, a member of the Institute of International Commercial Law and Development (IDCID), a Brazilian think tank devoted to promoting access to medicines. According to Rodrigues, the disagreements over the granting of pharmaceutical patents lies in the fact that INPI and ANVISA apply different criteria when examining applications for pharmaceutical patents.⁶⁰ In examining pharmaceutical patent applications, ANVISA aims to find a compromise between the protection of IPRs and the protection of public health.⁶¹ ANVISA does this by seeking to exploit the flexibilities for the treatment of IPRs that are permitted by TRIPS and reaffirmed in the Doha Declaration.⁶² In contrast, INPI simply examines the applications

production and marketing of products and services subject to health surveillance. The latter embraces premises, processes, inputs and technologies related to the same. In addition, the Agency shall exercise health and hygiene control over ports, airports and the country's borders."

⁵⁹ ANVISA website, at www.anvisa.gov.br/eng/institution/competencies.htm.

⁶⁰ Rodrigues, *supra* note 27, at 4.

⁶¹ *Id.*

⁶² *Id.*

this obligation can be waived by a member during emergency situations.²⁷³ The last important safeguard of compulsory licensing is that TRIPS requires that the patent holder be paid “adequate remuneration” for each compulsory license issued. When Brazil is compelled to limit a pharmaceutical IPR by denying it protection under *anuencia previa* for lack of other options, the applicant will never enjoy any patent right, let alone the generous safeguards associated with a program that relies on compulsory licensing.

XII. Conclusion

Brazil and the rest of the developing world have been struggling to ensure new obligations to protect pharmaceutical IPRs under TRIPS don't impede their population's access to essential medications. During TRIPS first decade, there have been developments which have clarified that the agreement should not be a detriment to public health and tried to ease the fears of the developing world. The Doha Declaration was important for affirming members had an absolute right to fully use the flexibilities of TRIPS in pursuing an agenda to ensure access to essential medications. Exactly how this should be done has proved a difficult dilemma for Brazil.

In 1999, Brazil implemented the program of *anuencia previa*, which charged the Ministry of Health with granting final approval for all patent applications for pharmaceutical products and processes. The law, and the vagaries of its implementation, has created a vigorous debate within Brazil over the law's legitimacy. The analysis of the debate over *anuencia previa* shows that a group's views on the law are determined by interest the group is trying to defend. Groups that have an agenda of promoting public health uniformly support *anuencia previa*, while groups that benefit from pharmaceutical

²⁷³ Article 31(b) of TRIPS.

IPRs uniformly denounce the law. The debate further demonstrates that TRIPS is able to accommodate different views on the legitimacy of a law such as *anuencia previa* and that the developed and developing world still have different interpretations on where TRIPS establishes the balance of rights between pharmaceutical IPRs and access to essential medicines.

Anuencia previa is also gaining importance in Brazilian relations with the developed world. The United States and multinational pharmaceutical companies have made known their concerns over *anuencia previa*. They argue it is in conflict with Brazil's obligations under TRIPS for its lack of transparency and discrimination towards pharmaceutical patents. The concern of the United States government over *anuencia previa* appears to be growing, and the possibility of a complaint within the WTO over the law is always a possibility. Brazil responds by pointing towards the objectives and principles of TRIPS and, more importantly, the Doha Declaration as vindication for a law meant to protect public health.

After examination of what is known of *anuencia previa*, the law appears to be in conflict with Brazil's obligations under TRIPS. Even if the law could be reformed to meet TRIPS obligations, Brazil would be wise to simply abandon the contentious law in pursuit of other options. Brazil's treatment of IPRs is far from perfect. The developed world and multinationals will not be satisfied until Brazil effectively enforces its intellectual property. The United States and pharmaceutical companies have been particularly wary of Brazil's treatment of pharmaceutical patents. Having a law such as *anuencia previa* can only serve to encourage those cynics who believe Brazil is deliberately neglecting its obligation to protect pharmaceutical IPRs.

The best option available for Brazil and the United States is Brazil's adoption of a program that would rely on compulsory licensing to limit pharmaceutical IPRS when necessary to ensure access to medicines. If done with respect to the requirements of Article 31, such a program would find great support in TRIPS and the Doha Declaration. Use of compulsory licenses would be more effective than *anuencia previa* in protecting both public health and the intellectual property rights of holders of pharmaceutical patents.

But much of blame for why a problematic law such as *anuencia previa* exists must fall on the developing world, and especially the United States. The United States' aggressive stance towards Brazil's flirtation with compulsory licensing has left the country in a position where it has little faith in compulsory licensing as the savior of public health. Until the United States improves its receptiveness to the idea that compulsory licensing is sometimes necessary to ensure access to drugs, Brazil will continue to see the granting of a pharmaceutical patent as a bargain they can not get out of. And Brazil will rely on programs such as *anuencia previa*, which seek to exclude some pharmaceuticals from patent protection.

Brazil and the United States will not resolve their differences in opinion over the correct balance between pharmaceutical IPRs and access to medicines overnight. The debate over *anuencia previa* demonstrates that they still have divergent views over how TRIPS is to be interpreted in a post-Doha world. However, the suggestions presented in this paper could help diffuse the tension that currently exists. In choosing an agenda that relied on compulsory licenses to protect access to medicines, Brazil could abandon *anuencia previa* to show that it respects the United States' interest in protecting

pharmaceutical IPRs abroad. Likewise, the United States could move to show it respects Brazil's need to protect public health by presenting a less intimidating attitude towards Brazil's potential use of compulsory licensing. In moving to show respect for each others interests, perhaps the dialogue on how to ensure access to essential medications under the TRIPS regime could eventually converge on a place of shared understanding.