

**MARKET CONCENTRATION OF THE TRANSNATIONAL PHARMACEUTICAL  
INDUSTRY AND THE GENERIC INDUSTRIES IN THE WORLD:  
Latest Trends on Mergers, Acquisitions and Other Transactions\***

*“Intellectual property protection is important, but, almost of necessity, imperfect. It is harder and therefore more costly to define than conventional property, and by the same token, it is costlier to enforce intellectual property rights. In some cases, the inventor gets more than his marginal contribution, in other cases, less. Intellectual property protection strengthens dynamic efficiency and competition, but often at the expense of static efficiency and competition. If overly strong, it can actually hinder both dynamic and static efficiency and competition. Public policy towards intellectual property must take into account this perspective. There is no simple prescription; as in other areas of what economists refer to ‘the economics of second best’, appropriate policy needs to take into account the facts and circumstances pertinent to different situations” - Joseph E. STIGLITZ<sup>1</sup>*

It was stated, already in 1999, that the pharmaceutical industry was in the midst of a wave of consolidation, as some of the largest multinational companies were involved in mergers<sup>2</sup>. Since then, this tendency was even intensified, as the number of other megamergers and concentration has been continuously growing in this market<sup>3</sup>. Pfizer, for instance, a company that did not even figure among the industry’s top ten a decade ago, after a number of acquisitions, became the largest world company and expects revenue of \$53 billion in 2004, about 40% bigger than n° 2 - GlaxoSmithKline PLC<sup>4</sup>.

The subtext for this trend of consolidation in the pharmaceutical market is particularly related to the role intellectual property rights (IPRs) play in this field. When a wide number of important products are going out of patents, companies need to guarantee their profits and market share - especially in a field of global competition, technological change and high regulatory barriers<sup>5</sup>.

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<sup>1</sup> Joseph E. STIGLITZ, “Public Policy Towards Intellectual Property”, INTERNATIONAL COMPUTER LAW ADVISER 6, June 1991.

<sup>2</sup> See BALTO, David; MONGOVEN, James F., “Antitrust Enforcement in Pharmaceutical industry mergers”, 54 FOOD AND DRUG LAW JOURNAL 255.

<sup>3</sup> Among the largest mergers and acquisitions, in the last six years, it is worth mentioning Zeneca’s acquisition of Astra, the acquisition of Marion Merrel Dow by Hoechst’s, the merger between Sandoz and Ciba-Geigy and Glaxo with SmithKline, the recent hostile takeover of Sanofi-Syntelabo S.A. by Aventis and the merger of Pharmacia & Upjohn with Monsanto.

<sup>4</sup> See WALL STREET JOURNAL A1, “Biggest Drug Firm Faces Generics But has an Edge: Its Very Bigness”, August 23<sup>rd</sup>, 2004.

<sup>5</sup> BALTO (*supra* n. 2, at 255) defines those as the main characteristics of the sector.

And, as research seems not to have been enough to bring new technologies to the market<sup>6</sup>, empirical evidence shows that companies are engaging different strategies to try to limit competition both from newly developed drugs by other companies, as well as from generic ones. Among those practices, mainly encompassed by large pharmaceutical companies, we should include mergers, acquisitions, some other common contractual arrangements (such as co-marketing and co-promotion agreements) and, also, some conducts which try to lengthen patent life of brand name drugs beyond patent terms.

A quick exam into the above mentioned practices lead to the conclusion that companies aim for profiting from IPRs as much as they can, which is particularly possible in this market due to its structural characteristics. Besides, in some situations it is possible to identify that, with that purpose, IPRs are being stretched in a way that is not adequate to achieve IPRs social purpose of promoting dynamic efficiency but, rather, with the only scope of maintaining market shares for profitable drugs, which not always are the best.

Considering that competition, particularly through off-patent (generic) products, is a necessary condition to decrease price of drugs and, consequently, promote access to medicines in developing countries, the above mentioned practices must be carefully scrutinized by antitrust authorities, in order to guarantee that they are efficient and capable of benefiting consumer welfare. *Therefore, the purpose herein is to address some of those new trends of the transnational pharmaceutical industry, analyzing to what extent those conducts can affect the pharmaceutical market's structure – particularly in which refers to generic competition – and, thus, prevent access to medicines.*

This exercise will lead to the conclusion that, even though competition law and policy cannot be seen as a panacea to solve problems of affordability and access to drugs in developing countries and transition economies, they undoubtedly play a fundamental role to achieve such purpose by limiting the formation of anti-competitive structures and abuses of market power. Based on this assumption, it is possible to indicate some sensitive issues related to the patterns of competition in the pharmaceutical markets, especially where brand name drugs figure as leaders, so as to offer some possible analysis about the feasibility of antitrust law to improve conditions of access to medicines, as well as to invite other proposals. This analysis will emphasize the importance of building and strengthening institutional antitrust capacities in developing countries – which, no doubt, is a burdensome task by itself.

### **Competition in the Pharmaceutical Market: Brief Comments on IPRs and Other Market Failures to be addressed**

In an intense research and development (R&D) sector such as the pharmaceutical, IPRs play an important role to promote dynamic efficiency and, consequently, improve welfare. Therefore, the statement that “while patent law attempts to protect the monopoly right of excluding third parties from exploiting the patent, antitrust law attempts to prevent monopolies, encouraging competition”<sup>7</sup> is not to be understood as if both fields were to be in conflict.

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<sup>6</sup> See, e.g., WALL STREET JOURNAL, *supra* n. 4, at A1 (“To continue growing at double-digit levels, the company [Pfizer] by 2003 will need to be launching at least three or four drugs a year that can do \$1 billion in annual sales. By 2007, when some of Pfizer’s key patents expire, the company will need to launch five or six huge-selling new drugs each year. Pfizer’s own labs have come up with just seven drugs in the past 10 years, and licensed four. Warner-Lambert’s labs [recently acquired by Pfizer] came up with six drugs in that time and licensed a seventh - one of which was withdrawn and three of which have low sales. Together, the two companies’ labs produced fewer than two new drugs a year, not nearly enough for future growth. To create a 10% compounded annual return on its \$4.7 billion research and development investment, Pfizer researchers will have to come up with products in 10 years that create \$12 billion in new revenue that tenth year”).

<sup>7</sup> *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 9<sup>th</sup> Circuit, 1981.

Even though it might be true that, in the short run, static competition tends to be reduced due to patents (even sometimes creating certain allocative inefficiencies with heavy social costs particularly in developing countries<sup>8</sup>), patents are designed to have positive effects in terms of dynamic efficiency as, in the long run, they are supposed to stimulate new entry of products in the market. Due to this fact, even though there is a potential conflict among patent and antitrust laws and, at first glance, their aims and objectives may seem wholly at odds. They have *complementary* scopes, as both are aimed at encouraging innovation, industry and competition<sup>9</sup>. It has been even said that they are *interdependent*<sup>10</sup>.

However, notwithstanding such complementarity has been broadly recognized, courts and competition agencies face trouble when translating it into the application of rules and principles<sup>11</sup>: there is no right solution about which should be the right balance among those institutes in each particular situation, so as to guarantee that IPRs will reach their purpose. As suggested by STIGLITZ, even though patent law is needed, if overly strong it can hinder both dynamic and static efficiency and competition, and any public policy towards intellectual property must take this perspective into account<sup>12</sup>. Note that this statement is particularly true in the pharmaceutical industry, where IPRs are usually pushed to their limits in an attempt to maximize profits.

Therefore, among other policy makers, antitrust authorities have the complex task of translating the complementarity of IPRs and antitrust law into enforceable rules and principles with the purpose of reducing patents' social costs and balancing static and dynamic efficiency. This goal is to be achieved both when reviewing contractual transactions, as well as when investigating anti-competitive practices. It should also be taken into account when designing and enforcing intellectual property policies and rules<sup>13</sup>.

An overview on the characteristics and structure of pharmaceutical market hints quite a wide range of market failures, usually aggravated by patent protection. Among them, we note (a) high market shares in each of the relevant markets, (b) low demand elasticity due to the essentiality of the product, (c) low product interchangeability due to product differentiation, (d) existence of asymmetric information, (e) presence of substitute consumer (physician) and (f) high barriers to entry due to regulatory barriers, brand loyalty and need of high R&D investments. While enforcing antitrust laws in the sector, particular attention should be paid to such characteristics, which are likely to be an

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<sup>8</sup> Aidan HOLLIS and Sean FLYNN propose that, even though the patent system is based on a trade-off between the "deadweight losses" caused by market power and the incentive to innovate created by profits, in developing countries the deadweight losses of patents are relatively larger compared to potential (monopolistic) profits (See "An economic analysis of compulsory licenses for needed medicines", *mimeo*, December 15, 2003).

<sup>9</sup> See, e.g., *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572 (Fed. Cir. 1990), p. 1576.

<sup>10</sup> UNCTAD/ICTSD, *Intellectual Property Rights and Competition*, RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICAL GUIDE TO THE TRIPS AGREEMENT 5, available at <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>, 2003.

<sup>11</sup> David A. BALTO, Andrew S. WOLMAN, *Intellectual property and antitrust: general and antitrust*, 43:3 IDEA: THE JOURNAL OF LAW AND TECHNOLOGY 397, July 2003.

<sup>12</sup> See STIGLITZ, *supra* n. 1, at 6.

<sup>13</sup> For a detailed analysis of the relationship among IPRs and antitrust, see, e.g., FEDERAL TRADE COMMISSION, REPORT ON HOW TO PROMOTE INNOVATION THROUGH BALANCING COMPETITION WITH PATENT LAW AND POLICY, available at [www.ftc.gov](http://www.ftc.gov), October 28<sup>th</sup>, 2003.

important tool for striking a proper balance between the concerns of producers and consumers, addressing abuses or market dominance in a wide range of cases, with a view of reducing unduly IPR protection.

It is worth noting that, even though developed countries' competition authorities have been quite intensively scrutinizing the pharmaceutical market, mainly focusing on the effects of IPRs, developing countries and transition economies have had a very limited experience in exploring the interface between IPRs, competition policy and access to medicines. Brazil, for instance, which has solid antitrust law and authorities and is more experienced than most of the other Latin American countries in merger review, few times had the opportunity to analyze cases where intellectual property issues were important. With regard to anti-competitive conduct investigations, there are even fewer cases.

### **Merger and Acquisition Trends in the Transnational Pharmaceutical Market**

Mergers and acquisitions are increasingly becoming strategic for pharmaceutical companies, with firms trying to gain competitive advantage or respond to larger economic forces: some firms seek to acquire market share, expand product lines, combine R&D capabilities, seize control of key inputs or achieve efficiencies of integration<sup>14</sup>. If we were to summarize the reasons for consolidation, *patent expiration* and *technological development of new products* are possibly the main ones.

As deterrence of anti-competitive *structures* in the market is a pre-condition to avoid *abuse of dominant position*, merger control must be made under careful scrutiny. Therefore, in reviewing a transaction, antitrust agencies must attempt to determine whether a merger or acquisition will lead to higher prices, low supply or less innovation and what remedies are necessary to overcome these risks.

Any antitrust analysis starts from an assessment of market power and, at first glance, the pharmaceutical industry does not appear to be concentrated, as only one company has more than a two digit percentage of market share globally, as seen in Table 1:

**Table 1**

| <b>Ranking</b> | <b>Corporation</b> | <b>Market Share (%)</b> |
|----------------|--------------------|-------------------------|
| 1              | Pfizer             | 11                      |
| 2              | GlaxoSmithKline    | 6.9                     |
| 3              | Merck & Co         | 5.0                     |
| 4              | AstraZeneca        | 4.8                     |
| 5              | Johnson & Johnson  | 4.7                     |

**Source: IMS, 2003<sup>15</sup>**

However, when pharmaceutical sales are properly divided into narrower sub-markets, in which products are grouped only with their competitors, figures indicating a much higher concentration appear<sup>16</sup>. Therefore, besides the fact that the definition of relevant market in the pharmaceutical field

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<sup>14</sup> See BALTO, supra n. 2, at 256.

<sup>15</sup> Those figures refer to 2003. It is worth mentioning that after a hostile takeover of Aventis, in 2004, Sanofi-Syntelabo possibly became the third largest global company.

<sup>16</sup> In the pharmaceutical market of prescription drugs, for instance, it is quite common that one single drug has more than 50% of its relevant market. When there is a patented drug, this percentage is usually even higher; in some cases, the active principle of a patented drug may even correspond to a relevant market.

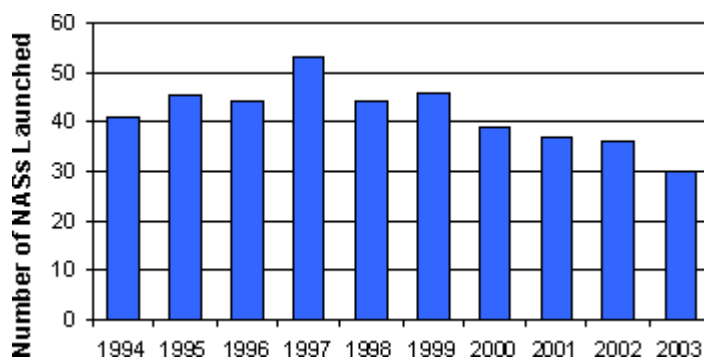
is not an easy task<sup>17</sup>, in those cases where a precise definition could be reached, authorities were able to conclude that markets are quite concentrated. Based on this fact, there is no doubt that antitrust authorities must carefully examine conducts and transactions in this market, focusing on market preemption.

If we were to list the most frequent type of merger and acquisition cases, we would identify two main tendencies in the last decade.

The *first* is the acquisition of small biotech companies, as large laboratories need third generation drugs to guarantee high levels of profit and there is an assumption that small biotech labs may be better at discovering drugs than the giants<sup>18</sup>.

The *second* group include large pharmaceutical companies which enter into transactions with effectively or potentially competing companies, in many cases when patents are about to expire, so as to maintain its market share and try to reduce competition with other new generation drugs. The large number of Pfizer's acquisitions in the last years, for instance, is possibly based in the fact that, until 2007, at least four of its big-selling drugs will lose patent protection and nearly a quarter of its revenue could possibly disappear, as cheaper generics rush in to replace them<sup>19</sup>. And, to sustain growth rates, there are all sorts of formulas available indicating that firms will need to put out at least three or four new chemical entities per year and there's no firm right now doing anything more than one per year, according to Kenneth Kaitin, director of the Tufts Center for the Study of Drug Development<sup>20</sup> (see, for example, in Table 2, data about the number of new drugs launched from 1994-2003).

**Table 2**



Fonte: IMS LifeCycle R&D focus

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<sup>17</sup> The definition of relevant market in this sector is not different than in other industries, but it is not an easy task, as it must be applied with sensitivity to the industry's characteristics. Among others, the effects of IPRs – particularly patents and trademarks – must be taken into account. According to Howard MORSE, one must consider as well “whether drugs may be substitutes for the treatment of a particular disease or condition, taking into account the drugs’ mechanisms of action, therapeutic profiles, side effects, and methods of administration. The analysis must consider the impact of doctors, pharmacists, patients, and third-party payers on the use of drugs, to analyze the likelihood of switching in response to relative price increases, and the impact of such switching on profitability” (*Product Market Definition in The Pharmaceutical Industry*, 71 ANTITRUST LAW JOURNAL 633, 676).

<sup>18</sup> Gardiner HARRIS, *Drug Firms, Stymied in the Lab, Become Marketing Machines*, DNA BRIDGES – BRIDGING SCIENCE AND PRODUCTS, available at <http://www.dnabridges.com/hotspot/2000/2000JUL6.htm>, JULY 6<sup>TH</sup>, 2000. While little data support this notion so far, a Tufts University study found that the number of drugs approved by the FDA that were discovered by the firm asking for the approval fell to 61% in the mid-1990s from 72% in the mid-1960s and the growing biotech alliances suggest that the number is even lower now.

<sup>19</sup> WALL STREET JOURNAL, *supra* n. 4, at A1.

<sup>20</sup> *Id.*

Therefore, it seems that, in this field, bigger is better<sup>21</sup>. Accordingly, new trends of mergers and acquisitions in the transnational pharmaceutical market may suggest that, for the drug industry, those transactions are an appropriate way of neutralizing competition and securing revenues and high market shares. The rationale that underlies those mergers is to be taken into consideration by antitrust authorities when reviewing the cases: they are not necessarily efficient and, considering the role IPRs play in this market, they must be a particular focus of concern.

In this context, it is worth mentioning that the particularities of the pharmaceutical market require that attention is given not only to transactions involving companies competing in the same market, but also to transactions that may be inhibiting future competition, either by increasing barriers to generic entry or causing potential harm to innovation. In this regard, the Federal Trade Commission of the United States has required merging pharma companies to divest, license or abandon intellectual property rights in order to resolve antitrust law concerns<sup>22</sup>. In developing countries, however, this experience has been very limited and needs to be matured, specially to guarantee that those transactions will not create artificial barriers to generic entry. This issue is particularly sensitive in these countries, as the existence of generic competition is the minimum necessary requirement to provide some preliminary conditions to promote access to medicines.

If small biotech and large pharmaceutical companies are targeted in perennial merger and acquisition transactions, the situation is slightly different in which refers to generic companies. As these companies may become strong rivals once patent expires<sup>23</sup>, it is possible to identify a tendency of them being targeted by large laboratories subject to some other kind of strategic alliances: co-marketing and/or co-promotion agreements<sup>24</sup>. These contractual arrangements are standard agreements and practice in the pharmaceutical industry, used for selling, marketing and distributing products and it is possible to identify that they are mainly entered once the product is about to go out of patent.

### ***Co-Marketing and Co-Promotion Agreements: Pro or Anti-Competitive Agreements?***

If in merger and acquisition cases antitrust authorities – particularly from developed countries – have defined some guidelines so as to prevent consolidation of anti-competitive structures<sup>25</sup>, such rationale is not directly applicable to co-marketing and co-promotion arrangements, either if entered among

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<sup>21</sup> *Id.*

<sup>22</sup> See Laura J. GLASGOW, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41:2 IDEA: THE JOURNAL OF LAW AND TECHNOLOGY 227, 243-247 (analyzing requirements imposed in six large merger cases reviewed by the FTC, focusing on intellectual property issues).

<sup>23</sup> More and more generic companies are entering the market and increasing shares, usually with prices at least 40% (forty percent) less than the branded drugs. The largest global generic companies are Teva, Hexal, Schwarz, Barr, Apotex, IVAX, Pliva, Watson, Mylan, Ranbaxy, with increasing shares, in some cases through merger and acquisitions. Generic-generic alliances, even though mentioned in the paper, are not the main focus in this think piece and, therefore, I will not examine them on details herein. About the topic, See David REIFFEN and Michel WARD, *GENERIC DRUG INDUSTRY DYNAMICS*, available at <http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf>, February 2002.

<sup>24</sup> Co-marketing is the sale and marketing of a defined product, which is to be conducted independently and under different trademarks by each party. Co-promotion consists of the sale and marketing of a defined product under a single trademark, where the parties co-operate in managing the overall process of commercialization, from manufacture through to sale to the ultimate consumer (Carlo PIRIA, *The position of Co-Marketing and Co-promotion between EU Regulatory and Competition Rules*, 13(8) REGULATORY AFFAIRS JOURNAL 653, 654).

<sup>25</sup> According to MORSE (*supra* n. 16, at 642), the Federal Trade Commission has challenged, since 1990, at least twenty mergers involving pharmaceuticals, most of them resolved through a consent order.

brand name and generic firms or if they constitute generic-generic alliances. Even though companies remain as separated entities, those arrangements imply a coordination of policies that may include co-ordination of price policies to offer the same product, irrespective of the eventual existence of different of trademarks.

As a nuance of licensing agreements, co-marketing and co-promotion arrangements are becoming increasingly usual and important in the pharmaceutical sector. Even though, on the one hand, they might rise some important antitrust concerns, on the other they might also have some pro-competitive effects, which makes their antitrust analysis not trivial. The analysis is deemed to become particularly complex if the licensor possesses a high degree of market power and licensee and licensor are actual or potential competitors – which, in fact is the most common situation. Also, sometimes those alliances somehow permit unduly extension of patents, increasing exclusionary rights and mitigating competition for longer than necessary to provide follow on innovation.

Evidences show that brand name companies tend to engage in strategic alliances with generic companies when patent of a well-known brand name product is about to expire. This type of alliance might be particularly critical to the generic drug industry because it permits firms to tackle different skills and resources in order to compete more effectively, which may discourage other generic companies from entering in the market, as they will have much higher risks and costs.

On the one hand, generic drug firms face substantial costs to develop and market individual drugs and, like all pharmaceutical companies, confront sophisticated buyers with the power to bargain lower prices – therefore, arrangements with the brand company may be attractive, specially in the short run, as sunk costs and other risks are reduced<sup>26</sup>. On the other hand, although strategic alliances offer firms the promise of substantial efficiencies in terms of lower cost, better service and faster introduction of generic drugs, on occasion they may raise antitrust concerns, particularly in which refers to market preemption<sup>27</sup>.

Ideally, generic drugs are sold at margins just slightly above cost. Thus, the generic drug market is the paradigm of a competitive market and, particularly in developing countries, it is necessary to encourage the development of technology and capacity for such industry, so as to introduce generics and promote effective competition.

In this context, some risks of generics' market preemption are to be considered. The first is that, as the production of generic drugs requires some level of technology, if generic companies become only distributors of brand name products, by means of co-marketing or co-production agreements, they might stop investing in research and will not be able to *produce* its own generics. This might have a negative effect in the market if a compulsory license is granted and there is no company capable of producing the off-patent drug. A second issue to be considered is that *any* agreement among current or potential competitors – even among generic producers – may lead to higher prices or less innovation, specially when they imply a coordination of policies that include pricing. A third, more directly related to market preemption and reduction of potential competitors, would be that, if one generic lab knows that other companies would take the advantage of not incurring in any risks to introduce the

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<sup>26</sup> See BALTO, *Generic Drugs Strategic Alliances: Competitive Opportunities and Antitrust Risks*, FDLI 4, March/April

2003.

<sup>27</sup> *Id.*

product in the market, they may end up deciding not to enter in such market<sup>28</sup>.

For the mentioned reasons, co-marketing and co-promotion agreements may be used as an effective way for brand companies to frustrate entry of their generic rivals. In fact, GlaxoSmithKline recently entered into licensing agreements with two American generic producers - allowing them to produce “authorized generics” - right after the announcement of a poor result for the first semester of 2004, caused by generic competition that knocked US\$ 1.4 billion off sales of its two blockbusters<sup>29</sup>. Even though such deals provide the company with modest revenue, half of its losses may allegedly be recovered due to them, as well as by the introduction of Glaxo’s own generic, as this strategy is supposed to deter entry of other generics<sup>30</sup>.

Therefore, there are quite high probabilities that this kind of alliance for the selling of “authorized generics” damage generic industry and mislead consumers, as stated by the chief executive of Mylan, a large American generic company. However, the case is far from being uncontroversial: America’s Food and Drug Administration (FDA), for instance, alleges that those drugs are to increase competition and promote lower prices<sup>31</sup>. Therefore, even though those arrangements can, in one hand, reduce barriers and accelerate generics entry in the market, on the other, they are likely to prevent (long run) entry, as well as mitigate real competition among brand name and generic firms – which may be truly costly particularly for developing countries.

All these issues are indicative of the strong need for antitrust authorities to closely examine the effects of co-marketing and co-promotion arrangements. This matter should concern particularly developing countries, where generic competition is supposed to play a particular important role in promoting access to medicines. It is worth noting that the criteria adopted in the analysis of those cases may eventually end up impacting in the very own structure and characteristics of the generic industry of developing countries.

### **Market Structures Allowing the Exercise of Anti-Competitive Conducts**

Based on the above, it is possible to say that new trends of mergers, acquisitions, co-marketing and co-promotion agreements specially of the transnational pharmaceutical market can, in some situations, be considered as tools to impair competition among current or potential competitors and, in many cases, to discourage entry of generic drugs. This is particularly true when the underlying rationale of the transaction is to prevent entry of new competitors in the market once patent is expired.

As much as possible, antitrust authorities should try to prevent the formation of market structures that may end up allowing anti-competitive practices. Therefore, whenever transactions indicate such risks, competition authorities must be ready to intervene and guarantee a more competitive environment. Nonetheless, if market power ends up providing conditions for anti-competitive practices, antitrust agencies may still intervene to restrain abuses of market power. Herein, we will quickly examine cases where having a dominant position, a patent or brand name holder abuses its market power by means of its IPRs.

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<sup>28</sup> In a deep study on the generic drug industry, David REIFFEN and Michel WARD (*supra*, n.23) mention that one relevant observation about competition is that the size of the market affects the expectation of entry and that some markets are too small to induce significant entry.

<sup>29</sup> *Unconventional Medicine*, THE ECONOMIST, July 29, 2004.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*



Competitive concerns vary according to jurisdictions, market structures and aimed competition policies. Besides, competition law and policy undoubtedly need to be coordinated and integrated with other public policies, including the balance with industrial policy and IPRs. In any case, there is no doubt that IPRs may be limited when abuses are identified, as recognized by the Trade Related Intellectual Property Rights Agreement (TRIPS), of the World Trade Organization.

According to article 40 of TRIPS, countries have full autonomy to define in its national laws what is to be deemed an anti-competitive conduct. Article 31 of the Agreement, which establishes conditions for national laws to adopt compulsory licenses schemes, also leaves to WTO members important flexibilities when the compulsory licenses is granted due to anti-competitive practices, such as the waiver excluding the need of previous negotiation with patent holder and the possibility of granting royalty free licenses.

Some countries use their competition laws to take advantage from this TRIPS' flexibilities<sup>32</sup>. This loophole is in fact a legitimate strategy that WTO Members need to explore and maintain, and which may be particularly valuable for developing countries. In this regard, special attention must be given to practices that, due to the structure and characteristic of the pharmaceutical market, inappropriately extend intellectual property rights beyond its main purpose of promoting technological innovation as, in those cases, IPRs are clearly not being used to reach its social purpose of promoting dynamic efficiency. As an illustrative example, let's examine some of them.

Some conducts practiced by means of IPRs are quite often referred as anti-competitive in different jurisdictions and, thus, are enforced so as to increase competition and, consequently, promote access to medicines. Among them, we may include tying arrangements, some exclusive and restrictive dealings, abuse of dominant position to restrain technological development and standardization problems, abuse of patent claims, cartelization through patent pools and cross licensing.

Some other conducts, however, are more controversial and not always identified as anti-competitive throughout jurisdictions. A practice that is treated in a non-uniform way by different legislation refers to excessive pricing. Article 85 of the Treaty of Rome, for instance, contemplates such behavior as anti-competitive, even though, in practice, Courts usually face difficulties in ruling what would be a competitive benchmark above which prices will be deemed anti-competitive<sup>33</sup>.

In Brazil, the situation is somehow similar: excessive pricing is defined as anti-competitive in antitrust law, nevertheless, it has never been enforced as such. Even though the subject has not been deeply analyzed by the Administrative Competition Court (*Conselho Administrativo de Defesa Econômica*), in some isolated cases, the Court ruled that the competition authority should intervene to induce and maintain competition, but not to set or fix prices<sup>34</sup>. Therefore, if this understanding is not overruled, it

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<sup>32</sup> Frederick SCHERER and Jayashree WATAL explain that even though the wording of article 40 appears to track in a general way the "abuse" doctrine of United States patent antitrust law, the whole can be reconciled with European legal traditions holding that failure to supply or license a patented product at all, or supplying the product at unreasonably high prices, might be deemed abusive (*Post-TRIPs Options for Access to Patented Medicines in Developing Nations*, 5(4) JOURNAL OF INTERNATIONAL ECONOMIC LAW 913, 915 (2002)).

<sup>33</sup> Frederick SCHERER mentions that "[i]t seems clear from the various higher German court decisions (...) that *high monopolistic prices would have been ruled abusive if competitive benchmarks could be established despite the existence of substantial research, development, and marketing costs*. The 'as if' problem could be surmounted if in some parts of the world generic substitutes are supplied by competitive firms paying 'reasonable' royalties to the patent holder and not subjected to governmental price controls" (THE ECONOMICS OF COMPULSORY DRUG PATENT LICENSING 7, *available at* [www.worldbank.org](http://www.worldbank.org), 2003).

<sup>34</sup> See, e.g., Maria Thereza LEOPARDI MELLO, *Questões de defesa da concorrência no setor farmacêutico*, in NEGRI, Barjas, DI GIOVANNI, Geraldo (org.), BRASIL: RADIOGRAFIA DA SAÚDE, 2001.

is unlikely that the provision can be used to effectively promote access to drugs, as occurred in the significant precedent set by the South African Competition authority. In December 2003, the latter issued a finding against pharmaceutical companies holding that they had charged excessive prices for patent-protected anti-retroviral medicines and that they had unlawfully refused to issue voluntary licenses to generic competitors and unreasonably restricted production of fixed-dose combination medicines<sup>35</sup>.

Specifically regarding IPRs, when patents are valid, antitrust authorities are supposed to examine whether there is some kind of abuse in the regular use of the exclusivity granted, such as the above mentioned. Once the patent expires, other types of practices may be identified, all of them with the purpose to try to extend market exclusivity. Among those, we may include the use of legal provisions to extend patent terms, the strategy of suing generic manufacturers for patent infringement so as to increase costs of generics entering the market and discourage entry (usually referred as sham litigation), the strategy of applying for excessively broad patents in order to block researches carried on by competitors, the modification of drug molecules or the recombination of existent drugs with the scope of applying for new patents and, still, the intention of layering several patents to secure broad and continual exclusionary rights and the use of brand name to increase barriers to entry for generic drug manufacturer<sup>36</sup>.

Notwithstanding, except from very few developing countries that are trying to take advantage from the possibility of limiting abuses of IPRs by means of antitrust enforcement, developed countries remain as the only ones that have been doing so. Therefore, we emphasize once again the need of strengthening the application of antitrust to IPRs abuses, so as to limit them with a view of promoting access to medicines.

#### ***Targets for Enforcement of Antitrust Policy in the Pharmaceutical Market: Developing Countries Perspective***

Competition law and policy is to be used by developing countries to prevent abuses of market power, with the scope of promoting a competitive environment that permits the implementation of public policies to address access to medicines. As much as possible, developing countries must have a clear policy as to the enforcement of competition law, preventing the consolidation of anti-competitive structures, as well as anti-competitive conducts. Herein, we particularly focused in the cases where competition law can work as an effective tool for addressing some of the adverse effects of IPRs in the pharmaceutical sector.

It is worth noting that more than one third of United States government antitrust enforcement actions raise intellectual property issues and, recently, the FTC has established task forces to identify intellectual property cases worth pursuing. A similar exercise could be done in developing countries, which usually have limited resources and lack institutional capacity. By identifying some sensitive cases and tendencies, authorities could work in a focused manner, so as to achieve effective results, even if in a limited number of cases in the short run. Nonetheless, even though developing countries and transition economies may profit from developed countries' experiences, they must also have in

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<sup>35</sup> See *Competition Commission Finds GSK and BI in Contravention of the Competition Act*, TREATMENT ACTION CAMPAIGN, available at <http://www.cptech.org/ip/health/sa/cc10162003.html>, CPTECH, October 16, 2003.

<sup>36</sup> See Timothy J. MURIS, *Competition and intellectual property policy: the way ahead*, speech before the American Bar Association, Antitrust Section Fall Forum, available at [http://www.ftc.gov/speeches/muris/N\\_23\\_#N\\_23\\_>](http://www.ftc.gov/speeches/muris/N_23_#N_23_>), November 15, 2001.

mind that public policy interests usually differ from jurisdiction to jurisdiction, and what properly *customized* policies are required.

In those countries, the development and existence of generic industries are necessary to promote competitive prices. If mergers, acquisitions and other arrangements, as well as potentially anti-competitive conducts, are not duly scrutinized by antitrust authorities, and eventually limited, it is likely that the new trends of the pharmaceutical industry referred above will end up affecting the respective generic market, due to the creation and increase of barriers to entry. Those arrangements might also have some other shortcomings in terms of dynamic efficiency: even though in the short run they might help pharmaceutical companies increasing the profits lost by patent expiration, there is a risk that no further intense investments in research will be done - in fact, many believe that the focus on mergers distract and hinder researchers' creativity<sup>37</sup>.

Therefore, the non-enforcement of antitrust rules may end up affecting the pharmaceutical industry of developing countries as a whole and, particularly, its *generic* industry. Generally speaking, generic companies are to compete with brand name companies. Therefore, even if there is some kind of co-marketing or co-promotion agreements – which in some situations may be considered pro-competitive - antitrust authorities must assure that current and potential competition will not be fully eliminated and other generic companies will still have the incentive to research and enter the market.

The enforcement of antitrust law to address competitive concerns in the pharmaceutical market can be done through a variety of remedies. And, if the main focus in this market is somehow related to IPRs, divestiture and compulsory licensing of these IPRs might be adequate tools to deal with them, by the way, in the same way they have been often used by developed countries.

Another issue of concern more related to trademarks than to patents concerns marketing strategies. If, as mentioned, the difficulty in producing enough new products continues, the industry will become increasingly reliant on costly marketing schemes, and relatively less on its research operations<sup>38</sup>. In fact, the pharmaceutical industry is gradually shifting the core of its business away from the unpredictable and increasingly expensive task of creating drugs and toward the steadier business of marketing them.

There is no doubt that the creation and enforcement of antitrust law require skills and expertise on the subject, and most of developing countries lack institutional capacity or expertise to adopt a proactive stance regulating or enforcing competition rules. Until those countries build capacity to deal with those issues, possibly through international antitrust technical assistance, other types of regulatory intervention will be needed.

The discussion above revealed there are a number of open-ended questions in this area. Therefore, to finalize it might be worth indicating some sensitive issues related to the new trends of practices adopted by transnational pharmaceutical that can be recognized as priority areas to study and discussion:

- Identify technical, political and institutional limitation to the application of antitrust policy to limit abuses of IPRs;

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<sup>37</sup> WALL STREET JOURNAL, *supra* n. 4, at A1.

<sup>38</sup> See Gardiner HARRIS, *Drug Firms, Stymied in the Lab, Become Marketing Machines*, available at <http://www.karlloren.com/biopsy/p18.htm>, July 6, 2000.

- Analyze the effect of co-marketing, co-promotion and other alliances in developing countries market structure, considering that, on the one hand, they can foster competition by lowering barriers to entry and accelerating introduction of the first generic in the market and, on the other hand, they may mitigate *effective* competition (mainly through generics, but not only) and, at the end, prevent the formation and consolidation of a generic industry in those countries;
- Explore the possibility of designing and stimulating alliances (either of brand- generic or generic-generic) which can provide efficiencies, enhance their competitive ability and benefit consumers;
- Discuss a framework for merger and acquisition analysis in pharmaceutical transactions, approving only transactions that are efficient and capable of benefiting consumer welfare, and not those where the sole purpose is to maintain market shares for profitable drugs, which not always are not the best ones;
- Explore all TRIPS flexibilities, particularly articles 8.1, 31(k) and 40, which lawfully permit to limit the abuse of intellectual property rights, when designing and applying intellectual property rules. Particularly, exploit the available remedies when implementing competition rules and policies;
- So as to identify proper situations to apply those available remedies, examine to which extent the essential facilities doctrine, as well as the excessive pricing criteria, may be used to limit IPRs and promote generic competition to the market. In this regard, it would be convenient to analyze the possibility of considering intellectual property as a “liability rule”<sup>39</sup>;
- Maintain the current international flexibility so as to design internal antitrust laws, avoiding regional intellectual property agreements or regional or multilateral competition agreements that curtails countries autonomy to define what is to be deemed an antitrust violation;
- Coordinate antitrust policy with other public policy concerns designed to promote access to drugs, such as industrial policy, IPR and transfer of technology;
- Profit from international experience of developed countries in the application of antitrust law and policy as a tool to limit IPRs; and
- Build or strengthen institutional antitrust capacity in developing countries, with the purpose of creating a minimum structure for local companies to develop: if there is no antitrust enforcement, generic companies will not have incentives and condition to entry the market. The creation of

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<sup>39</sup> According to Jerome REICHMAN, “a growing body of legal and economic research shows that developing countries’ efforts to stimulate investment in small-scale innovation could benefit more from new types of intellectual property protection sounding in ‘liability rules’ than from antiquated exclusive rights regimes, such as utility model laws and the like. Under hybrid exclusive property rights, there is an ‘absolute permission’ requirement, which usually means that second comers cannot engage in follow-on applications and improvements without an express license from the originator. Under liability rules, instead, there is a ‘take and pay’ regime, which enables second comers to borrow novel technology for purposes of improvements and follow-on applications, but obliges them to compensate originators for their investment in research and development by means of a relatively set table of royalties. Examples include laws prohibiting abuse of patent rights (and other intellectual property rights); laws allowing the imposition of compulsory licenses to lower prices or to promote greater competition in the public interest” (“*Managing the Challenge of a Globalized Intellectual Property Regime*”, ICTSD-UNCTAD DIALOGUE, 2<sup>nd</sup> Bellagio Series on Development and Intellectual Property, September 18-21, 2003).

institutional capacity in those countries reassures the importance of giving high priority to competition related issues in IP technical assistance programs.

The above list tackles, not all, but a number of complex antitrust-IPRs related issues in the pharmaceutical industry which will require a significant amount of work to be addressed. They call us to discuss and invite proposals to those concrete problems aiming to promote a competitive environment that guarantees the necessary basic conditions to address public policies, in order to increase access to medicines in developing countries.