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THE BOLAR EXCEPTION: LEGISLATIVE MODELS AND DRAFTING OPTIONS

Carlos M. Correa

RESEARCH PAPERS

66

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SOUTH CENTRE

MARCH 2016

THE SOUTH CENTRE

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I. INTRODUCTION

The basic principle of patent law is that once the term of a patent has expired, the protected subject matter becomes a part of the public domain. Hence, it can be freely used, including for commercial purposes, without the interference by the former patent owner. This allows competitors to enter the market immediately after such expiry, eventually leading to lower prices for consumers and welfare gains.

Pharmaceutical products, however, cannot be marketed[1] without prior authorization of the competent regulatory agency. Such authorization is conditional upon the submission and approval of an application that normally has to be accompanied with certain pieces of information. Regulatory requirements differ among countries. Despite some efforts towards harmonization,[2] there is considerable diversity in respect of what evidence is required, the applicable procedures, and how long it can take to obtain the approval.

In general, national regulations on marketing approval differentiate between pharmaceutical products that include new chemical entities or biological molecules – for which pre-clinical and clinical studies demonstrating efficacy and safety are needed – and 'generic' or 'similar' versions of drugs (hereinafter 'generic products'), for which information regarding efficacy and safety has already been submitted and evaluated by the same or other regulatory authorities. In this latter case, as discussed below, although the requirements imposed to the applicants vary amongst countries, generally abbreviated, simplified procedures are applied.

These abbreviated procedures are significantly shorter than those required for the approval of pharmaceuticals incorporating new molecules. However, the authorization of a generic drug does take some time: it has been estimated that procedures for marketing approval of generics may delay their commercialization by 2-3 years[3] or more in countries with generic pharmaceutical manufacturing capability. This in turn delays such entry in other countries importing generic products.[4]

The interface between the regulations for marketing approval of medicines and patent law explains the need for what has been termed as the "early working" or "Bolar exception" (hereinafter Bolar exception). If a producer of a generic or similar version is bound to wait until the last day of the term of patent(s) covering a pharmaceutical product, the owner of

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[1] The same applies to other regulated products, such as agro-chemicals. This chapter focuses on pharmaceuticals.

[2] Notably by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH, however, is a non-governmental organization where the "majority of the WHO member countries have no voting rights and which is dominated by pharmaceutical industry groups" (Rema Nagarajan, "Conflict of interest in setting norms for pharmaceuticals in WHO", The Times of India, 17 May 2014, available from http://timesofindia.indiatimes.com/city/delhi/Conflict-of-interest-in-setting-norms-for-pharmaceuticals-in-WHO/articleshow/35261958.cms.

[3] This delay may be longer for biosimilars, to the extent that additional testing is required.

[4] See, e.g., Jayashree Watal, "'Bolar' exception to patent rights: Some economic implications" SCP Seminar on Exceptions and Limitations to Patent Rights 03.11.2014, available from http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_ref_watal.pdf. In Europe the registration of a generic medicine usually takes 1 to 2 years, but can sometimes take longer (see http://www.britishgenerics.co.uk/about-generics/generics-faqs).

expired patent(s) will enjoy a *de facto* additional period of monopoly power, as long as a generic version of the product obtains market permission from the regulatory authority. During this period there can be no competition and, hence, the owner of the expired patent may continue to charge a monopolistic price.

Since governments and consumers would benefit from lower prices as the result of generic competition, the Bolar exception may play an important role in reducing the burden on health budgets and increase access to more affordable pharmaceuticals. Studies for the USA show, for instance, that drugs experiencing first generic entry in 1999-2000 maintained a share of 44 per cent of units at 1 year following first generic entry; in the period 2011-2012 the gain of market share by generics was much faster: originator products retained an average of only 16 per cent of units at 1 year (11 per cent in the case of products with sales greater than $250 million (in 2008 dollars) prior to first generic entry.[5]

The Bolar exception, first introduced by the US 'Drug Price Competition and Patent Term Restoration Act' of 1984 (and more commonly known as the 'Hatch-Waxman Act'),[6] intended to strike a compromise between the so-called 'innovator' and generic pharmaceutical producers. Generic producers were allowed to use the patented subject matter for the purpose of regulatory procedures before the expiry of relevant patent(s), while innovator companies were given the right to request, under certain circumstances and within some limits, an extension of the patent term to compensate for the delay in the FDA's approval process. The analysis of welfare implications of this Act indicated that:

> from the perspective of economic welfare, the Act is the source of large potential positive gains of two types. First, it eliminated costly scientific testing which served no valid purpose. Second, the Act lowered prices to consumers with some elimination of deadweight losses and large transfers from producers to consumers[7].

The name of the exception derives its origin from the earlier decision by the US Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.* (733 F.2d 858, 1984). The court held in this case that the experimental use exemption to patent infringement narrowly provided under US law (35 U.S.C. § 271(a)) did not allow for testing undertaken by Bolar Pharmaceutical to obtain marketing approval of a generic product. The "Hatch-Waxman Act" overturned this decision only a few months after its issuance.

This chapter briefly addresses, first, the regulatory requirements applicable to marketing approval of pharmaceutical products. Second, it examines the Bolar exception in the light of the Agreement on Trade Related Aspects of Intellectual Property Rights ('the TRIPS Agreement'), particularly on the basis of the findings of a WTO panel that examined the consistency of such exception with Article 30 of the said Agreement. Third, it analyses how the Bolar exception has been introduced in different countries without any intention,

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[5] Henry Grabowski, Genia Long and Richard Mortimer, 'Recent trends in brand-name and generic drug competition', *Journal of Medical Economics* 2013, 1-8, available at http://fds.duke.edu/db/attachment/2575.

[6] 35 U.S.C. § 271(e)(1): "it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

[7] W Viscusi, J Vernon and J Harrington, Economics of regulation and antitrust, (1997: Cambridge; Second Edition, The MIT Press) 857.

however, of presenting the full panorama. Finally, the chapter discusses several aspects that need to be considered in drafting and interpreting a Bolar-type provision.

II. MARKETING APPROVAL OF PHARMACEUTICALS

The marketing approval of a pharmaceutical product incorporating a new molecule generally requires tests in animals to assess its pharmacodynamic, phamacokinetic and toxicological profile, before tests in human beings are carried out. The latter are conducted in different phases, under protocols that vary in accordance with therapeutic classes and even among drugs within one therapeutic class. In "phase I" (focused on toxicity and bioavailability) a small group of healthy volunteers receive the candidate product for a short period; "phase II" has as a primary objective to assess the new substance's effectiveness. In "phase III" trials are conducted on a number of patients (often involving several hundred volunteers) for substantial periods (depending on the therapeutic class and the purpose of the study[8]) to determine efficacy and safety including side effects, drug interactions and specific dosage for different indications.[9]

In addition to these test data, national authorities normally require information on the quantitative and qualitative composition and other attributes of the product, as well as on manufacturing methods. Marketing approval is granted for a specific drug used as a specific therapy.

While these requirements apply to **new** pharmaceuticals, the marketing approval of a generic product is subject to the simplified procedures. For instance, the US Food and Drug Administration (FDA), as well as other regulatory authorities, do not require the repetition of preclinical and clinical studies to establish safety and effectiveness. Instead, the submission of data is required showing that the generic product is bioequivalent, i.e., that it performs in the same manner as the "innovator" drug, including the time it takes the drug to reach the bloodstream (bioavailability), tested in 24 to 36 healthy volunteers.[10]

Other regulatory authorities, however, do not require demonstration of bioequivalence in all cases; it is sufficient to show chemical equivalence with the "originator" product. Under some regulations, for instance, chemical equivalence and evidence that the product has been approved by the regulatory authority of a country that applies high standards for assessing efficacy and safety are sufficient to register a generic product. The time needed to market a

[8] For instance, the approval of the second indication of a known medicine may require clinical studies involving a small number of volunteers for a short term. For example, a US company obtained FDA approval for a colchicine product ('Colcrys') to treat acute gout pain on the basis of clinical studies involving 185 patients for one week (see Aaron S. Kesselheim and Daniel H. Solomon, "Incentives for Drug Development – The Curious Case of Colchicine", *NEJMP*, 14 April 2010, available from 10.1056/nejmp1003126.

[9] Long-term animal toxicity studies are also undertaken to determine the effects of the prolonged exposure and on subsequent generations.

[10] See "Abbreviated New Drug Application (ANDA): Generics", available from www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/.

generic product after the expiry of a patent will be generally shorter in countries that provide for this kind of approval by reference.

In the case of biologicals (therapeutic substances consisting of or derived from biological sources, such as vaccines, proteins, hormones), which account for a growing share of the pharmaceutical market,[11] special requirements apply. There has been considerable debate regarding the approval of 'biosimilars' once the respective patents have expired. In many cases, biologicals – such as those for anti-cancer therapies – are highly priced[12] and the early introduction of biosimilars may have a major impact in terms of access to treatment.

While the "innovator" companies have argued that it is not possible to show equivalence (or "biosimilarity") for biologicals as in the case of chemical entities,[13] several countries have adopted regulations to make it possible to obtain an abbreviated or simplified marketing approval of biosimilars. Applicants need to submit a series of data (such as product characterization, *in vitro* and/or *in vivo* studies, toxicity studies, some clinical studies, etc. to allow comparability with the "innovator" product), which differ among jurisdictions. Biosimilars have been available in Europe since 2006. Specific guidelines concerning the scientific data needed to establish similarity between the referenced and the similar biologic products have been developed, so as to fulfil the requirements of Annex I of Directive 2001/83/EC.[14] The biosimilarity is established on the basis of analytical models, manufacturing process as well as clinical models. In the USA, the "Biologics Price Competition and Innovation Act" (BPCIA) of 2009 established an abbreviated pathway for biologicals[15] which are shown to be biosimilar to an FDA licenced reference product.[16] Many developing countries, such as Argentina,[17] India[18] and Colombia,[19] have also adopted guidelines on the subject to speed up the registration of biosimilars.

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[11] It is estimated that by biologicals account for to 20 per cent of the global pharmaceutical market. See, e.g., Ralf Otto, Alberto Santagostino, and Ulf Schrader, "Rapid growth in biopharma: Challenges and opportunities", December 2014, available at http://www.mckinsey.com/insights/health_systems_and_services/rapid_growth_in_biopharma.

[12] See, e.g., John Gapper**,** "The unhealthily high price of cancer drugs", 3 June 2015, available from http://www.ft.com/cms/s/0/9033f5fc-09d6-11e5-b6bd-00144feabdc0.html.

[13] Thus, it has been argued that clinical studies should be repeated for each biosimilar, which would significantly raise the cost of entry of competitive products. It has also been suggested that biosimilars should not be allowed to use the same non-proprietary name as the "innovator" product, in order to distinguish them from the "innovator" products. The US Federal Trade Commission has opposed a proposal by the US FDA to distinguish biological products through the use of a randomly assigned unique four letter suffix following the product's nonproprietary name, on the ground that "price competition is more intense when the products are seen as close substitutes for one another". See, e.g. http://www.raps.org/Regulatory-Focus/News/2015/10/29/23487/Industry-Patient-Groups-Weigh-in-on-FDAs-Biosimilar-Naming-Guidance/#sthash.vauDaJJN.dpuf.

[14] See http://ec.europa.eu/health/files/eudralex/vol1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf.

[15] See *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product Guidance for Industry*, available from http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf.

[16] The approval of the first biosimilar accepted in the USA – Novartis's drug "Zarxio", which contains the same active ingredient as Amgen's 'Neupogen'– was the subject of litigation based on the interpretation of some aspects of the BCPIA. In March 2015 a US District Court judge dismissed Amgen's claim. See, e.g. REUTERS, 'Judge Rejects Bid by Amgen to Block Biosimilar Drug by Novartis', 19 March 2015, available from http://www.nytimes.com/2015/03/20/business/judge-rejects-bid-by-amgen-to-block-biosimilar-drug-by-novartis.html?_r=0.

[17] See ANMAT Disposición 7729/11 and Disposición 7075/11.

[18] See *Guidelines on Similar Biologics: Regulatory Requirements for Market Authorization in India*, available at http://dbtbiosafety.nic.in/Files%5CCDSCO-DBTSimilarBiologicsfinal.pdf.

[19] Germán Velásquez, La sana victoria de los biotecnológicos', *Semana*, 20/09/2014, available from http://www.semana.com/nacion/articulo/la-sana-victoria-de-los-medicamentos-biotecnologicos/403469-3.

Although generic products and biosimilars[20] are normally subject to conditions for marketing approval much less complex and time – and investment – consuming than those for new molecules, the time needed to obtain such approval may considerably delay the commercialization of competitive products after the expiry of the relevant patents, if the procedures for approval are not initiated before that date. As mentioned, this time-lag would allow the owner of the expired patent(s) to prolong the monopolistic position. On the contrary, allowing for generic products and biosimilars to enter the market immediately after patent expiry, may make available cheaper alternatives to the 'innovator' product. While the latter will inevitably lose its market share, it can still be sold at a high price as a result of marketing strategies and brand loyalty.[21]

The Bolar exception serves the interest of the public as well as governments and social security systems that bear the cost of medicines. There is ample evidence indicating that, after the first generic is introduced following patent expiration, price is reduced, albeit it may not be initially significant. In the USA, for instance, the introduction of the second generic, on average, has been reported to reduce the price by half and that when a larger number of generic manufacturers enter the market, the average price may fall to 20 per cent or less of that of the brand-name product.[22]

III. CONSISTENCY OF THE BOLAR EXCEPTION WITH THE TRIPS AGREEMENT[23]

In accordance with the TRIPS Agreement, patents confer exclusive rights to the holder of making, using, offering for sale, selling, or importing (except to the extent that parallel imports are allowed)[24] for those purposes a protected product.[25] These rights, however, are subject to exceptions under the general requirements contained in Article 30 of the Agreement.[26]

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[20] In the remainder of this chapter, references to "generics" or "generic products" are intended to encompass biosimilars as well.

[21] See, e.g., Caves, Richard E., Michael D. Whinston, and Mark A. Hurwitz, "Patent Expiration, Entry, and Competition in the U. S. Pharmaceutical Industry: An Exploratory Analysis", *Brookings Papers on Economic Activity*, 7 (Special Issue on Microeconomics), 1991:1-48; Frank, Richard G., and Davis S. Salkever, "Pricing, Patent Loss and the Market for Pharmaceuticals", *Southern Economic Journal*, 59(2), October 1992:165-179; Grabowski and Vernon (1992); Freudenheim, Milt, "Cleaning Out the Medicine Cabinet", *New York Times*, 11 September 1997:C1, available from www.gphaonline.org; González Rodríguez, Jorge; Sismeiro C.; Dutta S.; Stern P., "Can Branded Drugs Benefit from Generic Entry?: The Role of Detailing and Price in Switching to Non-Bioequivalent Molecules", International Journal of Research in Marketing, Vol. 25, No. 4, 2008, pp. 247-260, available at 10.1016/j.ijresmar.2008.08.002 (DOI).

[22] See https://www.express-scripts.com/art/pdf/kap17Medications.pdf.

[23] This section is partially based on Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights (Volume VI of Commentaries on the GATT/WTO Agreements)*, Oxford University Press, 2007.

[24] See article 6 of the TRIPS Agreement.

[25] Article 28.1(a) of the TRIPS Agreement.

[26] Article 30: 'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.

The consistency of the Bolar exception with Article 30 of the TRIPS Agreement was tested in a case initiated in November 1998 by the European Communities and their member States (EC) against Canada, which had introduced a Bolar exception in 1991. The challenged provision explicitly allowed a third party to use the patented invention to submit the information required for marketing approval (in Canada or abroad) as well as to stockpile the product (for up to six months) for release immediately after the expiry of the patent.[27]

In March 2000, the WTO panel concluded that Canada was not in violation of the TRIPS Agreement in terms of its practice of allowing the development and submission of information required to obtain marketing approval for pharmaceutical products carried out without the consent of the patent holder. However, Canada was found to be acting inconsistently with the Agreement in terms of its practice of manufacturing and stockpiling pharmaceutical products during the six months immediately prior to the expiry of the 20-year patent term.[28]

The admissibility of exceptions to patent rights is subject, under Article 30 of the TRIPS Agreement, to three conditions which, in the view of the panel, are:

> cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed.[29]

The panel added that:

> The three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy. Normally, the order of listing can be read to suggest that an exception that complies with the first condition can nevertheless violate the second or third, and that one which complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be "limited" and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not "unreasonably conflict with normal exploitation" could nonetheless "unreasonably prejudice the legitimate interests of the patent owner.[30]

The consideration of the three conditions established by Article 30 as ‘cumulative’ does not find support in the text of the provision nor is it justified under an interpretation in accordance with the Vienna Convention on the Law of the Treaties. As noted in the

[27] Patent Act, Section 55.2(1): “It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product”. Patent Act, Section 55.2(2). “It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires”. In accordance with the Manufacturing and Storage of Patented Medicines Regulations, “the applicable period referred to in subsection 55.2(2) of the Patent Act is the six month period immediately preceding the date on which the term of the patent expires”.

[28] WT/DS114/R.

[29] Ibid., para 7.20.

[30] Ibid., para 7.21.

'Declaration on Patent Protection. Regulatory Sovereignty under TRIPS' elaborated under the auspices of the Max Planck Institute for Innovation and Competition:

> Contrary to what a panel of the WTO's Dispute Settlement Body seemed to assume (cf. WT/DS114/R of 17 March 2000), the three conditions are not cumulative. The three-step test may be understood to require a comprehensive overall assessment rather than a separate and independent assessment of each criterion. Failure to comply with one of the three conditions need not result in the exception being disallowed.[31]

The first condition to be met under the referred to Article 30 of the TRIPS Agreement is that the exception must be "limited". In accordance with the WTO panel:

> The word "exception" by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term "limited exception", the word "limited" must be given a meaning separate from the limitation implicit in the word "exception" itself. The term "limited exception" must therefore be read to connote a narrow exception – one which makes only a small diminution of the rights in question[32].

> In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged. The term "limited exceptions" is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with.[33]

By adopting a narrow concept of "limited", the panel focused on the extent of the curtailment of rights and not on the economic implications thereof. Hence, an exception with little economic effects might be disallowed under this doctrine even if the patent owner is not negatively affected in practice. The panel's view that the economic impact of the exception must be evaluated under the other conditions of Article 30 unduly narrows down the scope of admissible exceptions.

The language of the second condition established by Article 30 (the exception should not "unreasonably conflict with the normal exploitation" of the patent) was substantially borrowed from article 9 (2) of the Berne Convention. Canada argued that "exploitation" of the patent involved the extraction of commercial value from the patent by "working" the patent, either by selling the product in a market from which competitors are excluded, or by licensing others to do so, or by selling the patent rights outright. The EC defined "exploitation" by referring to the same three ways of "working" a patent, but differed on the interpretation of the term "normal".[34] In the panel's view, "normal" is "regular, usual, typical, ordinary,

[31] Available at www.mpg.de/8132986/Patent-Declaration.pdf, p. 8.
[32] WT/DS114/R, para. 7.30.
[33] Ibid., para. 7.31.
[34] Ibid., para. 7.51.

conventional".[35] The panel did not take a position with regard to the empirical or normative connotation of the concept. It held that:

> the term can be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement. The Panel concluded that the word "normal" was being used in Article 30 in a sense that combined the two meanings (para. 7.54).
>
> The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws[36].

The panel's reasoning is questionable since the right to exclude the use of the patented subject matter by third parties is not a form of exploitation of the patent, but a legal power established by law that may be exercised or not. However, the panel analysis led to the conclusion that in the case of the Canadian provision there was not conflict with the 'normal' exploitation of a patent. As a result, it was not necessary to elucidate whether the Canadian exception was reasonable or not.

The third condition of Article 30 requires that the exception does 'not unreasonably prejudice the legitimate interests of the patent owner'. While the EC argued that that "legitimate interests" were essentially "legal" interests, in rejecting this interpretation the panel considered that:

> To make sense of the term 'legitimate interests' in this context, that term must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms. This is the sense of the word that often appears in statements such as "X has no legitimate interest in being able to do Y".[37]

The panel added that "a definition equating 'legitimate interests' with legal interests makes no sense at all when applied to the final phrase of Article 30 referring to the "legitimate interests" of third parties" (para. 7.68).

In relation to the last part of Article 30 'taking account of the legitimate interests of third parties' – which is absent in Article 9(2) of the Berne Convention and in article 13 of the TRIPS Agreement – the panel noted that:

> Absent further explanation in the records of the TRIPS negotiations, however, the Panel was not able to attach a substantive meaning to this change other than what is already obvious in the text itself, namely that the reference to the "legitimate

[35] The New Shorter Oxford English Dictionary, p. 1940.
[36] WT/DS114/R, para. 7.55
[37] Ibid., para.7.69.

> interests of third parties" makes sense only if the term "legitimate interests" is construed as a concept broader than legal interests[38].

Based on this reasoning and other convergent arguments, [39] the panel concluded, as noted, that the Canadian Bolar exception was consistent with the TRIPS Agreement. The panel ruling dismissed the argument suggesting that the owner of an expired patent had a right to a *de facto* extension of its monopoly resulting from the delay in the approval of generic products. However, as the panel found that the stockpiling provision was inconsistent with Article 30 of the TRIPS Agreement. Canada subsequently amended its legislation in this regard.[40]

IV. THE BOLAR EXCEPTION IN NATIONAL LAWS

Since this panel decision, the Bolar exception has been incorporated in many national laws.[41] It is clearly one of the 'flexibilities' allowed by the TRIPS Agreement widely recommended to mitigate the negative impact that patents may have on access to medicines, particularly in developing countries.[42] There are differences, however, regarding the scope of acts shielded from infringement claims.

In the USA, a number of court cases have clarified some aspects of the Bolar exception under the Hatch-Waxman Act.[43] In *Eli Lilly and Co. v. Medtronic*, the Supreme Court affirmed that the exception not only applied to drugs but also to medical devices.[44] In *Merck KGaA v. Integra Lifesciences I*, Ltd.,[45] the same Court reversed the decision by the Federal Circuit and held that pre-clinical studies, if undertaken with the intent of making a

[38] Ibid., para. 7.71.

[39] Thus, it rejected the argument that the Canadian exception was discriminatory (and hence incompatible with article 27.1 of the TRIPS Agreement). It is worth noting that the challenged Section 55.2(1) applied to any regulated products, and not only to pharmaceuticals, that it allowed for submission of information in other countries and that it was not linked to an extension of the patent term.

[40] Patent Act SC 1993, C.2, Section5 5.2 (1): 'It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product. […] (6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent'.

[41] See, e.g., WIPO, Exceptions and Limitations to Patent Rights: Experimental Use and/or Scientific Research, A report prepared by the Secretariat of WIPO for the SCLP, Twentieth Session Geneva, January 27 to 31, 2014 (SCP/20/4).

[42] See, e.g., Germán Velásquez, Carlos Correa and Xavier Seuba, *IPR, R&D, Human Rights and Access to Medicines - An Annotated and Selected Bibliography* , South Centre, Geneva, 2012.

[43] See Anthony Tridico, Jeffrey Jacobstein and Leythem Wall, Facilitating generic drug manufacturing: Bolar exemptions worldwide, *WIPO Magazine*, June 2014, available at http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html.

[44] 496 US 661 (1990).

[45] 545 U.S. 193 (2005).

submission to the FDA, even if the product was not finally made,[46] were exempted under 35 U.S.C. § 271(e)(1). The court stated that '[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included',[47] and that the application of the exception was not limited to situations in which a pharmaceutical candidate had already been identified and was being tested in order to obtain the FDA approval. The Supreme Court thus confirmed that the Bolar exception applied to preclinical and clinical studies related to safety and efficacy of a drug, including studies on the mechanism of action, pharmacology, and pharmacokinetics. It held that a reasonable basis for believing that the experiments will produce the types of information that are relevant to a new drug application was sufficient for the Bolar exception to apply. In a later decision, the Federal Circuit considered that the exception also covered post-approval testing, "even if the information collected [was] never submitted to a regulatory agency, provided that the agency require[d] such testing or the retention of records for possible inspection."[48]

In European countries, the experimentation **on** an invention (as opposed to **with** an invention) has been generally allowed, without excluding acts done for commercial purposes. Case law on this exception relating to pharmaceutical or agrochemical products accepted, for instance, research undertaken to find out more information about a product, provided that it was not made just to convince licensing authorities or customers about the virtues of an alternative product, and to obtain further information about the uses of a product and its possible side-effects and other consequences of its use.[49] In a case decided in 1997 by the German Federal Supreme Court[50] concerning erythropoietin, the court held that 'the intention that is associated with an activity begun and carried out for research purposes cannot render such an activity infringing merely because the results of the research will not solely serve research purposes but above all will serve commercial purposes', thereby suggesting that research done for submitting the results of trials to the drug regulatory authority might be admissible under certain circumstances.

The situation was clarified in the European Union in 2004 through Article 10(6) of the Directive 2001/83/EC (as amended) in accordance to which:

> Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

This Directive – which entered into force in October 2005 – exempts the use of a patented invention that is made to comply with the requirements for the marketing approval for generic medicines.[51] Since it does not clarify the terms 'studies and trials', it has not led to

[46] Merck tested patented RGD peptides, in vitro and in vivo, covered by five Integra's patents in an effort to develop integrin antagonists as angiogenesis inhibitors.
[47] Merck KGaA v. Integra Lifesciences I, Ltd 545 U.S. 193, 202 (2005).
[48] Anthony Tridico, Jeffrey Jacobstein and Leythem Wall, op. cit.
[49] See, e.g., W Cornish "Experimental Use of Patented Inventions in European Community States", 29 IIC 7, (1998) 736. See also Carlos M. Correa, International Dimension of the Research Exception, SIPPI Project, AAAS, Washington D. C., available at http://sippi.aaas.org/intlexemptionpaper.shtml.
[50] Clinical Trials II [1998] RPC 423.
[51] Article 27(d) of the Agreement on a Unified Patent Court reiterates the Directive's exception: 'The rights conferred by a patent shall not extend to any of the following: (d) the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC 1 or Article 10(6) of Directive 2001/83/EC 2 in respect of any patent covering the product

the full harmonization within the EU, where many differences in the implementation of the exception exist.[52] On the one hand, while some countries (such as the United Kingdom, Belgium, Cyprus, Ireland, Netherlands and Sweden) only seem to apply the exception to activities relating to marketing approval of generic medicines and biosimilars, other countries (such as Austria, Bulgaria, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia and Spain) exempt uses in trials related to the development of new products.[53] On the other, some countries (such as Austria, Germany, Denmark and Italy) seem to also allow trials undertaken to comply with regulatory requirements abroad.[54]

The question whether outsourcing of an active pharmaceutical ingredient to a generic producer is exempted was considered in 2013 by the Polish Supreme Court in *Astellas Pharma Inc. Polpharma SA Pharmaceutical Works* (CSK 92/13). With regard to the argument that the supplier was unable to ensure that the purchaser effectively used the acquired product for the purposes allowed under the Bolar exception, the court ruled that the sale of the patented active ingredient, irrespective of its purpose, was not covered by it and constituted a patent infringement.[55]

In a similar case, the Düsseldorf Court of Appeal disagreed with the first instance decision that the sale of an active ingredient would be covered by the exception only if the supplier was the co-organizer of the tests and studies for regulatory approval.[56] The Court of Appeal referred in 2014 to the Court of Justice of the European Union (CJEU) the question whether the Bolar provision covered outsourcing and whether the supplier was bound to take measures to ensure that the active ingredient would only be used for obtaining regulatory approval.[57]

The Bolar exception has been adopted in many Latin American countries, such as Argentina (Law No 24.766 of 1996)[58], Dominican Republic (Law No 20–00 on Industrial Property of April 2000), Brazil (Law No 10.196/2001), Chile (Patent Law, Article 49), Andean Community (Decision 689)[59] and Uruguay (Law No. 17.164, Article 39). Interestingly, the exception was introduced in some countries as a result of the implementation of free trade agreements (FTAs) with the USA, which typically contain such

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within the meaning of either of those Directives…'.

[52] See, e.g., András Kupecz, Kristof Roox, Christian Dekoninck, Denis Schertenleib, Marco Stief, Fabrizio Sanna, Matteo Orsingher, Sergio Miralles, Elena Molina, Trevor Crosse, Mike Gilbert and Will James, 'Safe harbors in Europe: an update on the research and Bolar exemptions to patent infringement, *Nature Biotechnology,* 33, 710–715 (2015), 8 July 2015, available at http://www.nature.com/nbt/journal/v33/n7/full/nbt.3273.html.

[53] The same would apply in Norway and Switzerland; see Anthony Tridico, Jeffrey Jacobstein and Leythem Wall, op. cit.

[54] Ibid.

[55] The court also refused to refer to the Court of Justice of the European Union for a preliminary ruling regarding the interpretation of the Bolar exemption. See Marta Koremba, Aleksandra Karpińska, 'Poland: Outsourcing of API manufacture is not covered by the Bolar exemption', 6 February 2014, available at http://www.twobirds.com/en/news/articles/2014/global/life-sciences/poland-outsourcing-of-api-manufacture-is-not-covered-by-the-bolar-exemption.

[56] See, e.g., http://www.eplawpatentblog.com/eplaw/2014/01/cjeu-referral-d%C3%BCsseldorf-court-of-appeal-re-third-party-supply-for-bolar-exemption.html.

[57] See C-661/13, available at http://curia.europa.eu/juris/liste.jsf?language=en&num=C-661/13. Since the case was later withdrawn, the CJEU did not issue an interpretation on the subject.

[58] The exception was not contained in the patent law adopted in 1995, but later incorporated it in the law dealing with test data and confidential information.

[59] The incorporation of the exception into national laws is, however, facultative.

exception.[60] These FTAs, however, seem only to exempt the use of the protected product to file for the marketing approval of a generic drug. They also provide that 'if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party, thereby limiting the possibility of invoking the exception to seek regulatory approval in a foreign country. In Mexico, the Bolar exception is not recognized under the Mexican Industrial Property Law, but under article 167bis of the Reglamento de Insumos para la Salud (Regulations on Health-Related Consumable Goods), in accordance to which it shall be possible to undertake studies, tests, or experimental production of product, the substance or active ingredient of which is protected by a patent, to request registration of a generic version of the same, within a period of three years before the expiration of the patent.

Most countries in Asia provide for the Bolar exception, albeit with different scope. In some countries it is limited to marketing approval in its own territory (e.g. Pakistan, Singapore), while in others (e.g. India, Philippines, Israel) acts relating to submissions in other countries are also exempted in some cases.[61] In Japan, acts relating to the marketing approval of medicines were deemed by the Supreme Court as covered by the patents law's experimentation exception. In a unanimous decision, the court in *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd* confirmed that tests during the patent term to obtain data required for regulatory approval were not infringing under section 69(1) of the Japanese patent law.[62] Bolar-type provisions are also available in other jurisdictions, such as New Zealand and Australia.[63]

While some African countries have introduced a Bolar exception, the number of the countries that have done so seems lower than in other regions.[64] The Bangui Agreement Relating to the Creation of an African Intellectual Property Organization (OAPI), with the membership of 27 countries, currently does not include a Bolar exception among those provided for patent rights (article 8, Annex I). The 2007 review[65] of the national legislation in 39 out of the 47 Sub-Saharan African countries found that that, although most of them, including least-developed countries, provided patents for pharmaceutical products, the level of the incorporation of the flexibilities, including the Bolar exception was very low. Only three countries (Kenya, Namibia and Zimbabwe) specifically provided for the Bolar exception. Since the review, however, some African countries have incorporated it. For instance, a new Section 69A was introduced in the South African Patents Act by the legislative amendment in 2002 providing for an exception applicable to any regulated products. The provision specifies that the making, use or importation of the patented product must be 'on a non-commercial scale' to submit 'information required under any law that regulates the manufacture, production, distribution, use or sale of any product'. Bolar

[60] See, for instance, article 15.9.5 of the DR-CAFTA, available at https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf. See also the FTAs USA-Chile, USA-Colombia, USA-Peru.

[61] Anthony Tridico, Jeffrey Jacobstein and Leythem Wall, op. cit.

[62] Jennifer A. Johnson, 'The Experimental Use Exception in Japan: A Model For U.S. Patent Law?' *Pacific Rim Law & Policy Journal*, vol. 12, No. 2, 2003, p. 516.

[63] See below.

[64] See WIPO Regional Seminar on the Effective Implementation and Use of Several Patent-Related Flexibilities Bangkok, Thailand March 29 to 31, 2011, available at http://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_bkk_11/wipo_ip_bkk_11_ref_topic3.pdf.

[65] Sisule Musungu, *Access to ART and Other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations*, Report commissioned by UNDP, p. 13, available at http://apps.who.int/medicinedocs/documents/s18248en/s18248en.pdf.

exceptions can also be found in the laws of North African countries. For instance, in Egypt patent law exempts from patent infringement acts if 'a third party proceeds, during the protection period of a product, with its manufacturing, assembly, use or sale, with a view to obtain a marketing license, provided that the marketing starts after the expiry of such a protection period'. In Morocco, a Bolar exception was introduced by the FTA with the USA, with the limitation regarding submissions of information in other countries noted above.[66]

V. DESIGNING A BOLAR EXCEPTION

The previous overview suggests that there are several aspects that should be taken into consideration in drafting a Bolar exception. They are briefly referred to below.

Covered Products

As mentioned above, some Bolar exceptions apply to all products subject to regulatory approval (e.g., under the laws of New Zealand and Canada).

Under some formulations, however, the exception is limited to health products for human use, including pharmaceuticals and medical devices (such as in the USA, in accordance with courts' interpretation), while in some cases only pharmaceuticals are covered (Australia's Bolar exception, for instance, expressly excludes medical or therapeutic devices). In the EU and the USA, producers of veterinary products may benefit from the Bolar exception as well.

While public health concerns deserve particular attention, the most reasonable approach would seem to cover under the exception all regulated products, since there is no solid argument to differentiate between health-related and other products, the marketing of which is subject to prior regulatory approval. This does not mean, however, that exceptions limited to pharmaceuticals (or sub-categories thereof, such as medicines) would be inconsistent with the TRIPS Agreement since, as noted by the WTO panel in *Canada – Patent Protection of Pharmaceutical Products*, a special treatment based on public health considerations is justified under article 27.1 of said Agreement.[67]

Specific or General

It has also been mentioned above that a Bolar-type exception has been recognized through the interpretation of more general exceptions allowing for research and/or experimentation on a patented invention. This may be the outcome of courts' interpretation (like in the case of

[66] A similar provision is contained in the FTAs entered into by the USA with Bahrein. See Musungu, S., and C. Oh. 2005, *The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?* Study 4C. Geneva, Switzerland: CIPIH (Commission on Intellectual Property Rights, Innovation and Public Health), available at www.who.int/ intellectualproperty/studies/TRIPSFLEXI.pdf.
[67] WT/DS114/R, para. 92.

Japan) or be provided for by the statute. For instance, the patent law of Croatia (1999) exempts:

> acts done for the purposes of the research and development of the subject matter of the protected invention, in particular: making, using, offering for sale, importation, or exportation of the protected product, where such acts are reasonably connected with the experiments and tests necessary for the registration of the human and veterinary medicines, medical and veterinary products or preparations for the protection of plants (article 5.2).

Permitted Acts

In order to undertake testing of a generic product for approval by a regulatory authority, the applicant normally needs to work with samples of the drug embodying a patented invention. The required materials may be obtained through importation or production by the applicant. These possibilities are specifically spelled out in some laws (e.g. South African Patent Act). It is desirable to follow this approach in order to give certainty to both, patent owners and generic producers about the scope of their rights.

Of particular importance is also to clarify whether outsourcing of an active ingredient to conduct the necessary tests is covered by the exception. As noted above, this issue has been controversial in Europe. In order to achieve its purpose, a well-formulated Bolar provision should make it clear that outsourcing is not infringing. If it were not allowed, many generic producers (especially small and medium enterprises) could be de facto prevented from undertaking trials exempted under the exception, thereby limiting generic competition and its potential price-reduction effect.

Some differences in the scope of the exception may stem from the wording used to refer to the relationship between the acts that are exempted and their purpose. Expressions like ‘acts for regulatory approval’, ‘acts solely for uses reasonably related to regulatory approval’ or ‘acts exclusively aiming at regulatory approval’[68] may lead to various determinations regarding what types of activities are effectively shielded from infringement claims.

Pre-Clinical and/or Clinical Trials

Most Bolar exceptions do not clarify whether they apply to pre-clinical or clinical studies, or both. As noted above, in *Merck v Integra*, the US Supreme Court ruled that preclinical studies involving patented compounds may be exempted from patent infringement under 35 U.S.C. § 271(e)(1), to the extent that there is a reasonable basis to believe that those studies will produce information relevant to an application to be filed with the FDA. This seems the right solution, as there is no reason to distinguish between early and late stages of research involving a patented product.

[68] See WIPO, Exceptions and Limitations to Patent Rights, op. cit., para. 132.

A pro-competitive Bolar exception may also cover post-approval testing required by a regulatory authority, even if the information is not actually submitted to it. The *Momenta Pharm. v. Amphastar Pharm. (*686 F.3d 1348, 2012) mentioned above provides an example of a US precedent confirming the coverage under the Bolar exception of such testing.

Generic Versions and/or New Products

Another important dimension of the Bolar exception is whether it is only applicable to obtain the marketing approval of a *generic* product, or also to research that may lead to the development of a *new* product.

Some national laws do not distinguish whether the patented invention is used for the marketing approval of a generic or the development of a new pharmaceutical product. For example, Article 8 of Argentine law 24.766 of December 1996 states that:

> When a product or process is protected by a patent, any third party shall be able to use the invention before the expiration of the patent, with experimental aims and to gather the information required for the approval of a product or process by the competent authority, for its commercialization after the expiration of the patent.

The Thai Patent Act B.E 2522 (1979), as amended by B.E 2535 (1992), provides that the patentee's exclusive rights shall not apply to:

> any act in respect of applications for drug registration, the applicant intending to produce, sell or import the patented pharmaceutical when the patent expires (article 36.4).

The doctrine developed by US courts, as referred to above, is also relevant in this respect. The Canadian courts have likewise extended the Bolar exception to include material that is not submitted to a regulatory authority but is subject to potential inspection, including samples and data stored pursuant to regulatory requirements.[69]

A Bolar exception should apply to submissions relating to generic products as well as if the application for the approval of a generic product is not filed, for instance, because the tests did not produce outcomes of immediate use.

Term to File an Application

Can testing and research be conducted under a Bolar exception at any time during the life of the relevant patent? Normally, generic producers will start such activities within a reasonable period before the expiry of the patent, once the commercial attractiveness of a product can be established with some certainty, and there is no need to wait for a long period before the investment made to obtain the required authorization can be recouped.

Most national laws do not address this issue; the decision when to start the procedures is left to the interested parties. In the case of the Mexican law, however, the defense under the

[69] See Anthony Tridico, Jeffrey Jacobstein and Leythem Wall, op. cit.

Bolar-like exception, as noted, is available only when a patent on a chemical is within three years of expiration.

Submissions in Foreign Countries

Some laws contain Bolar-type exceptions that only permit acts relating to the submission of an application in the respective country, while others also allow, as mentioned above, to make submissions abroad.[70] There is no solid justification for a limitation regarding submissions in foreign countries. The legitimate interests protected under a patent granted in the country where trials take place are not affected by acts made in another jurisdiction. Patents are of territorial nature. Whether the submission of information in a foreign country, before the expiry of a patent granted there, is admissible or not is a matter solely subject to the law of that country.

Taking advantage of the precedent set by the Canadian Bolar exception, many countries allow acts the purpose of the registration of generic products in foreign countries. For instance, the patent law of Croatia, mentioned above, explicitly refers to exportation of the protected products. Brazilian Law 10.196 (2001) contains an exception for acts performed by non-authorized third parties, regarding patented inventions, which aim exclusively at the production of information, data and test results directed to procure commercial registration, in Brazil or any other country, to allow the exploitation and commercialisation of the patented product, after the termination of the patent (Article 43 (VII)). Section 107(a) of the Indian Patents Act more broadly exempts acts relating to the development and submission of information required by law **"in India or in a country other than India"**. A similar far-reaching exemption is also found in the Universally Accessible Cheaper and Quality Medicines Act of 2008 (Section 72(4) of the Philippines.

Extension of the Patent Term

The introduction of the Bolar exception, as provided for in most countries, has not been linked to an extension of the term of the respective patent, as it is the case of the USA, given the particular circumstances under which that exception was introduced. There is nothing in the TRIPS Agreement or in other international instrument requiring an extension of the patent term as a condition for providing for a Bolar exception. Canadian law scrutinized and found WTO-consistent in *Canada–Pharmaceutical Patents* (except with regard to the stockpiling of products) likewise did not grant such an extension.

[70] In the case of Israel, this is limited to other countries where a Bolar exception is also recognized.

IV. CONCLUSIONS

The Bolar exception has clear pro-competitive effects, which are of particular importance in the area of public health. Since the exclusive rights of the patent owner are not affected during the patent term, its incorporation into patent regimes (or other relevant legislation) is amply justified. The Bolar exception is one of the important flexibilities allowed by the TRIPS Agreement. In fact, its recognition long preceded the adoption of that Agreement, and is today broadly accepted in developed and developing countries. Lawmakers and courts should we aware of a diversity of aspects that determine, in practice, the scope of acts permissible under the exception. The broader the formulation of the exception in terms of covered products, sources of samples, type of trials allowed, time to undertake them, and geographical scope, the more competitive environment is ensured that will benefit consumers, health providers and other public agencies.

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