ISSN 1900-6381

# ECUADOR'S VIAGRA® CASE DIVERGENCE BETWEEN COMPETITION AND INTELLECTUAL PROPERTY

David A. Sperber[1]

Abstract

The convergence between competition and industrial property is a relevant matter of discussion and study. This paper analyzes patent protection and the constitutional right to petition through precautionary measures to protect said rights, contrasted with competition and the possibility of abuse of dominant position based on a patent. Therefore, we analyzed the first case decided in Ecuador, which imposed a sanction by the Competition Authority on this matter, *Swiss & North Group versus Pfizer* in 2011.

**Key words:** Industrial property; patents; competition law; abuse of dominance; right to petition.

1 David A. Sperber. Partner. AntiTrust Consultores & Abogados, Quito - Ecuador www.antitrust.ec. First National Advisor of the Ecuadorian Competition Authority at the Ecuadorian Ministry of Industry. J.D. Pontificia Universidad Católica del Ecuador. LL.M. Harvard Law School 02'. Ph.D. Universidad de Barcelona 12'. Professor Universidad Internacional del Ecuador. dsperber@antitrust.ec; davidspeber@hotmail.com.

# *EL CASO DEL VIAGRA EN ECUADOR: DIVERGENCIA ENTRE LA LIBRE COMPETENCIA Y LA PROPIEDAD INTELECTUAL.*

*Resumen*

*entre la libre competencia y la propiedad industrial existe una estrecha relación y discusión, razón que lo convierte en un tema relevante para estudio. Este trabajo analiza la protección de los derechos de patente y el derecho constitucional de petición incluyendo las medidas preventivas o cautelares para precautelar su derecho, frente a ello la competencia económica y la posibilidad de efectuar abuso de posición de dominio can base al derecho de propiedad intelectual. Por ser ello de gran interés, analizamos el primer caso en Ecuador, Swiss & North Group versus Pfizer en 2011, en el cual la Autoridad de Libre Competencia dictó sanción contra el titular de la patente.*

***Palabras clave:*** *propiedad industrial; patentes; libre competencia; abuso de posición de dominio; derecho constitucional de petición.*

## I. Introduction

The convergence between antitrust and industrial property rights has and continues to be the subject of innumerous discussion and study[2]. For this reason, we will analyze the decisions and case law relevant to this current conflict in Ecuador.

2 See e.g. Bowman Ward S. WSB. Patents and antitrust law: A legal and economic appraisal. Chicago. 1973.; American Bar Association, Section of Antitrust Law ABA. U.S. Antitrust law in international patent and know-how licensing. Chicago Ill. 1981.; Holmes William C. WCH. Intellectual property and antitrust law. New York. 1986.; Baxter William F. WFB., "Legal restrictions on exploitation of the patent monopoly. An economic appraisal". *Yale Law Journal*. 1966.

Antitrust, on the one hand, is the branch of law that studies both policies and anticompetitive conducts, where competition is based on the freedom of decision or choice of market players along with clear rules. Ecuador's National Antitrust Law, *Ley Orgánica de Regulación y Control del Poder de Mercado* (LORCPM[3]) enacted in 2011, has as its goal to protect the competitive process and proscribe anticompetitive practices all in defense of the general well-being and of consumers[4].

Given that there is not a specific rule as to how to investigate and analyze conducts where an interaction between antitrust and industrial property rights[5] takes place, such as patent licenses, restrictions on competitors and abuse of dominant position must fall under Articles 7 and 8 of Decision 608 of the Andean Community, or its European and U.S. equivalents: Articles 101 and 102 of the Treaty on the Functioning of the European Union and Articles 1 and 2 of the Sherman Act (and subsequent legislation), respectively.

This paper will not focus on the treatment given by antitrust law to license contracts and transfer of technology. Refusal to license to competitors at the same level of the supply chain is

3 Ecuadorian Competition Law, Ley Orgánica de Regulación y Control de Poder de Mercado LORCPM. Ecuador. R.O. S. 555. 13-X-2011.

4 Ecuadorian Competition Law Ley Orgánica de Regulación y Control de Poder de Mercado LORCPM. Art. 1. "The object of this Law is to avoid, prevent, correct, eliminate and sanction the abuse of economic agents with market power; the prevention, prohibition and sanction of collusive agreements and other restrictive practices; the control and regulation of concentrations; and, the prevention, prohibition and sanction of disloyal commercial practices, seeking market efficiency, fair commerce and the general well-being and that of consumers and users, for the establishment of a social, solidarity and sustainable economic system".

5 An exception to this is, Rule CE of technology. Commission Rule (CE) n° 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements. April 27, 2004.

not illicit[6], although, it can still be analyzed as a potential abuse of dominant position. Case law in other countries has authorized the granting of compulsory licenses because of harm caused to competition, like in the European case *Windsurfing International Inc.*[7], or when it is a health or public emergency. Furthermore, in the Ecuadorian *Viagra case*, we analyzed a pharmaceutical for human use, which is a means to access the right to health, a fundamental right contained and protected by the Ecuadorian Constitution[8].

## II. Legal Framework

### 1. Industrial Property: Applicable Legislation In Ecuador

With regards to industrial property, the main applicable legislation is the following:

1. Constitution of the Republic of Ecuador[9].
2. Paris Convention for the Protection of Industrial Property[10].
3. Trade-related aspects of intellectual property rights (TRIPS) [11].

---

6 See "Data General v. Grumman Systems Support, 36 F.3d 1147 (1st. Cir. 1994)". *U.S. Case Law*. 1994.

7 See "Windsurfing International Inc. c. Commission, Case 193/83". *European Court of Justice*. 25-II-1986.

8 Constitución de la República del Ecuador CRE. Ecuador. R.O. 449. 20-X-2008. See Art. 32.

9 CRE. Ecuador. R.O. 449. 20-X-2008. See Art. 322.

10 Paris Convention for the Protection of Industrial Property as amended on September 28, 1979. See Art. 5." (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

11 "Trade-Related Aspects of Intellectual Property Rights". *WTO Uruguay Round Agreement: TRIPS*. Marrakesh, Morocco. April 15, 1994. Art. 40.

4. Andean Community Decision 486, Industrial Property[12].
5. Intellectual Property Law[13] and its Rules[14].
6. Presidential Decree 118[15].

According to Article 2 of the 486[16] Decision and Articles 131[17] and 170[18] of the Intellectual Property Law, a patent has territorial protection in the country where it is registered. The Paris Convention, which Ecuador ratified on 1999[19], establishes the obligation that member countries must recognize intellectual property rights recognized in other member countries.

The patent can protect a new procedure, a new instrument, a new product or an improvement[20] on those. Because of this, the 486 Decision and the Intellectual Property Law distinguish between a product patent[21] and a procedure patent[22]. Generally, a product patent provides greater legal protection to pharmaceutical products than that afforded by a procedural patent, given

12 "Régimen Común Sobre Propiedad Industrial". *Decisión del Acuerdo de Cartagena 486.* R.O. 258. 02-II-2001.

13 Ley de Propiedad Intelectual LPI. Ecuador. R.O. S. 426. 28-XII-2006.

14 Reglamento a la Ley de Propiedad Intelectual RLPI. Ecuador. R.O. 120. 01-II-1999.

15 Instructivo Concesión Licencias Obligatorias de Patentes de Fármacos. Ecuador. R.O. 141. 02-III-2010.

16 "Régimen Común Sobre Propiedad Industrial". *Decisión del Acuerdo de Cartagena 486.* R.O. 258. 02-II-2001. Art. 2.

17 LPI. Ecuador. R.O. S. 426. 28-XII-2006. Art. 131.

18 LPI. Ecuador. R.O. S. 426. 28-XII-2006. **Art. 170.**

19 Paris Convention for the Protection of Industrial Property as amended on September 28, 1979.

20 "Transferencia de tecnología". *http://www.madrimasd.org/transferencia-tecnologia/proteccion-de-la-innovacion/propiedad-industrial/patente/default.aspx.*Last visited 1-IX- 2013.

21 "Régimen Común Sobre Propiedad Industrial". *Decisión del Acuerdo de Cartagena 486.* R.O. 258. 02-II-2001.

22 Ley de Propiedad Intelectual LPI. Ecuador. R.O. S. 426. 28-XII-2006.

that other manufacturers can find a mechanism to circumvent the procedural patent of an active ingredient if no product patent is present. As such, the active ingredient is the most valuable part of a pharmaceutical[23].

### 1.1 Patent Rights

The World Intellectual Property Organization (WIPO) has stated that a patent is "an exclusive right granted for an invention- a product or process that provides a new way of doing something, or that offers a new technical solution to a problem. A patent provides patent owners with protection for their inventions; protection is granted for a limited period"[24], which in the Andean Community and Ecuador is for 20 years[25].

The ownership of a patent or any intellectual property right does not *per se* confer market power, as it is understood under the antitrust statutes[26]. The holder of a patent might be motivated to create, carry out or force anticompetitive conditions as a way to establish or increase benefits or monopolistic profits. On the contrary, antitrust law seeks to protect effective competition between efficient economic agents[27]. Productive efficiency is transferred to consumers in the form of lower prices, greater quality and variety of products, generating an increase in social welfare.

---

23 See "Case COMP/A.37.507/F3, AstraZeneca". *EU Commission*. 15-VI-2005. pg.5.

24 "What is Intellectual Property?". *World Intelectual Property Organization WIPO. http://www.wipo.int/export/sites/www/freepublications/en/intproperty/450/wipo_pub_450.pdf*. pg.4.

25 "Régimen Común Sobre Propiedad Industrial". *Decisión del Acuerdo de Cartagena 486*. R.O. 258. 02-II-2001. Also, Ley de Propiedad Intelectual LPI. Ecuador. R.O. S. 426. 28-XII-2006. Art. 50.

26 See e.g. "Tiboni y Cía. c. Sorensen y Cía". *Comisión Nacional de Defensa de la Competencia CNDC*. 18-VIII-1981.

27 See Ley Orgánica de Regulación y Control del Poder De Mercado LORCPM. Ecuador. R.O. S. 555. 13-X.-2011. Art. 2.

## 2. Antitrust Legislation Applicable In Ecuador

The main applicable legislation in Ecuador:

1. Constitution of the Republic of Ecuador[28].
2. Andean Community Decision 608, "Rules for the protection and promotion of competition within the Andean Community".
3. Andean Community Decision 616, "*Entry into force of Decision 608 for the Republic of Ecuador"* (suspended by the LORCPM) and the Presidential Decree 1614[29] (repealed by the LORCPM).
4. Ecuador's National Competition Law - Law for the Regulation and Control of Market Power *(Ley Orgánica de Regulación y Control de Poder de Mercado* - LORCPM).
5. Rules to Ecuador's National Competition Law (*Reglamento de Aplicación a la Ley Orgánica de Regulación y Control de Poder de Mercado* - RALORCPM).

Due to a lack of a national competition law and Ecuador's obligation (until October 2011), established in Article 2 of the 616 Andean Community Decision that stated that "At the latest August 1, 2005, Ecuador must name its interim National Competition Authority who will be the one in charge of enforcing the 608 Andean Decision", a claim was filed before the Secretariat-General of the Andean Community alleging Ecuador's failure to comply with its obligation[30]. As a result of said claim, the Ecuadorian government enacted the Presidential Decree 1614. It is important to note that Article 1 of the 616 Andean Community

28 Constitución de la República del Ecuador CRE. Ecuador. R.O. 449. 20-X-2008. Arts. 304, 335, 336, 363.7.

29 Decreto Presidencial 1614. Ecuador. R.O. No. 558. 27-III-2009.

30 Andean Community General Secretariat. Secretaria General de la CAN. Resolution 03-2009, G.O.A.C. Year XXVI, No. 1723, 10-VI-2009.

Decision states that Ecuador can apply as a national law Andean Community 608 Decision, until Ecuador enacts its own national antitrust law. Said Decree determined, among other things, a special procedure for this subject and the Ministry of Industry and Productivity (MIPRO) as Ecuador's national interim competition authority.

### 2.1 Anticompetitive Conducts.

While the Presidential Decree 1614, the only rule in Ecuador that regulated the application of the 608 and 616 Decisions, detailed the investigative procedure that the authority and parts had to follow, the anticompetitive conducts were typified in the supranational law -Andean Community 608 Decision-; Article 9 of the 608 Decision defines dominant position and Article 8 typifies it[31]. In addition, Articles 7, 8, 9 and 34 of this Decision determine that current and potential economic agents within a market have standing in an antitrust investigation.

Being that both antitrust law and intellectual property law are part of the same legal system, they share common goals including promoting economic efficiency and the general economic well-being. Patent rights restrict competition with relation to the scope of the patent, while antitrust law seeks to undue restrictions to the competitive process.

## 3. Industrial Property And Antitrust

We must highlight that these two branches of the law look to promote and improve economic welfare and increase economic efficiency through different avenues. Patent law restricts competition with regards to scope of the patent during a determined

31 Decisión 608 Normas para la protección y promoción de la libre competencia en la Comunidad Andina. R.O S. 18 de 25-feb.-2008. Art. 8.

time period, usually 20 years, after which it can be freely exploited. Meanwhile, antitrust law tends to prohibit any restriction to competition. When these two branches converge, discrepancies between the two can become apparent. In determining which of the two prevail -industrial property or antitrust-, Article 83 of the Ecuadorian Constitution makes it clear that the latter prevails, since said Article dictates that the rights of the collectivity must prevail over those of individuals.

## 4. Case Law Related To Abuse Of Dominant Position And Patent Rights

### 4.1 European Union. ITT Promedia NV[32].

In *ITT Promedia NV v. European Commission*, ITT Promedia requested the annulment of the Commission decision because according to them the suits presented against Belgacom SA before Belgian tribunals were not vexatious.

Until 1995, Belgacom S.A. and ITT Promedia NV had an agreement in which Belgacom granted ITT an exclusive right to publish and distribute telephone books from a database provided by Belgacom. The parts negotiated a renewal of the contract without reaching an agreement, and a month later ITT Promedia announced that it would continue publishing the telephone books. To this, Belgacom responded by suggesting that ITT was infringing their intellectual property rights.

The European General Court considered of great importance the right to petition the government. We must not forget that economic operators that hold a dominant position can be forbidden from adopting certain conducts or actions, which are not in them-

32 "ITT Promedia NV v Commission of the European Communities T-111/96, Judgment of the Court of First Instance (Fourth Chamber, extended composition". *Court of First Instance*. July 17th, 1998.

selves abusive or reproachable if they would have been adopted or carried out by a non-dominant operator.

In its ruling, the Court makes it clear that an effective access to justice is a fundamental right and established 2 criteria to determine if an action is abusive:

1. When it is "manifestly unfounded," in the sense that it cannot reasonably be considered an attempt to establish the rights of the undertaking concerned; and
2. Was conceived as part of a plan to eliminate competition.

### 4.2 European Union. AstraZeneca[33]

AstraZeneca (AZ) was investigated for hindering and delaying the entry of generic versions of Omeprazol in some European countries. One of the conducts that was investigated were the false statements made by AZ before patent offices in Belgium, Denmark, Germany, Norway, the Netherlands, and the United Kingdom, as well as, before national courts in Germany and Norway. Additionally, AZ deregistered marketing authorizations for the capsule form of the drug Losec, while introducing a tablet form.

This misleading information induced errors that allowed AZ to maintain the concession of an exclusive right, constituted a practice contrary to antitrust law, and as such its acts were considered abusive.

### 4.3 U.S. Noerr –Pennington Doctrine

U.S. jurisprudence related to sham litigation finds its beginnings in the Noerr-Pennington Doctrine[34], and the consequent exception

33 "Caso AstraZeneca vs Comisión Europea". Causa T-321/05. UE. *Tribunal General.* Sentencia de 1-VII-2010.

34 See "Eastern Railroad Presidents Conference (ERPC) v. Noerr Motor Freight, 365 U.S. 127" *U.S Supreme Court*. 1961.; y "United Mine Workers v. Pennington, 381 U.S. 657". *U.S Supreme Court*. 1965. See also, ABA Section of Antitrust Law.

of sham to this doctrine; exception that established the general parameters to determine if a petition is not immune from antitrust scrutiny.

In the first case, Noerr and ERPC were competing firms in the heavy load long distance transportation market. ERPC using a public relations company carried out actions looking to have the government adopt regulations which would penalize trucking companies that circulated Pennsylvania roads, something that Noerr considered violated the Sherman Act. The Supreme Court ruled that, "No violation of the Sherman Act can be predicated upon mere attempts to influence the passage or enforcement of laws".

The Pennington case arises from a controversy between trustees of *United Mine Workers of America (UMW)* and *Pennington*, because the UMW through the Secretary of Labor obtained that a higher minimum salary be established for the carbon industry than for other industries. The Supreme Court found that no violation of the Sherman Act could arise from influencing public officials to modify a law, ratifying Noerr.

*A posteriori*, the Supreme Court in *California Motor Transport Co. v. Trucking Unlimited*[35] ruled on an exception to the Noerr-Pennington Doctrine, establishing that said immunity is non-applicable when the acts are a sham to cover the intention to interfere in the activities of a competitor through the filing of actions before judicial and administrative bodies, thereby abusing their right to petition. The *Noerr-Pennington Doctrine* is an expression of the prevalence of the freedom of speech and in particular the right to petition the government. In *California Motor Transport Co.* the Court clarifies that antitrust immunity extends

Monograph 25, The *Noerr-Pennington* Doctrine. Chicago: ABA Publishing. 2009.

35 "California Motor Transport Co. V. Trucking Unlimited, 404 U.S. 508". *U.S Supreme Court.* 1972.

both to administrative and judicial bodies[36], as long as its use and application does not constitute an abuse of the right to petition.

### 4.4 U.S. Lasercomb America Inc[37].

In *Lasercomb America, Inc.,* the Federal Court of Appeals determined that the granting of special privilege to an inventor through a patent has the purpose, as per established in the Constitution, to promote scientific progress and of the arts through the granting for a limited time of an exclusive right to the invention. However, a patent cannot be used to protect or ensure a right that has not been granted by the Patent Office or that is contrary to the public policy related to the granting of patents. With relation to this, the Supreme Court made reference to *Morton Salt Co. v. G.S. Suppiger*[38], one of the first cases where a patent misuse defense was alleged by the defendant. In said case, the plaintiff Morton Salt sued based on the fact that the defendant had infringed its salt machine patent. The patent did not protect the salt machine tablets, but the license that Morton Salt granted for the use of its patent required that the beneficiary of the licenses use only the salt tablets produced by Morton. Because of this, the Court determined that Morton Salt used its patent to restrict competition. The High Court ruled that it would not help Morton Salt protect its patent given that Morton had used said patent in way contrary to public policy.

---

36 Fischel Daniel R. DRF. Antitrust Liability for Attempts to Influence Government Action: The Basis and Limits of the Noerr-Pennington Doctrine. University of Chicago Law School. 1977, p. 86.

37 "Lasercomb America, Inc. v. Reynolds. 911 F.2d 970 (4th. Cir. 1990)". *U.S Court Appeals*. 1990.

38 "Morton Salt Co. v. G.S. Suppiger, 314 U.S. 488, 62 S.Ct. 402, 86 L.Ed. 363". *Supreme Court.* 1942.

### 4.5 Ecuador. Constitutional Court.

The Ecuadorian Constitutional Court[39] ruled in the case *Acromax versus Pfizer* (2009) regarding two injunctions granted against the pharmaceutical drug Max (Sildenafil) sold by Acromax. The Court resolved that misleading assumptions were presented by the petitioner on which the injunctions were granted, so abuse of the right to petition existed and the injunctions granted monopolistic commercial advantages to one party (Pfizer).

## III. The Antitrust Case Of Viagra In Ecuador

We summarize the relevant facts and issues raised in the first sanctioned case by the Ecuadorian Competition Authority.

### 1. Parties

*a. Plaintiff-*

In July 2009 the Ecuadorian economic group[40] SWISS & NORTH GROUP SA ( SNG), a generic drug manufacturer, presented a claim before the Ministry of Industry and Productivity (MIPRO) alleging breach of Decision 608 of the Andean Community for anticompetitive practices (Article 7), abuse of dominant position (Article 8) and unfair competition against PFIZER.

39 "Resolución 024-09-SEP-CC". *Corte Constitucional*. Ecuador. 29 – IX - 2009.

40 The companies SIONPHARM CIA. LTDA.; SWISS & NORTH GROUP S.A.; BIODENTAL CIA. LTDA.; VARTRAXHEALTH S.A.; GINSBERG ECUADOR S.A.; REPRESENTACIONES WHITEHOUSE S.A.; y HELSINNPHARM CIA. LTDA. were declared an economic group according to Art. 1 of Decisión 608 Normas para la protección y promoción de la libre competencia en la Comunidad Andina. R.O. S. 18. 25-II-2008.

*b. Defendants*

Pfizer Ireland Pharmaceuticals (owner and holder of patents) and its related companies Pfizer Cia. Ltda. (Ecuador) and Pfizer Overseas Pharmaceuticals Co., hereinafter PFIZER.

## 2. FACTS

In synopsis, SNG in 2004 obtained the governmental approvals to sale "Medovigor" (active ingredient Sildenafil) and the same product under the commercial names "Sildenafil 50" and "Vigoril 50") containing Sildenafil. PFIZER solicited and obtained precautionary measures against SNG on June 26th, 2006 before a Civil Judge for alleged violation of its patent for a process for the preparation of Sildenafil marketed under the brand name Viagra®.

## 3. ALLEGED INFRINGEMENT

The complainant presented by SNG was for an alleged infringement of Articles 7.a., 8.b., 8.g. and Article 9 of Decision 608 of the Andean Community and unfair competition, since "Pfizer illegally monopolized the active ingredient Sildenafil which serves for the production of various medicines, especially for erectile dysfunction under the brand name VIAGRA®" and that PFIZER abused its dominant position in the relevant market by presenting illegal administrative and judicial lawsuits creating artificial barriers to entry for competitors with products containing the active principle Sildenafil.

## 4. RELEVANT MARKET

### 4.1 PRODUCT MARKET

In this case, the relevant product market is the active ingredient (in some pharmaceutical cases is not applicable de active ingre-

dient to define the relevant market) the Sildenafil for medical use for the treatment of sexual impotence or erectile dysfunction in men, even though at first it was used for high blood pressure and angina. From the supply side of Sildenafil, legal barriers exist for the sale of the product since it is a medicine, which are:

1. Sanitary registration.
2. Maximum ex-ante sale price resolved by a governmental agency[41].

According to Article 7 of the Instructions for Drug Pricing, "The medical records must be current and on behalf of the company submitting the application for the establishment or revision of prices to the National Council on the date of filing of the application [...]".

From the demand side, legal and practical barriers exist to purchase Sildenafil (prescription restricted drug - Ox) by a patient (end consumer):

1. Doctor's visit.
2. Physician exams and tests.
3. Doctor's prescription specifying the active ingredient to treat erectile dysfunction.

Each of these active principles are a specific relevant market; Sildenafil, Tadalafil[42] (i.e. Cialis®) and Vardenafil[43] (i.e. Levitra®) are three unique markets and distinctive, therefore separate

41 Reglamento Fijación de Precios Medicamentos de Uso y Consumo Humano. Ecuador. R.O. S. 299. 29-VII-2014.

42 See (6*R-trans*)-6-(1,3-benzodioxol-5-yl)- 2,3,6,7,12,12a-hexahydro-2-methyl-pyrazino [1', 2':1,6] pyrido[3,4-*b*]indole-1,4-dione

43 See p.e. 4-[2-ethoxy-5-(4-ethylpiperazin-1-yl)sulfonyl-phenyl]- 9-methyl-7-propyl- 3,5,6,8-tetrazabicyclo[4.3. nona-3,7,9-trien-2-1.

and independent. Another factor to consider is that the process patent of Pfizer's Viagra® and other Sildenafil process patents (e.g. Max®, Xex®, Vigoril®, Davigor®, Medovigor®, Venux®) correspond only to the active ingredient Sildenafil. Meanwhile Tadalafil and Vardenafil constitute different patents; so the owner of a patent of Sildenafil -such as Pfizer- should not prevent the use by others of another active principle (i.e. injunction) that produces, distributes or sale drugs containing other active ingredient. Also, given that Sildenafil is not interchangeable with Tadalafil and Vardenafil, each active ingredient constitutes for competition purposes a different market. The explanation given by the Undersecretary of Competition was clear and convincing as to provide a solid legal basis concluding the relevant market of Sildenafil as a unique relevant market.

### 4.2 Geographic market.

Since the government approval for sale of Sildenafil was nation wide, the relevant market in this case is the Ecuadorian territory. Moreover, none of the parties objected the geographic market definition.

### 4.3 Temporary Market.

The temporary market seeks to define the timeframe of the anticompetitive conduct. In this process, the conduct complained started on May 26, 2006 when the Civil Court ordered the injunction and the preventive measures were implemented successively and simultaneously until April 2011 (date of the resolution of this case by the Minister of Industry and Productivity).

## 5. Market Power And Abuse Of Dominant Position Based On A Patent

### Dominant position and precautionary measures

PFIZER in various civil lawsuits in Ecuador raised and implemented precautionary measures, including the following:

a. Prohibition to import the raw material containing the active principle Sildenafil by officiating the Ministry of Public Health and the Customs authority.
b. Refrain the Ministry of Public Health from granting authorizations or permits of any nature that allow the import and sale of Sildenafil.
c. Prohibition to market and/or sale of the drug in Ecuador subject to injunction.
d. Withdrawal from commercial channels of the product containing Sildenafil.

Over the years, PFIZER has sought to eliminate actual and potential competitors of SILDENAFIL, such as[44]:

1. ARYL S.A. (2004; 2005).
2. Medicamentos Ecuatoriana S. A., Acromax S.A., Rocnarf S.A y Distribuidora Francor S.A (2005; 2006).
3. Laboratorios Chalver del Ecuador (2005).
4. SWISS & NORTH GROUP S.A. (2007).
5. Ginsberg Ecuador S.A. y Biodental Cía. Ltda. (2008).
6. MagicSex (2008).
7. Vartrax Health S.A y Ginsberg Ecuador S.A. (2008).

44 See Ministerio de Industrias y Productividad MIPRO. Ecuador. Process No. I-C-17885-2009-SCS and case No. MIPRO-001-2011.

### 6. Resolution and Fine

In this case, the implementation of precautionary measures by PFIZER based on its patent rights restricted, affected and substantially distorted the market for erectile dysfunction of Sildenafil, in violation of paragraph g) of Article 8 of Decision 608 of the Andean Community for abusing its dominant position. Therefore, the Ministry of Industry and Productivity (MIPRO) sanctioned PFIZER CIA. LTDA. (Ecuador), PFIZER IRELAND PHARMACEUTICALS and PFIZER RESARCH AND DEVELOPMENT and resolved:

1. Pfizer should desist from all precautionary measures and other actions related to the active ingredient Sildenafil regarding the complainant.
2. A fine of USD $ 549,183 U.S. dollars.

## IV. Conclusions

The convergence between competition law and industrial property remains a matter of discussion and analysis by the doctrine and jurisprudence. Patent Law is an exception to antitrust law, since a patent is a temporary legal monopoly and recognized as such by international and national legislation. However, the holder of an industrial property right is forbidden to abuse his rights.

The abusive behavior of administrative and judicial measures in order to prevent or affect an actual or potential competitor in the relevant market is complex, since it constitutes a limitation on the right to petition guaranteed by the Constitution.

Decision 616 of the Andean Community "nationalized" Decision 608, which defines anti-competitive behavior in the Andean sub-regional framework. Even though Decision 608 exemplifies some of the acts of abuse it includes a general prohibitory clause, novel for Ecuadorian legislation and case law.

The Presidential Decree No. 1614 of 2009 constituted and implemented the procedure to apply Decision 608 to local cases, until enactment of the new Organic Law for the Regulation and Control of Market Power (2011).

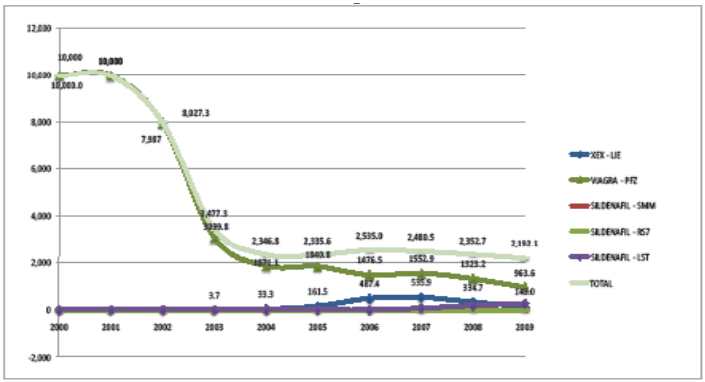
In the analyzed case, SWISS & NORTH GROUP SA denounced PFIZER for anticompetitive practices (Article 7 of Decision 608 of the Andean Community), abuse of dominant position (Article 8) and unfair competition; being discarded anticompetitive practices and unfair competition.

The Ecuadorian Competition Authority based on the evidence and declarations on the record declared and confirmed that PFIZER in Ecuador had dominant position in the relevant market of Sildenafil (brand name Viagra®), and in consequence had abused it. The abuse of market power occurred by imposing unwarranted judicial and administrative precautionary measures that seriously affected competition. This is the first case in Ecuador in which a company was sanction and fined with over half a million dollars for abuse of its dominant position.

# ANNEX I

Índice HHI

Mercadeo de Productos con el Principio Activo Sildenafil en el Ecuador

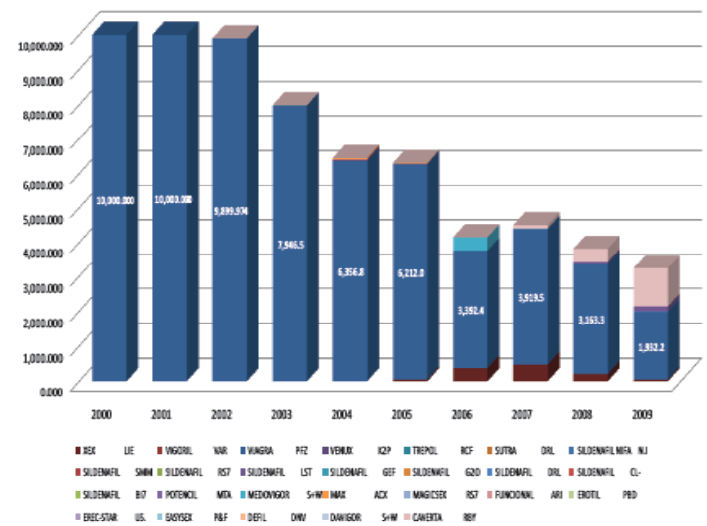



**FUENTE: Ranking IMS**
**ELABORACIÓN: Subsecretaría de Competencia**

Índice de Dominancia

Mercadeo de Productos con el Principio Activo Sildenafil en el Ecuador

Índice de Dominancia del Mercado del Sildenafil en Dólares




**FUENTE: Ranking IMS**
**ELABORACIÓN: Subsecretaría de Competencia.**