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SOUTH CENTRE

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ABSTRACT

This Research Paper addresses the growing problem of access to essential medicines, focusing on the role of intellectual property rights, particularly patent rights, in restricting access by enabling pharmaceutical market monopolies that keep drug prices high. The paper explores the Bolar exception, a legal mechanism designed to allow generic drug manufacturers to seek regulatory approval before a patent expires, thus preventing the de facto extension of patent monopolies. The study examines the transformation of the Bolar exception from a specific legal case into a significant tool of intellectual property, commercial, and pharmaceutical law. The paper analyzes key international legal frameworks and European directives related to the Bolar exception and highlights divergent interpretations of the Exception in German and Polish case law. Through this comparative analysis, the paper argues for the broader implementation of Bolar exceptions to improve access to affordable medicines and reduce healthcare costs.

Este Documento de Investigación aborda el creciente problema del acceso a los medicamentos esenciales, centrándose en el papel de los derechos de propiedad intelectual, en particular los derechos de patente, en la restricción del acceso al permitir monopolios del mercado farmacéutico que mantienen altos los precios de los medicamentos. El documento explora la excepción Bolar, un mecanismo legal diseñado para permitir a los fabricantes de medicamentos genéricos solicitar la aprobación regulatoria antes de que expire una patente, evitando así la extensión de facto de los monopolios de patentes. El estudio examina la transformación de la excepción Bolar de un caso jurídico específico en una importante herramienta del derecho de propiedad intelectual, comercial y farmacéutico. El documento analiza los principales marcos jurídicos internacionales y directivas europeas relacionados con la excepción Bolar y destaca las interpretaciones divergentes de la excepción en la jurisprudencia alemana y polaca. A través de este análisis comparativo, el documento aboga por una aplicación más amplia de las excepciones Bolar para mejorar el acceso a medicamentos asequibles y reducir los costes sanitarios.

Ce Document de Recherche aborde le problème toujours plus aigu de l'accès aux médicaments essentiels, en se concentrant sur le rôle des droits de propriété intellectuelle, en particulier les droits de brevet, qui restreignent l'accès en permettant des monopoles sur le marché pharmaceutique qui maintiennent les prix des médicaments à un niveau élevé. Le document explore l'exception Bolar, un mécanisme juridique conçu pour permettre aux fabricants de médicaments génériques de demander l'approbation réglementaire avant l'expiration d'un brevet, empêchant ainsi l'extension de facto des monopoles de brevets. L'étude examine la transformation de l'exception Bolar d'un cas juridique spécifique en un instrument important en matière de droit de la propriété intellectuelle, de droit commercial et de droit pharmaceutique. Elle analyse les principaux cadres juridiques internationaux et les directives européennes relatifs à l'exception Bolar et met en évidence les interprétations divergentes de l'exception dans les jurisprudences allemande et polonaise. Grâce à cette analyse comparative, le document encourage une mise en œuvre plus large des exceptions Bolar afin d'améliorer l'accès à des médicaments abordables et de réduire les coûts des soins de santé.

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1. INTRODUCTION

Access to essential medicines is a growing problem in many countries.[2] Intellectual property rights, in particular patent rights, are often considered by some researchers to be major obstacles to access to essential medicines. Indeed, patent rights contribute to market monopolization and, consequently, to keeping drug prices high.[3] This market monopoly by pharmaceutical companies weighs heavily on national health budgets, and can lead to serious difficulties by unduly restricting patient access to essential medicines.[4] The issue of access to medicines is part of the United Nations' Sustainable Development Goals.[5]

In the pharmaceutical field, companies developing medicines can obtain patents on active ingredients – the components of medicines with the therapeutic power.[6] By its very nature, such a patent excludes any manufacture, storage or use of the active ingredient by third parties.

However, drugs cannot be marketed without prior authorization from the relevant regulatory agency. Regulatory requirements differ from country to country. In general, national marketing authorization regulations distinguish between pharmaceutical products comprising new chemical entities or biological molecules – for which preclinical and clinical studies demonstrating efficacy and safety are to be submitted to the competent authority by their inventor – and "generic" or "similar" versions of medicines, for which information concerning efficacy and safety has already been submitted and evaluated by the said competent authority. In the latter case, although the requirements imposed on applicants vary from country to country, abbreviated and simplified procedures are generally applied. These are considerably shorter than those required for the approval of pharmaceutical products incorporating new molecules. However, they can delay the marketing of generics by two to three years.

If a producer of a generic or similar version has to wait until the last day of the patent term covering a pharmaceutical product to start proceedings, the holder of the expired patent will de facto benefit from an additional period of monopoly, as long as a generic version of the product obtains marketing authorization. To avoid this distortion of the law, it has proved necessary to implement an exception to patent law commonly referred to as the "Bolar exception". This exception, which takes its name from an American case law, aims to balance the interests of patent holders and potential competitors, by allowing generic drug manufacturers to take the necessary steps to obtain regulatory approval before the patent expires, and launch their product as soon as the patent expires.

Since governments and consumers would benefit from lower prices thanks to generic competition, the Bolar exception could play an important role in reducing the burden on healthcare budgets. It could significantly improve access to more affordable pharmaceuticals. Medicines that received their first generic entry in 1999-2000 retained a market share of 44 percent of units one year after entry. In 2011-2012, generic drugs gained market share much

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[2] CHAN Margaret, "Access to medicines: making market forces serve the poor*", Ten years in public health, 2007-2017* [online], pp. 13-24, [accessed March 5, 2024]

[3] GURGULA Olga and LEE Wen, "COVID-19, IP and access: Will the current system of medical innovation and access to medicines meet global expectations?" *Journal of Generic Medicines* [online], 2021, pp. 61-70, [accessed March 26, 2024]

[4] CORREA Carlos. *The Bolar Exception: Legislative Models and Drafting Options* [online], South Centre, 2016, p.1, [accessed March 16, 2024]

[5] UNITED NATIONS, *The 17 goals* [online], [consulted on May 12, 2024]

[6] LAROUSSE, *Principe actif* [online], [consulted on March 2, 2024]

more rapidly: originator drugs retained an average of only 16 percent of units one year after generic entry.[7]

The aim of this research paper is to explore the transformation of the Bolar case – an ordinary court case – into an important source of law, which has had a significant impact on intellectual property law, commercial law and the law governing pharmaceutical products. After outlining the history and legal content of the Bolar exception, the paper analyses the main Bolar exceptions in international law, namely Article 30 of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and European Directives 2001/82/EC, 2001/83/EC and 2004/27/EC. Secondly, examples of significant differences in the interpretation of the Bolar exception are provided, with focus on German and Polish cases, bearing in mind that the courts of these two EU states have provided two entirely different interpretations of the exception. Finally, this comparative analysis will enable us to demonstrate the support of the implementation of Bolar exceptions in domestic laws.

[7] GRABOWSKI Henry et al, "Recent trends in brand-name and generic drug competition", *Journal of Medical Economics* [online], 2013, pp. 1-8, [accessed March 16, 2024]; CORREA Carlos. *The Bolar Exception: Legislative Models and Drafting Options* [online], South Centre, 2016, p. 2-3, [accessed March 16, 2024]

2. ROCHE PRODUCTS, INC. V. BOLAR PHARMACEUTICAL CO.

Roche Products, Inc (Roche) of Basel held a US patent on flurazepam hydrochloride, the active ingredient in the sleeping pill "Dalmane", which expired in 1984.[8]

In 1983, Lagos-based Bolar Pharmaceutical Inc (Bolar) considered marketing a generic equivalent to Dalmane after patent expiry. Bolar began the process of obtaining marketing approval for its generic Dalmane from the Federal Drug Administration (FDA) without waiting for patent expiry, knowing that commercial success depended on its speed to market after patent expiry. Bolar obtained five kilograms of the active ingredient from a foreign manufacturer in 1983 to develop the capsule dosage form, obtaining the necessary data to submit a new application to the FDA.

Roche filed suit in the US District Court for the Eastern District of New York, which held that Bolar's use of the patented active ingredient for federally mandated testing was not an infringement of the patent in question, as Bolar's use was *de minimis* and experimental. Roche then filed its notice of appeal with the U.S. Court of Appeals for the Federal Circuit, which held that Bolar infringed Roche's patent rights and reversed the district court's judgment.

However, shortly afterwards, the U.S. Congress passed a new law – the Drug Price Competition and Patent Term Restoration Act, also known as the "Hatch-Waxman Act",[9] considered to be the first Bolar exception. Under this law, it is not an act of infringement to make, use, offer for sale, sell in the United States or import into the United States a patented invention solely for uses reasonably related to the development and submission of information in connection with the manufacture, use or sale of veterinary drugs or biological products.[10]

[8] US patent no. US3299053A, *Novel 1-and/or 4-substituted alkyl 5-aromatic-3h-1, 4-benzodiazepines and benzodiazepine-2-ones*, January 17, 1967
[9] UNITED STATES, CONGRESS, *Public law 98-417, Drug Price Competition and Patent Term Restoration Act of Sept. 24, 1984.*
[10] Roche Products Inc. v. Bolar Pharmaceutical Co, 733 F.2d 858 (Fed. Cir. 04/23/1984)

3. THE BOLAR EXCEPTION WITH TRIPS

3.1 General Considerations

The TRIPS Agreement[11] is an annex to the Agreement Establishing the World Trade Organization (WTO).[12] Administered by the WTO, it applies the principles of the trading system to intellectual property rights, and establishes minimum standards for the protection and enforcement of intellectual property rights for WTO members.[13]

The TRIPS Agreement implicitly recognizes that the protection of public health may justify limitations on the rights of a patent holder over a pharmaceutical or other invention. It admits the possibility of subjecting the exclusive rights deriving from the patent to the limited exceptions provided for in its Article 30, while framing these exceptions by the requirement that such measures be compatible with the provisions for the protection of patented subject matter.[14]

The general scope of Article 30 of the TRIPS Agreement is broad, as it does not explicitly address the Bolar exceptions, but concerns all potential exceptions to the rights conferred by a patent. However, given that the agreement was adopted in 1994, eleven years after the Bolar case, it is likely that the authors of the treaty text took this precedent into account.

Article 30 of the TRIPS Agreement is both optional and mandatory. On the one hand, it allows WTO Member States to establish their own rules for restricting exclusive intellectual property rights, as defined in Article 28 of the TRIPS Agreement. This is not an obligation for States, since the verb used in the article is "may" ("may[...]"), not "shall". On the other hand, being a framework agreement, it establishes three minimum conditions, which must be met for an exception to comply with the agreement. They state that i) exceptions must be "limited"; ii) they must not unreasonably conflict with a normal exploitation of the patent; and iii) they must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. They have been designed to secure patent law by not granting overly broad exceptions. Such a configuration is also due to the principle of territoriality, as set out in article 4 let. A ch. 2-3 of the Paris Convention.[15] In effect, patent law is limited to the borders of States, and the power to define what may be patented is a matter for national law. According to Prof. Georg Bodenhausen: "the countries of the Union[16] are free to define in their national legislation the subject matter indicated, to which the Convention will then apply."[17]. Since this is an exception, in the event of litigation, the onus would be on the defendant to prove that the provisions at issue are in conformity with the provisions of the Agreement.

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[11] WORLD TRADE ORGANIZATION, *Agreement on Trade-Related Aspects of Intellectual Property, Marrakesh, April 15, 1994,* TRT/WTO01/001

[12] WORLD TRADE ORGANIZATION, *Agreement Establishing the World Trade Organization*, Marrakech, April 15, 1994, TRT/WTO/001

[13] YU Peter, *The Objectives and Principles of the TRIPS Agreement* [online], 46 Hous. L. Rev. 979 (2009), p. 1, Available at: https://scholarship.law.tamu.edu/facscholar/457

[14] BRIDJI, Ozoua Marie Chantal, *Brevet pharmaceutique et l'accès aux médicaments dans les pays en voie de développement* [online], thesis, business law, Université Toulouse Capitole, 2013, p. 122, [accessed April 3, 2024]

[15] WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Paris Convention for the Protection of Industrial Property*, Paris, March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and amended on September 28, 1979, TRT/PARIS/001, page 3

[16] Professor Bodenhausen refers to the Union for the Protection of Industrial Property, established by the Paris Convention of 1883.

[17] BODENHAUSEN Georg, *Guide d'application de la Convention de Paris pour la protection de la propriété industrielle telle que révisée à Stockholm en 1967,* BIRPI, 1969, p. 22

3.2 Interpretation Principles

The Understanding on Rules and Procedures for the Settlement of Disputes, a document included in the Agreement Establishing the WTO, establishes the means for resolving disputes between Member States. It establishes the WTO Dispute Settlement Body (DSB). In accordance with Article 3(2) of the Memorandum, the interpretation of the provisions of the TRIPS Agreement falls within the competence of the DSB.[18] The DSB interpretative function is relevant when a Member State contests a measure adopted by another State.[19]

The codified principles of interpretation are to be found in articles 31 and 32 of the Vienna Convention on the Law of Treaties (VCLT). According to article 31(1) VCLT, the principal rule of interpretation is that a treaty is to be interpreted in a fair manner, giving the terms of the treaty their ordinary meaning in their context, and having regard to its object and purpose.[20] It recognizes the principle of good faith, aimed at ensuring a balance in the interpretation of treaty terms to avoid injustice to either party. It requires the interpreter to give the terms their ordinary meaning in their context and in accordance with the treaty's object and purpose, thus necessitating a textual and teleological approach. The objectives and purpose of the treaty play a crucial role in this interpretation.

The second paragraph specifies that the context includes the text, preamble and annexes of the treaty, as well as any agreement between the parties concerning its conclusion and any instrument drawn up by at least one party and accepted by others in connection with the treaty. This provision enables the interpreter to take into consideration any element that may shed light on the context.

In addition, the third paragraph of the article extends the scope of interpretation by referring to subsequent agreements between the parties, subsequent practices concerning the interpretation of treaties, and relevant rules of international law applicable between the parties.

If the application of these instruments leaves the meaning "ambiguous or obscure, or leads to a manifestly absurd or unreasonable result", article 32 of the VCLT suggests the use of additional means of interpretation, such as the preparatory work of the treaty and the circumstances of its conclusion.

The context of the terms of the TRIPS Agreement includes, among others, the preamble to this agreement as well as that of the GATT 1994,[21] to which the TRIPS Agreement is annexed. The preamble to the TRIPS Agreement recognizes the underlying public policy objectives of national systems of intellectual property protection, thus legitimizing measures that affect such protection and pursue development objectives. It also recognizes the specific needs of developing countries for flexibility in the implementation of national laws and regulations in order to develop a sound technological base. Similarly, the preamble to the 1994 GATT sets out the main objectives of the WTO, emphasizing the importance of balancing social and economic interests for sustainable development, while respecting the autonomy of states in assessing their public policy interests.

Articles 7 and 8 of the TRIPS Agreement relate to the object and purpose of the Agreement. They provide objective guidance on how ambiguous terms in the TRIPS Agreement should be interpreted, making them crucial to the interpretation of Article 30. They are an essential source

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[18] WORLD TRADE ORGANIZATION, *Memorandum of Understanding on Rules and Procedures for the Settlement of Disputes,* Marrakech, April 15, 1994

[19] PRIFTI Viola, *The Breeding Exception to Patent Rights: Analysis of Compliance with Article 30 of the TRIPS Agreement* [online]*,* Springer, 2015, para. 6.1

[20] UNITED NATIONS ORGANIZATION, *Vienna Convention on the Law of Treaties,* Vienna, May 23, 1969, entry into force January 27, 1980, United Nations, Treaty Series, vol. 1155, p. 134

[21] WORLD TRADE ORGANIZATION, *General Agreement on Tariffs and Trade 1994*, Marrakesh, April 15, 1994

of flexibility on which WTO members must rely when interpreting and implementing Article 30, in order to ensure balanced protection of intellectual property rights.

Article 7 states that the objective of the TRIPS Agreement is not solely to protect intellectual property rights as an end in itself, and that the protection of these rights does not necessarily guarantee welfare gains. On the contrary, the agreement seeks a balance between encouraging technological innovation and facilitating the transfer and dissemination of technology, taking into account the interests of users and producers of technical knowledge, as well as the rights and obligations of WTO members. Fundamentally, Article 7 encourages an interpretation of the Agreement's provisions that is proportionate to social and economic needs, in the overall interest of society.

Article 8 gives States the leeway to adopt public policy measures aimed at protecting the interests of society, thus recognizing their ability to legitimately adapt their intellectual property systems to their level of development and specific needs. Moreover, by allowing States to determine what constitutes "public interests in sectors of vital importance", this article gives them considerable latitude in defining the content and scope of the measures they adopt. It also includes a compliance clause, requiring all measures adopted by States to comply with the provisions of the TRIPS Agreement.[22]

Moreover, identifying the object and purpose of the TRIPS Agreement is different from characterizing the object of intellectual property rights, since the objectives pursued by governments with these rights, as well as the way in which they are implemented, may differ significantly, even if they comply with the standards of the Agreement and other applicable international treaties.[23]

In 2001, during the Doha Round of WTO negotiations, WTO members adopted two key documents: the Doha Ministerial Declaration[24] and the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).[25] Both documents significantly reinforce the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement. The Ministerial Declaration states that the TRIPS Council will be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement, and will take full account of the development dimension.[26]

According to the main operational provisions of the Doha Declaration, the TRIPS agreement does not and should not limit WTO members in their ability to take measures to protect public health. It can and should be interpreted and applied in such a way as to support the right of WTO members to protect public health and, in particular, to promote access to medicines for all. WTO members have the right to make full use of the flexibilities offered by the TRIPS Agreement, including: the right to interpret each provision of the TRIPS Agreement in the light of its objective and purpose as expressed, inter alia, in its objectives and principles; the right to determine what constitutes a national emergency or other circumstances of extreme urgency, recognizing that public health crises can be both emergencies and circumstances of extreme urgency.[27]

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[22] TESORIERO Amy, "Using the flexibilities of Article 30 TRIPS to implement patent exceptions in pursuit of Sustainable Development Goal 3", *The Journal of Intellectual Property* [online], 2022, pp. 516-535, [accessed 16 March 2024]

[23] CORREA Carlos and HILTY Reto, *Access to Medicines and Vaccines. Implementing flexibilities under intellectual property law* [online], Springer, 2022, p. 20, [accessed 16 March 2024]

[24] WORLD TRADE ORGANIZATION, Doha WTO Ministerial 2001: Ministerial Declaration, WT/MIN(01)/DEC/1, November 20, 2001

[25] WORLD TRADE ORGANIZATION, Doha WTO Ministerial 2001: TRIPS, WT/MIN(01)/DEC/2, November 20, 2001

[26] YU Peter, "The Objectives and Principles of the TRIPS Agreement", *Houston Law Review* [online], 2009, pp. 5-6, [accessed March 3, 2024]

[27] WORLD TRADE ORGANIZATION, Doha WTO Ministerial 2001: TRIPS, WT/MIN(01)/DEC/2, November 20, 2001, para. 5(c)

The Doha Declaration has been recognized as a "subsequent agreement" of WTO members in accordance with Article 31(3)(a) of the VCLT. It provides general guidance on the interpretation of all provisions of the TRIPS Agreement. Consequently, although the compliance clause in Article 8(1) may initially appear to limit the scope of measures that States may take in pursuit of public policy objectives the Doha Declaration reconciles the fact that the TRIPS Agreement is not in conflict with public health objectives, as it must be interpreted in a way that is consistent with them. The Doha Declaration thus confirms the approach to interpretation aimed at balancing social and economic interests in the context of public health protection by WTO members when implementing national intellectual property regimes. However, some researchers argue that the importance of the Doha Declaration in shaping the interpretation of the TRIPS Agreement should not be overestimated.[28] According to researcher Susy Frankel: "[Doha] may rightly have limited attempts to suggest meanings other than that each member can determine what a 'national emergency' is, but the idea that the declaration brings any clarity to already clear words seems a politically convenient exaggeration that turns a blind eye to the principles of treaty interpretation.".[29]

In addition to codified principles of interpretation, other non-codified principles, such as the principle of effectiveness developed in WTO rulings, play a role in treaty interpretation. This principle requires the interpreter to ensure the integrity of the treaty text by favoring a reading that achieves the objectives of the treaty to the greatest extent possible, thus promoting a coherent interpretation. These principles guide the DSB in giving precise meaning to terms.[30]

3.3 Interpretation

The DSB examined the conformity of the regulatory review exception with Article 30 of the TRIPS Agreement in the "Canada - Patent Protection for Pharmaceutical Products" case. This procedure was initiated in 1999 by the European Communities and their Member States against sections 55.2(1) and 55.2(2) of the Canadian Patent Act. Section 55.2(1) allowed the production of samples of the patented product for regulatory review, while section 55.2(2) authorized the production and stockpiling of generic drugs six months prior to patent expiry.[31]

The DSB assessed whether the provisions of Canadian patent law were justified in the light of Article 30 of the TRIPS Agreement,

The DSB ruled that article 55.2(1) was justified under article 30 because it met the three cumulative conditions of that article. In this case, in the DSB's view, the exception was "limited" for the following reasons: "it reduces to a narrow margin the rights provided for in article 28.1. As long as the exception is circumscribed to the conduct necessary to satisfy the requirements of the regulatory approval process, the scope of acts not authorized by the right holder that are permitted by the exception will be small and narrowly circumscribed. While regulatory approval processes may require the production of large quantities of products for testing to demonstrate manufacturing reliability, neither are the rights of the patent holder themselves

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[28] TESORIERO Amy, "Using the flexibilities of Article 30 TRIPS to implement patent exceptions in pursuit of Sustainable Development Goal 3", *The Journal of Intellectual Property* [online], 2022, pp. 516-535, [accessed 16 March 2024]

[29] FRANKEL Susy, "WTO application of the 'customary rules of interpretation of public international law' to intellectual property", *Virginia Journal of International Law* [online], 2006, pp. 365-431, 401, [accessed March 17, 2024]

[30] PRIFTI Viola, *The Breeding Exception to Patent Rights: Analysis of Compliance with Article 30 of the TRIPS Agreement* [online], Springer, 2015, para. 6.1

[31] WORLD INTELLECTUAL PROPERTY ORGANIZATION, PERMANENT PATENT COMMITTEE, *Reference document on the exception relating to measures taken with a view to obtaining regulatory approval from the authorities,* SCP/28/3, May 14, 2018, p. 7-8

infringed by the size of these production runs, as long as they are solely for regulatory purposes and there is no commercial use of the resulting end products."[32]

With regard to the second condition of Article 30, which prohibits exceptions that "unreasonably conflict with a normal exploitation of the patent", the DSB found that: "Canada, however, had a stronger position when it argued that the additional period of de facto market exclusivity created by the use of patent rights to prevent submissions for regulatory approval should not be considered 'normal'. The additional period of market exclusivity in this situation is not a natural or normal consequence of exercising patent rights. It is an unintended consequence of the joint application of patent and product regulatory legislation, whereby, under the combined effect of patent rights and the chronological imperatives of the regulatory process, the exercise of certain patent rights is accompanied by a period of market exclusivity longer than the normal period".[33]

As for the third condition, the DSB concluded that the exception provided for in section 55.2(1) of the Canadian Patent Act did not prejudice the legitimate interests of the patent holder within the meaning of Article 30 of the TRIPS Agreement, subject to the following considerations: "on balance, the DSB concluded that the interest alleged on behalf of patent holders whose effective period of market exclusivity had been reduced by delays in obtaining marketing approval was neither compelling nor widely recognized to the extent that it could be considered a 'legitimate interest' within the meaning of Article 30 of the TRIPS Agreement. Despite the number of governments that had reacted positively to this alleged interest by granting patent term extensions as compensation, the issue itself had been around for a relatively short time, and there were clearly still differences between governments over the merits of these allegations".[34]

The DSB ruled that the three conditions of Article 30 are cumulative and represent a "three-step test" for verifying the legitimacy of an exception. In addition, he concluded that Canada complied with the TRIPS Agreement by authorizing the development and presentation of information necessary to obtain marketing approval for pharmaceutical products without the consent of the patent holder.

However, article 55.2(2) was found not to comply with the first condition of art. 30 of the TRIPS Agreement, because there was no limitation on the quantity of production to be stored, which resulted in a substantial reduction in extended market exclusivity and was therefore not "limited" as required by article 30 [35]

The DSB's interpretation was criticized by researchers at the Max Planck Institute in the "Declaration of Patent Protection. Regulatory Sovereignty under TRIPS". This work questions the cumulative approach of the three DSB conditions. According to the authors, the three-step process should be interpreted as requiring an overall rather than an independent assessment of each criterion, and failure to meet one of the three conditions does not automatically lead to rejection of the exception.

According to the Declaration of Patent Protection, for an exception to be considered "limited", it does not necessarily have to be narrow in scope. It is considered limited in accordance with Article 30 of the TRIPS Agreement if its scope is reasonably proportionate to its objective and purpose. An exception "unreasonably conflict[s] with a normal exploitation of the patent" if it compromises its functional effectiveness as a price-fixing mechanism. This occurs when it

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[32] WORLD TRADE ORGANIZATION, *Canada - Patent Protection of Pharmaceutical Products,* WT/DS114/R, p.190, para. 7.45
[33] Ibid, p. 193, para. 7.57
[34] Ibid, p. 202, para. 7.82
[35] CORREA Carlos, *The Bolar Exception: Legislative Models and Drafting Options* [online], South Centre, 2016, p. 6, [accessed 16 March 2024]

excessively limits the rewards for innovation provided by the market. An exception "unreasonably conflicts with the normal exploitation of the patent" if it compromises its functional effectiveness as a price-setting mechanism, thereby unduly limiting the incentives for innovation provided by the market. An exception does not "unreasonably prejudice legitimate interests" when it is proportionate and justified. In this context, it must take into account all interests, including those of the patent holder as well as current or potential licensees, other inventors, competitors and other market players operating under conditions of effective competition, scientific and academic researchers needing access to the results of basic research, consumers enjoying the benefits of technological progress, as well as social, economic and cultural well-being. Consequently, even apparently "open-ended" exceptions such as the stockpiling of generic medicines prior to the expiry of the relevant patents may be considered compatible with Article 30 of the TRIPS Agreement, provided that the principle of proportionality is respected and that all the interests at stake are taken into account.[36]

Professor Carlos Correa argued that, in narrowly defining the term "limited", the DSB focused solely on the extent of the restriction of rights, and not on its economic implications. Consequently, an exception with little economic effect can be rejected under this doctrine, even if the patent owner is not adversely affected in practice. In his view, the DSB opinion that the economic impact of the exception must be assessed under the other conditions of Article 30 unduly narrows the scope of admissible exceptions. He found the DSB reasoning with regard to the second condition questionable, as the right to exclude the use of the patented subject matter by third parties is not a form of exploitation of the patent, but rather a legal power established by law which may or may not be exercised. He also criticized the DSB for failing to elaborate on the content and implications of articles 7 and 8.1, despite the specific reference to them made by the parties in their submission.[37]

Professor Annette Kur criticized the DSB reasoning as superficial and flawed. In particular, she pointed to the lack of discussion of the policies underlying the limitations in place, which should be considered an important source of interpretation. She also criticized the repetition in the DSB argumentation, despite the latter's insistence on avoiding redundancy.[38]

Professor Kur proposes guidelines for interpreting the three-step test proposed by the Dispute Settlement Body. In her view, three fundamental principles should guide this interpretation. Firstly, it is inappropriate to apply a scheme of "property logic", where intellectual property is seen as an objective in itself. Secondly, it is crucial to take into account the objectives and principles of the TRIPS Agreement when assessing limitations. Thirdly, the assessment must always respect the principle of proportionality, measuring the severity of limitations against the importance of the underlying objectives.

With regard to the three-step test, Professor Kur explains that the first step is to determine the scope of the rule. In the second step, it is necessary to analyze the economic consequences, taking into account both restrictions on exploitation and incentives for innovation. Finally, in the third step, the conflicting interests of rights-holders and third parties need to be identified and assessed, taking into account the underlying policies.

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[36] LAMPING Matthias et al, "Declaration on Patent Protection - Regulatory Sovereignty under TRIPS", *International Review of Intellectual Property and Competition Law* [online], 2014, Vol. 45, Is. 6, Max Planck Institute for Innovation & Competition, paras. 22-25, [accessed March 17, 2024]

[37] CORREA Carlos, *Trade-Related Aspects of Intellectual property Rights: A Commentary on the TRIPS Agreement* [online], Oxford University Press, 2007, p.102, [accessed March 17, 2024]

[38] KUR Annette, "Of Oceans, Islands, and Inland Water - How Much Room for Exceptions and Limitations Under the Three-Step Test?", *Competition & Tax Law Research Paper Series, Max Planck Intellectual Property Research Institute No. 08-04* [online], 2008, p.30-31, [accessed March 18, 2024]

More generally, Professor Kur maintains that the principle of proportionality must guide the overall assessment. A limitation is permissible when other, less restrictive means would not achieve the same political objective.[39]

[39] Ibid, p. 40-41

4. IMPLEMENTATION OF THE BOLAR EXCEPTION IN EUROPEAN UNION LAW

4.1 General Considerations

Prior to the introduction of a specific exception in Europe, it was common practice for generic manufacturers' activities relating to the regulatory review process during the patent protection period to be subject to judicial assessment. These activities were often considered an infringement, and in some cases fell under the experimental use exception. However, although judicial practice has become less restrictive with regard to such activities, the divergence of approach between EU Member States prompted the European Union to consider the introduction of specific legislation on infringement, leading to consideration of the adoption of a specific exception in this field.[40] Thus, Directive 2001/82/EC[41] [article 13(6)] and Directive 2001/83/EC [42] [article 10(6)] were adopted. Directive 2001/83/EC [43] was subsequently amended by Directive 2004/27/EC, according to which the performance of studies and trials [relating to generic medicinal products and biological medicinal products] necessary for the application of paragraphs 1, 2, 3 and 4, and the practical requirements resulting therefrom, shall not be considered contrary to patent rights and supplementary protection certificates for medicinal products.

These provisions provide a common framework for the regulatory scrutiny exception for all EU Member States. According to Articles 289 and 291 of the Treaty on the Functioning of the European Union (TFEU),[44] to make these Directives binding, Member States must transpose them into national law. This transposition and the implementation of the exception at national level have not been uniform. More specifically, an analysis of national provisions and case law concerning the regulatory scrutiny exception in different EU countries shows that the wording, scope and interpretation of the exception vary.[45]

The discrepancies are due, in part, to the fact that the wording of Article 10(6) is not very clear. For example, it does not specify the terms "studies and tests" or "practical requirements arising therefrom", nor does it explain what types of activities fall within the scope of this exception.[46] Language differences also play an important role.

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[40] UNION EUROPEENNE, COMMISSION EUROPEENNE, *Report from the Commission on the experience acquired as a result of the operation of the procedures for granting marketing authorizations for medicinal products laid down in Regulation (EEC) No 2309/93, in chapter III of Directive 75/319/EEC and chapter IV of Directive 81/851/EEC on the basis of Article 71 of Regulation (EEC) No. 2309/93,* COM/2001/0606final; MIGNOLET Olivier et al, "Research and Bolar Exemptions from UPC, Belgian and French Perspectives*",* in DESAUNETTES-BARBERO Luc et al, *The Unitary Patent Package & Unified Patent Court,* Ledizioni, 2023, p. 493 [accessed March 27, 2024].

[41] EUROPEAN UNION, EUROPEAN PARLIAMENT, EUROPEAN COUNCIL, *Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products,* Official Journal L 311 , 28/11/2001 P. 0001 - 0066

[42] EUROPEAN UNION, EUROPEAN PARLIAMENT, EUROPEAN COUNCIL, *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, Official Journal L 311 , 28/11/2001 P. 0067-0128

[43] EUROPEAN UNION, EUROPEAN PARLIAMENT, EUROPEAN COUNCIL, *Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use*, Official Journal L 136 , 04/30/2004 P. 0034-0057

[44] *Treaty on the Functioning of the European Union,* Rome, March 25, 1957

[45] WORLD INTELLECTUAL PROPERTY ORGANIZATION, PERMANENT PATENT COMMITTEE, *Reference document on the exception relating to measures taken with a view to obtaining regulatory approval from the authorities,* SCP/28/3, May 14, 2018, para. 56

[46] GURGULA Olga, *The Bolar exemption and patent linkage in Ukraine* [online], 2024, p. 8, [accessed March 30, 2024]

4.2 Third parties as beneficiaries of the Bolar Exception

A key question concerns the scope of the Bolar exception in the EU concerning the manufacture, by a pharmaceutical drug producer, of patented active pharmaceutical ingredients (APIs), where the producer does not use and does not intend to use the APIs to obtain regulatory marketing approval, but rather to commercially supply generic drug manufacturers with APIs to conduct studies and trials.

The Polish Supreme Court and the Düsseldorf Regional Supreme Court have each had occasion to address this issue in a case involving the same parties and the same facts: Astellas Pharma Inc. of Tokyo, holder of a European patent covering solifenacin as an API, marketed under the name "Vesicare", brought an action for patent infringement against Polpharma SA Pharmaceutical Works of Starogard Gdanski, because Polpharma had manufactured, offered for sale and supplied, among others, a quantity of 30.5 kg of the API in question to Hexal AG, a German subsidiary of Sandoz AG, one of the world's leading producers of generic medicines. Polpharma raised the Bolar exception as a defense. It argued that the API delivered to Hexal was exclusively intended for studies and tests required to obtain regulatory marketing authorization.

A) The decision of the Polish Supreme Court

Poland's Supreme Court [47] upheld earlier lower court rulings, [48] affirming that the Bolar exception covers only entities carrying out trials, and not the manufacture and sale of APIs by third parties to manufacturers testing generic drugs and seeking regulatory marketing authorization. The Court emphasized that Article 69.1.4 of the Polish Industrial Property Act (IPL)[49] , which transposes the EU Bolar exception into Polish law, must be interpreted in the context of EU law. He added that the exclusive right protected by the patent was based on Article 28 of the TRIPS Agreement, and could only be restricted under the conditions set out in Article 30 of the TRIPS Agreement.

The Supreme Court observed that Article 10(6) of the Directive allows the performance of studies and tests necessary to obtain marketing authorization, but as an exception, it must be strictly limited, paying particular attention to the principle of balancing rights and interests. This balance must take into account the fact that the limitation of the exclusive right is a privilege of third parties to the detriment of the patent holder. Given that article 69.1.4 of the IPL authorizes the working of the invention "to the extent necessary", it should be borne in mind that all acts authorized on the basis of an exception constitute an act infringing the exclusive right of the patent owner. Consequently, the extent of the privilege must be determined with strict regard to the objectives of such a privilege. The producer of a generic drug has been granted the possibility of using, to an appropriate extent, the invention of another, in order to meet the objective of the exception, thus justifying the limitation of the rights conferred by a patent. Only in such circumstances is it certain that the acts of third parties exclusively serve the purposes of the provision, while the control of another company (the purchaser) over the acceptable use of the active ingredient protected by a drug patent would be illusory rather than real. Consequently, the patent holder can only be deprived of his exclusive right under section 69.1 of the Industrial Property Act to the benefit of a company that performs the actions required by law to obtain registration or authorization. The privilege does not extend to the exploitation of the invention by a company that does not intend to apply for marketing authorization or perform the necessary tests, but manufactures a product based on someone else's invention, with the

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[47] Astellas Pharma Inc v Polpharma SA, Supreme Court of Poland, Docket No IV CSK 92/13

[48] MARCINIAK Wojciech, "New Case Law Suggests a Bumpy Ride for Bolar Exemption in Poland" *IP Value* [online], 2014, p. 117, p. 119, [accessed April 15, 2024]; WITEK Rafał, "The European Take on the Bolar-Provision: Conclusions from Astellas v Polpharma" *Life Sciences Intellectual Property Review* [online], 2013

[49] POLAND, SEJM, *Act of 30 June 2000 on Industrial Property Law, as amended by act of January 24, 2004*

aim of offering it for sale and marketing it. These actions are not considered necessary to obtain authorization or registration.[50]

According to Professor Joseph Strauss, the Supreme Court has certainly misunderstood the Bolar exception and applied it in a manner quite different from the actual role of the provision as explicitly formulated by the Community legislator. It failed to take account of the fact that this rule is an integral part of wider Community legislation on the production and marketing of medicinal products in the Community. In particular, it failed to take account of the key role played by API suppliers in enabling generic manufacturers in the Community to carry out the studies and tests required to obtain marketing authorization. This decision deprives API suppliers established in the Community of the possibility of manufacturing and offering for sale the APIs needed by generic manufacturers who do not have the necessary API production facilities, who are otherwise unable to produce them or who, for economic reasons, cannot afford to produce all or part of the APIs needed to carry out the studies and trials of generic medicines for which they intend to obtain marketing authorization. The Court's decision clearly failed to understand the underlying function of the Bolar exception, and entirely ignored the consequences of the absence of third-party sources of API supply in the Community.

Hexal AG uses third-party API suppliers for economic reasons. Such a business model has a clear positive impact on the ability of generic manufacturers to offer their medicines at lower prices, which is exactly the aim of the Bolar exception.

In holding that the "privilege" of article 69.1.4 IPL does not extend to the exploitation of the invention by a company which does not intend to apply for marketing authorization or to carry out tests prior to such application, but which manufactures a product according to someone else's invention, with the intention of offering it for sale on the market, the Court overlooked two decisive aspects. Firstly, it failed to take account of the role played by Community suppliers in the context of the Bolar exception, namely increasing generic competition and reducing dependence on API suppliers outside the European Union. Secondly, the Court failed to note that the supply of APIs to generic manufacturers prior to patent expiry cannot be considered to be in the supplier's economic interest. It is common practice for the same API that was used in the development phase to also be used when the generic drug is placed on the market after patent expiry, since a change of API supplier requires a modification of the marketing authorization, which entails additional costs and delays. It is therefore when APIs are supplied after the expiry of the three statutory barriers to generic entry that the economic interest of API suppliers becomes clear. Until then, supply corresponds exactly to the model that the Community legislator envisaged with the Bolar concept: it provides generic manufacturers with everything they need in terms of "consequential requirements", and is essentially responsible for the "development of a competitive generics market" in the Community. This reasoning is fully supported by the facts of the Astellas/Polpharma case: a delivery of 30.5 kg of solifenacin to Hexal AG over a period of one year cannot be considered in isolation as a commercial activity. Rather, it constitutes a necessary investment to achieve the objective of the Bolar exception.

According to Professor Strauss, although the Supreme Court explicitly stated that limitations such as the Bolar exception must comply with Article 30 of the TRIPS Agreement, it limited itself to a simple reproduction of this article without further analysis. As the CJEU expressly stated in Daiichi Sankyo Co Ltd, et al v. DEMO Anonimos,[51] the provisions of the TRIPS Agreement are equally binding under EU law. As a result, the Supreme Court should also have examined the DSB decision in "Canada - Patent protection for pharmaceutical products". The

[50] STRAUS Joseph, "The Bolar exemption and the supply of patented active pharmaceutical ingredients to generic drug producers: an attempt to interpret Article 10(6) of Directive 2004/27", *Journal of Intellectual Property Law & Practice*, 2014, pp. 895-896

[51] Daiichi Sankyo Co Ltd, and others v DEMO Anonimos, C- 414/11, ECLI; EU: C: 2013: 520

interpretation of articles 28.1 and 30 of the TRIPS Agreement by which a patented medicine is manufactured, offered for sale and supplied to generic producers for the purpose of carrying out the studies and tests required to obtain a marketing authorization, complies with article 30 TRIPS, irrespective of whether the manufacturer and supplier also use the manufactured API for their own regulatory marketing authorization application, as long as no commercial use is made of the resulting end products.[52]

B) Referral to the CJEU by the Supreme Regional Court of Düsseldorf

The Regional Court of Düsseldorf, acting as a court of first instance, interpreted S 11(2b) of the German Patent Act (PatG),[53] which includes a Bolar exception. It ruled that, in order to benefit from the privileged status provided by the law, third parties must intend to carry out tests or studies when supplying patented products or substances. Simply knowing their customer's intention is not sufficient, nor is the fact that the supplier is aware of the customer's intention to use the substances supplied for privileged purposes. Even the fact that the third party takes steps to ensure that the customer uses the products or substances in accordance with section 11(2b) of the PatG, by imposing contractual restrictions, is not sufficient. The Court insisted that the intention to conduct experiments can only be presumed if the third party has a commercial interest in supplying its customer and an objective interest in conducting studies and tests. Thus, the third party must be considered as a co-organizer, and its interest in the studies and trials must be clearly demonstrated.

The Supreme Regional Court of Düsseldorf, on appeal from the judgment of the Regional Court of Düsseldorf, referred the following questions to the CJEU for a preliminary ruling:

> "Is Article 10(6) of the Directive to be interpreted as meaning that acts of supply by which a third party offers or delivers to a generic manufacturer, for purely commercial reasons, a patented active substance which the generic manufacturer intends to use for studies or tests with a view to obtaining a marketing authorization or an approval within the meaning of Article 10(6) are also excluded from patent protection?
>
> If the first question is answered in the affirmative: does the privileged status of the third party depend on whether the manufacturer of the generics supplied actually uses the active substance supplied in the context of privileged studies or trials within the meaning of Article 10(6) of the Directive? In this case, does the exclusion of patent protection also apply if the third party is unaware of the privileged use envisaged by his customer and has not verified whether this is the case? Or does the privileged status of the third party depend solely on whether, at the time of the act of supply, the third party can legitimately assume that, given the totality of the circumstances (i.e. the profile of the supplied company, the small quantity of the active substance supplied, the imminent expiry of patent protection for the active substance concerned, the experience gained regarding the reliability of the customer), the supplied generic manufacturer will use the active substance supplied solely for privileged tests and studies within the framework of a marketing authorization?
>
> As part of its act of delivery, is the third party required to take separate precautions to ensure that its customer will actually use the active substance for privileged tests and

[52] STRAUS Joseph, "The Bolar exemption and the supply of patented active pharmaceutical ingredients to generic drug producers: an attempt to interpret Article 10(6) of Directive 2004/27", *Journal of Intellectual Property Law & Practice*, 2014, pp. 905-907

[53] GERMANY, BUNDESTAG, *Patentgesetz in der Fassung der Bekanntmachung vom 16. Dezember 1980 (BGBl. 1981 I S. 1), das zuletzt durch Artikel 1 des Gesetzes vom 30. August 2021 (BGBl. I S. 4074) geändert worden ist*

> studies only, or do the third party's precautionary measures differ depending on whether the patented active substance is merely offered or actually delivered?"[54]

The Supreme Court pointed out that article 11(2b) PatG, which transposes article 10(6) of the Directive into national law, could be interpreted in various ways, all of which were plausible. However, this interpretation had to be made in the light of the wording and purpose of the directive in question, thus justifying a referral to the CJEU.

In its order for reference, the Supreme Court expressed its own view on the questions posed, stating in particular that commercial acts of supply by third parties are generally subject to the marketing authorization privilege under § 11(2b) PatG and § 10(6) of the Directive. However, the third party must be in a position to assume, depending on the circumstances, that the API supplied will be used for trials and preliminary studies with a view to obtaining a marketing authorization. In this context, factors such as the company's profile, the small quantity of API delivered, the proximity of the expiry of patent protection for the API in question, as well as past experience of the customer's reliability, may be relevant. In addition, the supplier itself must take precautionary measures to prevent unauthorized use of the delivered API. These measures vary depending on whether the third party simply proposes the API or actually supplies it. In the case of offering the API, it is sufficient to state clearly that small quantities of the product will be delivered for market research purposes only. In the case of deliveries, it is necessary for the supplying party and the customer to draw up regular usage agreements with appropriate penalty clauses. The Supreme Court also clarified that, in specific situations subject to particular circumstances, other measures may be necessary.

After analyzing all the paragraphs of Article 10 of the Directive to which its paragraph 6 refers, the Supreme Court concluded that the effects of a patent do not cover "studies" (notably clinical and pre-clinical), "trials" (i.e. activities planned to obtain data necessary for the marketing authorization procedure) and "consecutive practical requirements resulting from studies or trials". The court interpreted "consecutive practical requirements" as encompassing any use of the patented know-how necessary to carry out a privileged study or trial. This would include actions such as manufacturing or importing the API required to conduct the study, producing test samples such as tablet formulations, or other similar actions. Based on the history of article 11(2b) PatG, the Court also held that the privilege of marketing authorization – at least in principle – also extends to actions that significantly prepare the setting up of trials or studies. Consequently, the manufacture of medicinal products should also be covered by this provision, insofar as it is necessary for the performance of studies and trials. Thus, the party conducting studies or trials under section 11(2b) PatG should also be authorized to produce patented drugs or APIs used in the same studies and trials.

In the reasons set out by the legislator for section 11(2b) PatG, supply actions carried out by those conducting the tests are mentioned, while third-party suppliers are not mentioned at all. According to the Supreme Court, this does not strictly mean that only preparatory acts carried out by the test user himself are permitted, and that supply actions carried out by third parties are not taken into account. In the Court's view, the wording of article 11(2b) PatG includes third-party suppliers, as it does not refer specifically to the party filing the marketing authorization application, but simply to the purpose of the tests and studies carried out. The referring court also pointed out that, from a purely linguistic point of view, Article 11 (2b) can be regarded not only as a personal privilege, but also as a material privilege. For the application of article 11(2b) PatG, it was crucial that the tests and studies as well as the necessary supplies ("practical requirements"), irrespective of the supplier, contributed to obtaining a marketing authorization for the medicinal product.

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[54] GERMANY, SUPREME REGIONAL COURT OF DUSSELDORF, Case No I-2U68/12- *Marktzulassungsprivileg,* 2014, GRUR-RR 100, 104)

The Supreme Court ruled that its interpretation of article 11 (2b) PatG also applied, with the necessary adaptations, to the wording of article 10(6) of the Directive. Neither article 11 (2b) nor article 10(6) explicitly prohibit acts of supply to third parties; nor do they focus on the identity of the applicant for authorization. With regard to recital 14 of the Directive, the Supreme Court stressed that the Directive emphasized the need to favor generic manufacturers, thus offering them easier access to the Community market.

The order for reference also examined the objectives of Article 10(6) of the Directive in the light of the actual situation of generic manufacturers. The Supreme Court noted that, in many cases, it was impossible, or even very difficult, to carry out tests and studies to obtain marketing authorization without commercial third parties supplying the patented active substance. This is because not all manufacturers, particularly small generic companies, produce the active ingredients in-house. These companies must either purchase the API from foreign countries without patents, or acquire the final drug from a specialized manufacturer who not only synthesizes the active substance and formulates the drug, but also carries out the necessary tests and studies, obtains marketing authorization and offers the product for sale.

The Supreme Court stated: "Given this initial factual situation, it is not surprising that generic manufacturers do not supply the patented active substance to commercial third parties. To improve market access for generic manufacturers after patent expiry, it is crucial to extend the privilege of exclusion from patent protection not only to companies capable of producing in-house the active substances needed for marketing authorization studies, but also to those who rely on third-party suppliers due to lack of in-house production capacity. Market access should not be made unnecessarily difficult for them, and should be as easy as for a competing generic manufacturer with in-house production facilities to purchase the necessary quantities of the active substance locally, rather than in patent-free foreign countries (if appropriate sources exist in those countries)."[55]

The Supreme Court considered the legislative history of article 10(6) of the Directive and article 11(2b) PatG. It then considered, at least in part, how the interpretation of the application of the Bolar exception might affect generic manufacturers in the Community. However, it analyzed neither article 10(6) in the broader context of Community legislation, of which article 10(6) is truly an integral part, nor the conformity of the Community Bolar rule with articles 28(1) and 30 of the TRIPS Agreement.

According to Professor Straus, we can certainly share the Supreme Court's view that Article 10(6) of the Directive covers the manufacture, offering for sale and sale, for example, of APIs by third parties to generic manufacturers for use in studies and trials prior to marketing authorization; this interpretation correctly reflects the real underlying objectives of the Bolar exception, and is also in line with the position of the DSB report in the "Canada - patent protection for pharmaceutical products" case. However, the constraints which, according to the Court, must be imposed on third-party suppliers are neither necessary to comply with the TRIPS Agreement, nor fully in line with the role which the Bolar rule was designed to play in the context of wider Community legislation.

In addition to the undisputed need to balance the interests of patent owners, the Supreme Court's reasoning seems to focus on the interpretation of § 11(2b) PatG in the light of § 10(1) and (3) PatG. According to § 10(1) PatG, offering or supplying means relating to an essential element of the patented invention to a person not authorized to use it in Germany constitutes an act of (indirect) infringement, if the offeror or supplier is aware or if, due to the circumstances, it is obvious that these means are suitable for exploiting the invention. The

[55] STRAUS Joseph, "The Bolar exemption and the supply of patented active pharmaceutical ingredients to generic drug producers: an attempt to interpret Article 10(6) of Directive 2004/27", *Journal of Intellectual Property Law & Practice*, 2014, pp. 896-898.

problem seen by the court lies in article 10(3) PatG, which stipulates that persons who perform the acts referred to in article 11(1) and (3) are not considered entitled to exploit the invention within the meaning of paragraph (1). In other words, in the context in question, offering or supplying even essential elements of a patented invention for studies and tests prior to obtaining a marketing authorization (i.e. to persons entitled under article 11(2)(b) PatG) must be regarded as an act of indirect patent infringement.

The Supreme Court deduced from this that, if a third party offering or providing means which only concern an essential element of the invention, i.e. not the infringing product as such, can commit (indirect) infringement, then third parties offering, selling, etc. infringing products to those benefiting from the Bolar privilege should be subject to even stricter obligations than those required under section 10(1) PatG. However, article 10(3) PatG, which was not amended when article 11(2b) was introduced into the PatG, makes the use of the exception virtually impossible.[56] The application of section 10(3) could well lead to circumstances in which a party authorized to carry out experiments would be prevented from doing so because it would not have access to the necessary means. Arguments based on an analogy between Bolar's rule and article 10(3) PatG seem inappropriate and would clearly contradict the intention of article 10(6) of the Directive. According to the principles developed by the CJEU in Monsanto v Cefetra, it would be nullified by Community law. The interests of the public in general, as reflected in the interpretation of the Bolar rule, can only be adequately taken into account if producers of generic medicines in the Community are treated in accordance with the role assigned to them in the broader context of Community law. The German legislator is called upon to adapt article 10(3) PatG to the circumstances established under the harmonized Bolar rule.[57]

There is no guarantee that the CJEU will have the opportunity to clarify the access to information and privacy issues referred to it by the Düsseldorf Supreme Court, given that Astellas Pharma Inc. has withdrawn its actions against Polpharma before the German courts. However, this withdrawal does not render the questions posed by the court moot. On the contrary, they remain relevant and will be examined in detail later.[58]

4.3 The Future of the Bolar Exception in Europe

European legislators are working on a reform of the Bolar exception as part of the EU pharmaceutical package. This exception, which is in force during the period of patent or supplementary protection certificate (SPC) for a reference medicinal product for human use, is subject to changes proposed in a specific draft directive. This draft, set out in Article 85 of the "Proposal for a Directive of the European Parliament and of the Council on the Community code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC" of 26 April 2023, is currently subject to the ordinary legislative procedure in accordance with Article 294 TFEU. Three main shortcomings in the existing regulations concerning the Bolar exception, which hinder the regulatory objective both in legal terms and in terms of practical application, have been identified.

Firstly, the current scope of application is deemed too narrow due to inconsistent application of the Bolar exception among EU Member States. Thus, the draft proposes a significant expansion of the scope of the exception, covering a wide range of beneficiaries and exempt

[56] CHROCZEIL Peter and HUFNAGEL Frank-Erich, "Versuchsprivileg und Unterstützungshandlungen - Abgrenzungsfragen im 'Bermuda-Dreieck' der §§ 9, 10 und 11 Nr. 2/2b PatG" in BERGERMANN Michael and MES Peter, *Festschrift für Peter Mes zum 65.* Geburtstag [online], CH Beck, 2009, p. 59, [accessed April 25, 2024]
[57] STRAUS Joseph, "The Bolar exemption and the supply of patented active pharmaceutical ingredients to generic drug producers: an attempt to interpret Article 10(6) of Directive 2004/27", *Journal of Intellectual Property Law & Practice*, 2014, pp. 907-908.
[58] Ibid. pp. 898-899.

activities. This would include not only clinical studies and trials, but also activities required for health technology assessment and the pricing and reimbursement of medicines. Secondly, in addition to the activities currently exempted for the production of generic or biosimilar medicines, the draft also aims to allow studies and trials to be carried out to obtain data on hybrid or biohybrid medicines, as well as their subsequent variants. This clarification would explicitly include health technology assessment activities and pricing and reimbursement procedures. Finally, the draft also clarifies its application to commercial suppliers of active pharmaceutical ingredients when they supply patent- or SPC-protected medicines to generic manufacturers to conduct studies for marketing authorization.

5. DESIGN CRITERIA FOR A BOLAR EXCEPTION

According to WIPO data, as of April 2018, the Bolar exception has been implemented in the laws of 65 States.[59] Several other countries are in the process of making changes. The various criteria taken into account when developing an exception were set out by the WIPO Committee on Patents (SCP) and studied by Professor Carlos Correa.

In most countries, the use of a patented compound for the purpose of obtaining marketing authorization from the competent authorities can take place at any time during the validity of the patent. Some laws stipulate that such use of a patented compound must take place during a certain period before the patent expires (typically between thirty days and three years).[60] Usually, generic manufacturers begin research and experimentation within a reasonable time before patent expiry, once the commercial attractiveness of a product can certainly be established and it is not necessary to wait long before recouping the investment made to obtain the required authorization. As a result, most national legislations do not address the question of the point in the life of a patent at which a Bolar exception might be admitted. This choice is left to the interested parties.[61]

Certain Bolar exceptions apply to all products subject to regulatory approval. In some jurisdictions, this exception is extended to all healthcare products intended for human use, including medicines and medical devices, while in others, only medicines are concerned. The Bolar exception can also cover veterinary products, agricultural chemicals and even medical devices and tools.[62] According to Professor Correa, although public health concerns require particular attention, it seems logical to cover all products regulated by this exception, given that there is no solid justification for distinguishing health-related products from other products requiring regulatory authorization before they can be placed on the market.[63] However, this does not mean that exceptions limited to pharmaceutical products alone, or even to some of their sub-categories such as medicines, would be incompatible with the TRIPS Agreement. As pointed out by the DSB in the "Canada - patents for pharmaceutical products" case, special treatment based on public health considerations is justified under Article 27.1 of the TRIPS Agreement.

An exception may be rather restricted, being closely linked to the aim of obtaining a marketing authorization. A broader exception, extending in particular to research and/or experimentation on a patented invention, may be authorized in law or accepted by case law.[64] Differences in the scope of the exception may arise from the wording used to describe the relationship between the authorized acts and their purpose. Terms such as "acts with a view to regulatory approval", "acts solely for uses reasonably related to regulatory approval" or "acts aimed exclusively at regulatory approval" can lead to varying interpretations of the types of acts exempted under the exception.
The question of whether the exception applies to post-marketing studies is another area where narrow and broad interpretations of the Bolar exception persist in parallel. Some regulatory

[59] WORLD INTELLECTUAL PROPERTY ORGANIZATION, PERMANENT PATENT COMMITTEE, *Reference document on the exception relating to measures taken with a view to obtaining regulatory approval from the authorities,* SCP/28/3, May 14, 2018, para. 29
[60] Ibid, paras. 72-73
[61] CORREA Carlos. *The Bolar Exception: Legislative Models and Drafting Options* [online], Geneva, South Centre, 2016, p.15, [accessed 16 March 2024]
[62] WORLD INTELLECTUAL PROPERTY ORGANIZATION, PERMANENT PATENT COMMITTEE, *Reference document on the exception relating to measures taken with a view to obtaining regulatory approval from the authorities,* SCP/28/3, May 14, 2018, para. 69
[63] CORREA Carlos. *The Bolar Exception: Legislative Models and Drafting Options* [online], Geneva, South Centre, 2016, p.13, [accessed 16 March 2024]
[64] Ibid, para. 52

systems for the pharmaceutical sector continue to monitor pharmaceutical products even after they have been authorized for marketing. In such cases, the marketing authorization holder has important obligations to monitor and collect data on the pharmaceutical product after it has been placed on the market, commonly referred to as "pharmacovigilance". The collection and production of such data is essential for regulatory approval, and is a prerequisite for maintaining a pharmaceutical product's marketing authorization.[65]

Most Bolar exceptions do not specify whether they apply to preclinical or clinical studies, or to both. Professor Correa agreed with the solution provided by the US Supreme Court in Merck v Integra, according to which preclinical studies involving patented compounds should be exempt from infringement as long as there is a reasonable basis for believing that these studies will produce information relevant to an application to be filed with the competent authority, as there is no reason to distinguish between stages of research involving a patented product.[66]

An important dimension of the Bolar exception is whether it applies only to obtaining marketing authorization for a generic product, or also to research that may lead to the development of a new product. Some national laws make no distinction as to whether the patented invention is used for the marketing authorization of a generic product or for the development of a new pharmaceutical product. In cases where the application for approval of a generic product is not filed, for example, because tests have not produced immediately usable results, the Bolar exception should still apply.[67]

Some laws do not specify whether the steps involved in obtaining marketing authorization in third countries are covered by the exception. In others, an express provision may authorize or prohibit such steps, or make them subject to conditions, such as adherence to certain international or regional treaties.[68] According to Professor Correa, there is no solid justification for limiting foreign applications. The legitimate interests protected by a patent issued in the country where the trials take place are not affected by acts carried out in another jurisdiction. Patents are territorial in nature. Whether or not it is permissible to submit information in a foreign country before the expiry of a patent issued in that country is a matter exclusively for the legislation of that country. In practice, many countries allow acts for the purpose of registering generic products in other countries.[69]

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[65] WESTED Jakob and MINSSEN Timo, *Research and Bolar Exemptions in the U.S. and Europe: Recent Developments and Possible Scenarios* [online], 2018, p. 8, [accessed March 27, 2024]
[66] CORREA Carlos. *The Bolar Exception: Legislative Models and Drafting Options* [online], South Centre, 2016, p.14, [accessed March 16, 2024]
[67] Ibid., p. 15
[68] WORLD INTELLECTUAL PROPERTY ORGANIZATION, PERMANENT PATENT COMMITTEE, *Reference document on the exception relating to measures taken with a view to obtaining regulatory approval from the authorities,* SCP/28/3, May 14, 2018, paras. 61; 64
[69] CORREA Carlos. *The Bolar Exception: Legislative Models and Drafting Options* [online], South Centre, 2016, p.15, [accessed March 16, 2024]

6. CONCLUSION

The Bolar exception is an important flexibility that balances the private interests of pharmaceutical companies in protecting their medical inventions with the public interests of patients in ensuring timely access to affordable medicines. Provided it is properly implemented, it does not illegitimately infringe the rights of patent holders. It therefore complies with Article 30 of the TRIPS Agreement, and its integration into national legal systems is justified.

Poland's Supreme Court upheld rulings limiting the scope of the Bolar exception to entities conducting trials, excluding third-party manufacturing and sale of active pharmaceutical ingredients (APIs) for generic drug testing. The Court emphasized that the exception under Polish law, reflecting EU directives, must be interpreted strictly, balancing patent rights against the privileges granted to third parties. The ruling was criticized by Professor Joseph Strauss, who argued that it misunderstands the Bolar exception's role, particularly the importance of API suppliers in enabling generic drug development and fostering market competition. Strauss contended that the Court failed to recognize the broader implications for generic drug manufacturers and the Community's legislative intent, which supports the use of APIs by generic producers for testing even if the suppliers do not seek their own marketing authorization.

The Regional Court of Düsseldorf ruled that under the German Patent Act (PatG) Section 11(2b), the Bolar exception applies only when third parties supplying patented products intend to conduct studies or tests necessary for regulatory approval, and simply knowing the customer's intentions is not sufficient. The Supreme Regional Court of Düsseldorf, however, raised questions for the CJEU on whether Article 10(6) of the Directive permits third-party suppliers to benefit from the Bolar exception even when acting for purely commercial reasons. The court also explored whether the exception extends to acts by third parties that support generics manufacturers in obtaining marketing authorization, emphasizing the need for suppliers to ensure the patented products are used exclusively for such privileged purposes. The Supreme Court supported a broader interpretation, suggesting that the Bolar exception should cover necessary preparatory acts, including manufacturing or importing active ingredients, and stressed that restrictions imposed on third-party suppliers are unnecessary under the TRIPS Agreement and may hinder the broader goal of facilitating generic competition. However, the case was unresolved due to the withdrawal of the original case, leaving these important legal questions open for future examination.

The broader the formulation of the exception in terms of products covered, sample sources, types of tests allowed, testing schedules and geographical scope, the more competitive the environment will be, benefiting consumers, healthcare providers and other government agencies by reducing the burden on healthcare budgets and encouraging innovation. The pro-competitive effect of the Bolar exception is significant, and is amplified when the exception is broad. In view of this, it can be argued that a broad Bolar exception would help States to achieve the Sustainable Development Goals.

The Bolar exception is not yet implemented everywhere in the world. Some jurisdictions are currently just developing the first Bolar exception in their legal history, while others have a stable Bolar exception practice. As a result, the current interpretation of the Bolar exception varies considerably. Some courts consider that the exception should only cover bioequivalence studies, while the application for and granting of marketing authorization should not be covered by the exception and should therefore be considered as infringing activities. Such an interpretation, which would considerably delay the entry of generics onto the market, is not in line with established practice in jurisdictions such as the EU or the USA, and is contrary to the very essence of the exception. To avoid this artificial extension of the

monopoly, it is essential for the countries concerned to review the interpretation of this provision by their judicial systems, following the approaches of the above-mentioned jurisdictions. In particular, countries in the process of joining the EU should adopt European practice and extend the scope of the Bolar exception, to adapt their own legislations with that of the EU. We can therefore expect interesting developments in the implementation of the Bolar exception in the future.

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