NOBOA PAGÁN ABOGADOS
ACTUALIDAD REGULATORIA BOLETIN INFORMATIVO

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Editor's Note. *Schering-Plough Corporation, Upsher-Smith Laboratories, Inc. v. FTC.*[1] New evaluation criteria for patents and licenses' restriction of commerce reasonability.

Last March 8th, the Eleventh Circuit Court of the United States Court of Appeals ("Court of Appeals") made an important decision in the referred case, object to diverse commentaries and debates within the American Bar Association. The Pharmaceutical companies elevated request for review a resolution given by the United States Federal Trade Commission ("The Commission") that commands them to desist from taking part in certain transactions and agreements subscribed between S*chering- Plough Corp ("Schering")* respectively with another two companies, in the form of arrangements for demands referring to the violation of patents held by *Schering*. In the agreements, the two companies yielded to the petition made by *Schering*, to suspend the research, development, production, marketing and sales for a period of time, in exchange to monetary severance.

It is interesting to highlight that the underlying aspect that was brought to the courts by the appellants, is the existence or non-existence of sufficient evidence to support the Commission's decision, in the sense that the above mentioned agreements, restrict the commerce irrationally, in light of Section 1 of the United States Antitrust Law and other dispositions.

Schering is a known pharmaceutical company that develops markets and sells a variety of drugs based on scientific research. *Schering* develops and manufactures a micro-encapsulated product of chlorine and potassium, named K-Dur 20. This product is a supplement, generally taken together with drug treatments for high blood pressure or congestive heart disease. The active ingredient in K-Dur 20, potassium chloride, is of common use and not patentable. However, Schering, owns a formulation patent on the extended-release coating, which surrounds the potassium chloride in K-Dur 20; the patent expires on 2006.

Both *Upsher-Smith Laboratories*, and *ESI Lederle, Inc.*; *Schering* competitors, manufactured generic versions of K-Dur 20 (Klor Con M20 and Micro K-20), for which they requested FDA approval which consequently brought on several demands for patent infringement initiated by *Schering,* and that were finally resolved by way of agreements subject to test in the decision made last March by the Court of Appeals.

In 2001, more than 4 and 3 years respectively form the subscription of the before mentioned agreements, the Commission submitted an administrative resource in virtue of the *Sherman Law,* before mentioned, considering that *Schering* attempted to monopolize and conspired to monopolize the potassium supplement market. In first instance, the *Administrative Judge Law* or "ALJ" considered that the agreements were legal and a legitimate transactional method for patent demands and dismissed the claim. The ALJ considered the theories that the agreements were anticompetitive, if there was a presumption at least, that S*chering's* patent was invalid or that the generic products did not infringe *Schering's* patent. The ALJ did

[1] No. 04-10688 Agency No. FTC 9297, March 8, 2005.

not find evidence of any of these two possible causes. ALJ noted out, in addition, that the presence of transactional payments did not constitute per se a violation of the Antitrust Law. The ALJ considered that the strength of the patent by itself and its excluding power deserved to be evaluated. Specifically, it was taken into account that the Commission was not capable of proving to the ALJ the presence of payment, be them for the results of litigation or by conventional agreement, were going to delay the early entrance of generics to the market or that in their absence, these would enter more opportunely in the market. Finally, the AJL did not find evidence of the possession of an illegal monopoly by *Schering* on the potassium chloride supplement.

Taking into account important precedents, the Court of Appeals revised all the evidence to come to a conclusion in respect to the rationality of the Commission's findings. To those means, the court used the substantive evidence test. Being this test the verification of if the transactional agreements violate the Anti-trust Law by they restringing the commerce irrationally, several criteria from previous decisions, among those: (1) The ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue [2]. Modifying previous judgments decided that the "*monetary payments made for the alleged infringer of the right of competition as a part of a transaction does not constitute a violation per se of the Antitrust law".*

(2) The ALJ analyzed the Schering agreements according to the rule of reason analysis. This method takes into account if the restriction imposed is such, that regulates and maybe promotes competition or, if on the contrary is the type that suppresses or destroys competition [3]. However, while the ALJ continued the standard Rule of Reason test, that takes into account a) the strength of the patent; b) defines the geographic and product markets; c) calculates the market shares; and, d) afterwards, makes inferences regarding the market shares and other characteristics of the industry; from its part, the Commission considered this standard Rule of Reason procedure adequate and substituted it with the exception of the *Indiana Federal* case, that exonerates the relevant market test. In its place, the exception test only demands exhibiting the effects in the markets [4]. Applied to this concrete case, the Commission found that *Schering* and *Upsher* did not sufficiently establish that the challenged activities were justified by procompetitive benefits. Because of this, the Commission decided the absolute anti-competitive nature of the agreements and discounted the merits of the litigation on the patent disputed. In the opinion of the Court of Appeals, the Commission seems decided on arriving to a conclusion before considering any other alternative conclusion. Therefore, the Court of Appeals decided last March that neither

[2] Valley Drug. Co. v. Geneva Pharm., Inc., 334F.3d 1294, 1303-04 (11th Cir. 2003) (citando a NCAA v. Bd. Of Regenst Okla. Univ., 468 U.S. 85, 103, 104 S.Ct. 2948, 2962, 82 L. Ed.2d 70 (1984).

[3] FTC V. Indiana Federation of Dentist, 476 U. S. 447, 457, 106 S. Ct. 2009, 2017, 90 L.Ed.2d 445 (1986) (citing a Chicago Board of Trade v. United States, 246 U.S. 231, 238, 385, S.Ct. 232, 244 (1918).

[4] Indiana Federation 476 U.S. 460-61.

the *Per Se* Analysis, nor the Rule of Reason test were appropriate in this context. Following the Valley Drug precedent, the court considers that the correct method to test the case, seeing the presumption of the incentive to innovation that favors the right to patents, is a test to: (1) measure the reach of the patent's exclusion potential; (2) that the extension of the transactional agreements exceeds this reach; (3) and the anti-competition resulting effects.[5]

These advanced judicial criteria make us question if our legal and regulatory system in the matter of patent rights over the commercialization of prescription drugs, along with the constitutional and legal premises protect the right to competition in these and other economic activities, are sufficiently approximated by the adequate methods applied by the regulators and the competent judges. Are quantitative analysis applied, valuations and verifications that make possible the adoption of logical considerations in respects to the rationality of conducts, practices and their sanction, just as the Court did in the case, or if it's preferred, the standard followed by ALJ and the Commission?

In the matter of these industrial property rights a test of substantial evidence, demands as a minimum and analysis in regards to: a) The validity of a patent, in the understanding that it is presumed valid, if the requisites for its awarding have been met. It is important to accept the presumption of promotion of the efficiency via the incentive to innovation that the patent favors, because by its nature it awards certain authorities of exclusion to its beneficiaries, being able to decide with who it subscribes licensing agreements or not, save the hypothesis that obligate to consent obligatory licenses in conformity to the presumed points and in accordance to the procedure established by the law; b) Also, the analysis serves to verify that which the right to patent does not award, meaning, a right to extend the restriction beyond their right to exclusion. In this sense, an act that oversteps this spectrum or reach is not exempt from the provisions of the United States Anti-Trust Law and in our legal environment, of the dispositions of Article 8 Section 12 of the Constitution and complementary applicable legislation contained in Law No. 20-00[6], as well as in the ADPIC[7]. The Law No. 20-00 cannot be appreciated in black and white as a law protecting of the patent rights or of other industrial property rights. It is a legislation clearly intended with a public, social and economic imperative[8], because it guides the legislator to dispose a series of rules on the due process in the awarding, time tables and even exceptions to general rules. At the time, it is indispensable that the appreciation of the facts of the cause hat originate claim with regards to its dispositions, particularly those alleging restrictive practices, must meet a correct methodic treatment.

Quoting Judge Posner, we conclude with his significant warning: "Suppose a

[5] Valley Drug, 344 F.3d en 1312.

[6] Articles 179 and SS of Law No. 20-00.

[7] Section 8, Control of Anticompetitive Practices in Contractual Licenses.

[8] "That the legislative and institutional of the industrial property fitness regime, in consonance with the ADPIC, requires that a industrial property law contribute with the transference and diffusion of the technology, to reciprocally benefit the products and end users of the technological knowledge and so that it favors the country's social and economic well being. " (Preamble to Law No. 20-00).

seller obtains a patent that it know is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its paten in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the suit, and the settlement would be devices—masks—for fixing princes, in violation of antitrust law"[9].

Monetary and Financial Regulation.

Monetary Board Resolutions. .

The Monetary Board published last April 1st, seven resolutions dictated on March 10 and 19. Here we will enumerate the more relevant dispositions from each Resolution:

The **Fourth Resolution** from March 10, abolishes the ninth resolution emitted by the institution August 5th, 2004 and disposed that financial intermediary institutions, constituted as Savings and Credit banks, credit corporations, savings and credit associations, development banks, mortgage banks, financers, small account loan houses and National Housing and Production Incentive Bank, would be subject to similar requirements as multiple commercial banks in respects to the solvency coefficient, being this obligated minimum solvency coefficient, with no graduation, a 10%, calculated at the close of fiscal activity that concluded December 31st, 2004. In addition, this resolution establishes the procedure to be followed in case that the company had closed the fiscal year without meeting the minimum solvency and without registering or establishing the 100% of the no-graduation provisions; that starting January 2005 the above mentioned entities must apply the Rule of Assets Evaluation and determine the additional requirement of provisions by March 31st of the present year, which will be constituted progressively in a maximum period of three years; that for the coming April 30th, the entities must show the minimum solvency coefficient, because starting June, the Superintendence of Banks will conduct an evaluation of these entities to verify that they are correctly applying the Asset Evaluation Regulation of December 29, 2004 and the dispositions for the register of the total of the required provisions.

Meanwhile, the **Third and Sixth Resolution dated** March 29, approve the definite versions of the Market Risk Regulation and the modifications to point c) of table No. 1 of article 13, article 22 and table No. 9 of article 32 of the Asset Evaluation Regulation, respectively. The first of these regulations abolishes the Fourth Resolution dated January 9, 2001 and its modifications, article 24 of the Prudential Norms of Patrimonial Fitness, approved by the Second Resolution dated August 5, 2004.

On its part, the **Fourth and Fifth Resolution** of March 29 approves the definite versions of the Liquidity Risk Regulation and the Regulation for the Elaboration and Publication of Consolidated Financial Statements, respectively, authorizing their publication in a national circulation newspaper. The latter of the two regulations will come into effect 90 days after its approval.

On the other hand, the **Seventh Resolution** of March 29 authorizes the publication of the Regulation for the

[9] Magistrado Richard A. Posner, en Ashi Glass Co. Ltd. V. Pentech Pharmaceuticals, Inc. 289 F. Supp.2d 986, 991 (N. D. Ill. 2003).

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Elaboration and Publication of Consolidated Financial Statements Project, and sets a time limit of 20 days counted from its publication to receive the commentaries from the interested sectors.

Finally, the **14th Resolution** of March 29, introduces modifications to article 13 of the Currency Exchange Regulation, awarding a 15-day time period from the publication of the resolution, to gather opinions from the different sectors interested, on this proposal of modification.

Competition. The Executive Power presents a law that modifies Law No. 28-01.

The President of the Republic, Dr. Leonel Fernández, presented to the house of representatives last March 29, a proposal to modify article 2 and its sole paragraph of Law No. 28-01, that creates a Special Zone for Border Development, with the objective that service provider companies be expressly excluded as beneficiaries of this law and so that it is specified that the exemptions that this text foresees relate to the revenue tax, real state tax and taxes on the transference of property destined to the development of projects in the area, together with the 50% reduction to the payment of taxes related with free transit and use of ports and airports.

The project also commands an obligation from the beneficiary companies to meet with all the current legal normative in relation to labor and social security.

Energy. Choosing your energy.

The European's Union recent regulation establishes that starting July 2007, all consumers will be free to choose their own electricity and gas suppliers.

At the same time, the European Union is working so that the electricity and gas network infrastructure carry the energy in the most efficient way possible. This infrastructure is separate from the distribution companies and all will use the same tubes and cables, so that the consumers will not feel the difference.

For this, regulatory entities have been established in each of the member countries to see that all the distribution companies operate correctly and provide the promised service to their clients. In addition, the European Commission will closely monitor the market, identifying obstacles and defects.

Aeronautics. International Civil Aviation Organization Meeting.

The International Civil Aviation Organization will hold in the days 9 to 13 of May its 29th Occidental Caribbean Working Group Informal Meeting, which will be held in San Vincent and Grenadines.

Securities. New Risk Qualifier in our Securities Market.

The National Securities Council approved as a risk qualifier the firm Feller-Rate, through its sole resolution dated April 4th, so it can operate in the Dominican Securities Market. This firm is of Chilean capital, but it also has a strategic alliance with the American firm *Standard & Poor's Rating Service.*

Feller-Rate is the second risk qualifier to establish itself in the country after Fitch Ratings Dominican was approved in 2003.

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Free Trade. "DR-CAFTA" Free Trade Agreement.

Last April 28, the United States of America Chamber of Commerce and the Association of American Chambers of Commerce presented a declaration before the Energy Commission and the American House of Representatives explaining their arguments on the advantages derived form the implementation of this agreement, for the United States, Central America and the Dominican Republic.

To read the complete document, visit the following website: http://www.uschamber.com/issues/testimony/2005/050428drcafta.htm

News. GACETA JUDICIAL Seminary "Economic Administration, Regulated Sectors and Discretion Control."

The following May 11 GACETA JUDICIAL will conduct a workshop on *"Economic Administration, Regulated Sectors and Discretion Control"* conducted by Dr. Rosina de Alvarado, Dr. Angélica Noboa Pagán, Lic. Eduardo Jorge Prats, Lic. Olivo Rodríguez Huertas and Lic. Salvador Catrain, at the V Centenary Hotel. For registration, you may call the Gaceta Judicial offices at 809 540 3455.

In this workshop, la Dr. Noboa Pagán, will present a brief study titled: *"Methodical of the Right of the Competition. Tests and models for the evidence examination of the existence of incentives or restrictions to free, fair and effective competition in agreements among companies in the telecommunications, energy, patented prescriptions drugs commercialization, financial and civil aeronautics sectors."*

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