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# Scope of Competition Related Trips Flexibilities for Protecting Public Health in Developing Countries

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***Abstract:*** *The TRIPS agreement has consciously preserved a realm of policy space for its member states. It affords the member states the latitude to tailor the deployment of competition law as a tool of flexibility to place constraints on the exercise of intellectual property rights. Nonetheless, a measure of uncertainty prevails concerning the optimal utilization of this policy leeway, particularly within countries that lack an extensive history of enforcement of competition law and policy, due to the intricate interplay between intellectual property and competition concerns. Now, the operation of competition law must not curtail someone's patent rights. At the same time, a patent holder must not use his exclusive rights to adversely affect competition in the market. Articles 7 and 8-reliant interpretation of TRIPS allow for a pro-competitive effect of the TRIPS Agreement requiring exploitation of patent rights without infringing domestic competition laws. Articles 8(2), 40, and 31(k) of the TRIPS grant the World Trade Organization (WTO) Members the prerogative to invoke compulsory licensing as a corrective measure against such anti-competitive behaviors. At the same time, TRIPS member states are obligated to not use competition law to undermine patent holders' exclusive rights. The article aims to provide guidance and recommendations for developing countries on optimizing the balance between competition and patent laws within the TRIPS framework*

**Keywords:** competition, public health, TRIPS, flexibilities, patent

## 1. Introduction

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[1] mandates that member states must ensure the establishment of a "minimum standard of patent protection"[2] upon their graduation from Least Developed Country (LDC) status. The impending cessation of patent

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[1] Agreement on Trade-related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, U.N.T.S. 299, 33 I.L.M. 1197

[2] See for details, Ruth L. Okediji, 'Legal Innovation in International Intellectual Property Relations: Revisiting Twenty-One Years of the TRIPS Agreement' (2014) 36 University of Pennsylvania Journal of International Law 191, 202–03, 206

waivers upon LDC graduation is poised to result in a substantial escalation in the prices of medications,[3] particularly those under patent protection, including those for which reverse-engineered generics are available. This circumstance may give rise to a scenario in which individuals in need of medical treatment are unable to afford it, while patent holders wield monopolistic control over the market.[4]

TRIPS agreement's stringent and standardized approach to intellectual property rights protection and its rigorous enforcement mechanisms have failed to accommodate the specific developmental needs of developing and least developed countries.[5] Consequently, this oversight neglects essential human rights, including the right to livelihood, health, life, and education, among others.[6] Prior research indicates that the implementation of patent regimes in middle- and low-income developing countries is projected to lead to price increases ranging from 12% to 200% anticipated to significantly affect access to medicines in these regions.[7]

This article aims to undertake a comprehensive examination as to how TRIPS flexibilities may be strategically utilized to ensure competition for medications. In building a normative framework to deal with these challenges, this article shall focus on the limits of exploiting TRIPS flexibilities for ensuring competition to protect public health.

In theory, the grant of limited monopolies over patented inventions serves two principal objectives.[8] Firstly, it functions as an incentive for innovators to disclose their innovations,[9] and secondly, it acts as a reward for the efforts invested by investors in the realm of innovation. As emphasized by Daniel Gervais, the original draft text submitted by a consortium of developing countries on Article 40 of the TRIPS reflects their interpretation of the rationale underlying intellectual

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[4] For a study on the impact of TRIPS on LDCs, see Gustavo Ghidini, 'On the impact of TRIPS on 'least developed countries': a tale of double standards?' (2011) 1(1) Queen Mary Journal of Intellectual Property Law 73-79

[4] Pradip Royhan, 'Market access challenges and opportunities for Bangladesh pharmaceutical products under TRIPS' (2013) 8(12) Journal of Intellectual Property Law & Practice 932

[5] See for details, Mohammad Towhidul Islam, 'Protection of public interests through a human rights framework in the TRIPS Agreement: realities and challenges' (2009) 4(8) Journal of Intellectual Property Law & Practice 573

[6] Siva Thambisetty, 'Improving access to patented medicines: Are human rights getting in the way?' LSE Law Working Paper Series 03/2018

[7] UNCTAD, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide* (United Nations 2011) 4

[8] Philippe Aghion, Peter Howitty, Susanne Prantl, 'Patent Rights, Product Market Reforms, and Innovation' (2015) 20(3) Journal of Economic Growth 223-262

[9] See for detail, Dominique Guellec, 'Patents as an Incentive to Innovate' in Dominique Guellec, Bruno van Pottelsberghe de la Potterie (eds), *The Economics of the European Patent System: IP Policy for Innovation and Competition* (Oxford University Press 2007) 46-84

property rights.[10] According to these developing countries, the monopoly conferred through a patent is in exchange for the patent holder's commitment to exploit the protected subject matter for their own benefit,[11] and the country bestowing the protection.[12] However, this monopoly, during the patent protection term, exerts an influence on market competition making the patent holder a dominant entity in the relevant market and precipitates issues related to accessibility.

Notably, TRIPS prescribes a minimum standard of protection for patented products and processes, while concurrently affording member states the policy space to tailor their domestic legislation in accordance with their unique socio-economic conditions. Various terms have been employed in the literature to signify this policy discretion, including "room to maneuver," "margins of freedom," "safeguards," and "margin of discretion."[13] Recent studies allude to this policy latitude as 'flexibilities.'[14] The exploitation of these flexibilities constitutes the primary strategy of developing country member states within the TRIPS Agreement when addressing public health challenges stemming from the monopolistic control wielded by patent rights.

While the TRIPS member states are enabled to address the anticompetitive ramifications or the abuse of monopolistic patent privileges by patent owners, over the years there have been discernible shifts towards facilitating patent protection through the relaxation of eligibility criteria and the broadening of the scope of patentable subject matter.[15] Furthermore, patent holders have seen their rights extended, with lengthier patent terms and the implementation of more stringent sanctions for patent infringements. For instance, the Patents & Designs Act of 1911, which marked Bangladesh's first independent patent law, provided for a 16-year duration of patent protection at a minimum.[16] In contrast, the latest Bangladesh Patent Act 2022 now prescribes a 20-year term of protection, and extended patent

[10] Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell 2003) 280

[11] Notably, the local working requirement is heavily regulated under Article 5A of the Paris Convention, and Article 27(1) of the TRIPS Agreement

[12] Daniel Gervais (n 10) 280

[13] Germán Velásquez, 'Access to Medicines and Intellectual Property: The Contribution of the World Health Organization' (2013) South Center Research Paper No. 47 <https://www.southcentre.int/wp-content/uploads/2013/05/RP47_WTO-role-in-IP-and-access-to-medicines_EN.pdf> accessed 29 March 2023

[14] Carlos M Correa, 'Interpreting the Flexibilities Under the TRIPS Agreement' in Carlos M. Correa and Reto M. Hilty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer 2021) 1-30

[15] See for example, Christopher M. Holman, Timo Minssen, and Eric M. Solovy, 'Patentability Standards for Follow-On Pharmaceutical Innovation' (2018) 37(3) Biotechnology Law Report 131-161

[16] The Patents & Designs Act 1911, s 14(1)

rights.[17] In the United States, it has been reported that out of all patents issued by the government, at least 63.6% get some 'patent term adjustments' and get at least a year extension.[18] This evolution has significantly altered the equilibrium between private and public interests within patent law.[19] While patent rights have expanded, and the obligations of patent applicants have eased, safeguards to protect the public from patent monopolies have not witnessed a commensurate expansion. That is why Abbe E. L. Brown has correctly argued that patent owners possess too much power in the market, and it needs to be limited.[20]

Among the diverse flexibilities afforded by the TRIPS agreement, including exceptions to exclusive rights, compulsory licenses (CLs),[21] the principle of exhaustion of rights, research and development exceptions,[22] Bolar provisions,[23] and the like, competition law stands out as a notably extensive policy realm. All these options are well explored in the existing literature, however, the scope of the applicability of competition law has remained relatively under addressed. This study fills up that void by exploring the scope and limits of competition related TRIPS flexibilities upholding patent rights and ensuring market competition.

Now, does the purview of competition law-based measures remain at the discretion of WTO Members, even when such measures might potentially contravene the minimum standards dictated by TRIPS? Alternatively, to what extent is competition law subject to the ambit of TRIPS, or does it operate within a framework carved out from TRIPS standards? This article shall undertake a thorough doctrinal exploration of the scope of the TRIPS agreement concerning competition-related flexibilities.

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[17] The Bangladesh Patent Act 2022, s 20(1)

[18] Mark A. Lemley and Jason Reineck, 'Our More than Twenty-Year Patent Term' (2024) 39 Berkeley Technology Law Journal 681

[19] However, India has been a strong case against such practice of widening the ambit of patent protection. See for details, Ganesan Subramaniam and Deepa Daivasigamani, 'Protecting incremental invention in India' (2014) 9(12) Journal of Intellectual Property Law & Practice 993-998

[20] See for details, Abbe E. L. Brown, *Intellectual Property, Human Rights and Competition: Access to essential innovation and technology* (Edward Elgar 2012); also see Richard Milchior, 'Do IP owners have too much power?' (2013) 8(9) Journal of Intellectual Property Law & Practice 735

[21] E Durojaye, 'Compulsory Licensing and Access to Medicines in Post Doha Era: What Hope for Africa?' (2008) 55(1) Netherlands International Law Review 33-71

[22] Beas Rodrigues, Jr E, 'Patents and the R&D and genetic diagnostic test exceptions' in *The General Exception Clauses of the TRIPS Agreement: Promoting Sustainable Development* (Cambridge University Press 2012)159-236

[23] V Munoz Tellez, 'Bolar Exception' in Carlos Correa et al (eds), *Access to Medicines and Vaccines* (Springer 2022) 1-5

Part II of this article is dedicated to examining the breadth of the pertinent provisions within the TRIPS Agreement, specifically those addressing the intricate intersection of patent and competition issues. It commences by delving into the discourse surrounding Article 8 of the TRIPS Agreement, shedding light on how the flexibility inherent in this provision has been deliberately crafted within the Agreement. This part meticulously dissects the nuances of interpreting these flexibilities in the context of various other TRIPS provisions. It underscores that the phrase 'abuse of patent' remains open to interpretation by individual member states and highlights the necessity for competition law measures to align with the broader tenets enshrined in the TRIPS Agreement. This part effectively outlines the boundaries delineating the autonomy of member states in navigating the rights and obligations pertaining to patent protection.

Part III extensively explores the contours of Article 31 of the TRIPS Agreement, with particular emphasis on the prerequisites of prior negotiation and the predominant domestic need. It underscores the elevated status accorded to market competition over the safeguarding of patent rights and dissects the policy leeway inherent in defining 'anticompetitive practice.' Notably, this part engages with the facets of Article 40 of the TRIPS Agreement, which mandates the establishment of a compulsory competition regime while affording room for individual member states to shape the standards governing competition reviews. It also brings to attention that the examples of anticompetitive practices provided in Article 40 are not exhaustive, and offers insight into the deliberations, proposals, and eliminations during the negotiation process.

In the final part, this article culminates with a comprehensive summary of its findings, providing a synthesis of the key insights and outcomes derived from the explorations conducted in the preceding parts.

## 2. Objectives and Principles of TRIPS: In Action and/or Behind the Scene

The existing framework established by the TRIPS Agreement is perceived to be in conflict with the overarching WTO objective of sustainable development.[24] Consequently, adherence to the TRIPS Agreement's stringent protection and enforcement standards may be at odds with attaining economic and social prosperity.[25] Now, the TRIPS Agreement was adopted to establish baseline standards for the protection and enforcement of intellectual property (IP) while concurrently taking into consideration the potential ramifications for competition. In recognition of the intricate interplay between IP and competition law, the

[24] Johan Rochel, 'Intellectual property and its foundations: Using Art.7 and 8 to address the legitimacy of the TRIPS' (2020) 23 Journal of World Intellectual Property 21-39

[25] Henning Grosse Ruse-Khan, 'The (non) use of treaty object and purpose in intellectual property disputes in the WTO' (2011) Max Planck Institute for Intellectual Property and Competition Law Research Paper 1-35, 11-15.

Agreement incorporated certain provisions. Developing countries, typically net importers of technology, have the flexibility to employ competition law as a tool when implementing the TRIPS Agreement domestically.[26] This means that World Trade Organization (WTO) Member States possess the ability to leverage competition law to foster a competitive environment in the market, especially concerning access to patented items such as pharmaceuticals. Given the absence of a comprehensive multilateral agreement on competition law, this affords developing nations substantial policy latitude to utilize competition law frameworks to counteract the monopolistic dominance of patents.

The regulation of anticompetitive practices in the realm of IP protection is principally governed by Articles 8, 31, and 40 of the TRIPS Agreement. In the subsequent discussion, the scope of these three articles will be expounded upon. Specifically, this part will investigate the extent of policy space accorded to member states under the TRIPS Agreement with respect to crafting competition law frameworks that effectively address the intersection of patent and competition concerns.

### A. Role in Interpretation

Professor Henning Grosse-Ruse Khan argued that intellectual property rights are territorial, and Member States possess significant discretion in determining how to implement the minimum standards mandated by the TRIPS Agreement.[27] Now when interpreting the provisions of any agreement, it is imperative to gain a comprehensive understanding of the overarching objectives that underpin that agreement. This principle holds true for the TRIPS Agreement as well. Therefore, before embarking on an examination of Article 8, it is crucial to grasp the fundamental objectives of the TRIPS Agreement. The interpretative significance of Arts. 7 and 8 are underscored by the Doha Declaration on Public Health and the TRIPS Agreement.[28] Paragraph 5 of the Declaration explicitly emphasizes their value in interpretation.

> In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object

[26] Frederick Abbott, 'The competition provisions in the TRIPS agreement: Implications for technology transfer' (Joint WIPO-WTO Workshop on Intellectual Property Rights and Transfer of Technology, Geneva, 17 November 2003)

[27] Henning Grosse Ruse-Khan, 'From TRIPS to FTAs and back: Re-conceptualising the role of a multilateral IP framework in a TRIPS-plus world' in F. Amtenbrink, D. Prévost, & R. A. Wessel (Eds.), *Netherlands yearbook of international law 2017: Shifting forms and levels of cooperation in international economic law: Structural developments in trade, investment and financial regulation* (Hague: TMC Asser Press 2018) 57–107, 79

[28] WTO, 'Decision of the Council for TRIPS on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-developed Country Members for Certain Obligations with Respect to Pharmaceutical Products', 27 June 2002 (Document IP/C/25)

> and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Article 7 of the Agreement itself provides the objectives of the agreement as follows:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[29]

This provision unequivocally underscores that the protection and enforcement of patent rights under the TRIPS Agreement are designed to strike a delicate equilibrium between the rights and obligations of member states. Alison Slade has demonstrated that both Articles 7 and 8 have influenced the policy makers at the World Intellectual Property Organization (WIPO) and they constitute the foundations of the international intellectual property regime.[30] As a result, member states are compelled to ensure that a nuanced equilibrium is maintained, one that harmonizes their responsibility to safeguard patented inventions with their prerogative to curtail such protection when circumstances necessitate it. In this regard, Henning Grosse Ruse-Khan's contention that "Article 7 therefore is meant to serve as a general safeguard against a one-sided approach to IP protection that solely focuses on the interests of right holders and maximizes their incentives to innovate"[31] is well-founded. It underscores the overarching principle that TRIPS seeks to safeguard the collective interests of both rights holders and the broader public good.

Given that patent holders themselves are not the subjects of the TRIPS Agreement, the responsibility for compliance rests squarely on the member states as the signatory subjects. This entails a dual obligation: one, to fulfill their responsibilities toward patent holders, thereby incentivizing innovation, and two, to cater to the specific socio-economic conditions and needs of their citizenry within the framework of the TRIPS Agreement. Member states possess the latitude to meet these obligations through various means, including the enactment of suitable legislative measures, the implementation of executive actions, or through judicial measures. It is for this reason that scholars[32] advocating for the interests of

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[29] TRIPS Agreement, Art. 7

[30] Alison Slade, 'Articles 7 and 8 of the TRIPS Agreement: A Force for Convergence within the International IP System' (2011) 14(6) Journal of World Intellectual Property 413-440

[31] Henning Grosse Ruse-Khan, *The Protection of Intellectual Property in International Law* (Oxford University Press 2016) 458

[32] Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer Law International 2002) 292-93

developing countries have acclaimed this provision. It underscores the imperative of harmonizing the interests of patent holders with the imperative to address the unique socio-economic circumstances and welfare of their populations within the TRIPS framework.

While Article 7 mentions the objectives behind the TRIPS Agreement, Article 8 of the Agreement sets the 'public interest principles'[33] of this agreement. Article 8(1) states:

> Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Article 8(1) of the TRIPS Agreement confers upon WTO member states the authority to implement measures, both within and beyond the realm of patent law, with the aim of safeguarding public health and advancing the public interest, provided that these measures adhere to the prerequisite of TRIPS consistency. Article 8(2) explicitly recognizes that measures may be necessary to forestall the abuse of patent rights, as encapsulated in the following words:

> Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Carlos Correa astutely contends that Article 8(2) and Article 7 of the TRIPS Agreement represent pivotal tools for the interpretation and implementation of the agreement at the domestic level.[34] This assertion is grounded in the fact that Article 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) mandates that the interpretation of the TRIPS Agreement must adhere to the principles outlined in Articles 31 and 32 of the Vienna Convention on the Law of Treaties. Henning Grosse Ruse-Khan takes this argument a step further, positing that "Panels have a legal obligation to interpret TRIPS in light of Arts.7 and 8,"[35] in conjunction with Art. 31 of the Vienna Convention on the Law

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[33] Henning Grosse Ruse-Khan (n 31) 453

[34] Carlos M. Correa, 'Intellectual Property and Competition – Room to Legislate under International Law' in Frederick Abbott et al. (eds.), *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries* (New York: United Nations Development Programme 2014) 35–57, 46

[35] Henning Grosse Ruse – Khan, 'The (Non) Use of Treaty Object and Purpose in Intellectual Property Disputes in the WTO' (Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 11-15, September 28, 2011) <http://ssrn.com/abstract=1939859> accessed 09 April 2023

of Treaties.[36] In practical terms, this translates into an imperative that the relatively loosely defined TRIPS flexibilities must be construed in a manner consistent with good faith, aligning with the ordinary meaning of the text, and in accordance with the broader objectives and purposes of the Agreement.

Notably, there are concerns from the developed countries that Least Developed Countries will exploit these policy space to evade their obligations undermining the TRIPS Agreement.[37] Because a rigorous competition policy that broadly defines abusive and anti-competitive uses of intellectual property rights could significantly diminish the effectiveness of the TRIPS Agreement. That is why, even though the TRIPS permits the exploitation of its flexibilities within the mandate of the TRIPS Agreement, it is important to clearly set the boundaries of these flexibilities.

**B. Scope of Flexibility**

Upon closer examination of Article 8(2) of the TRIPS Agreement, it becomes evident that there are three distinct scenarios in which member states have collectively acknowledged that there may be grounds for implementing measures aimed at countering the monopolistic effects conferred by patents:

(a) When the patent owner engages in the abuse of patent rights.

(b) When the patent owner is involved in practices that unreasonably restrain trade.

(c) When the patent owner partakes in practices that have an adverse impact on the international transfer of technology.

A comprehensive reading of Articles 7, 8(1), and 8(2) unequivocally establishes that as long as measures taken to prevent the abuse of patent rights, even if they extend beyond patent law, conform to the provisions of the TRIPS Agreement, they are permissible within the scope of the Agreement. Therefore, Article 8 does not function as an independent defense, but rather sanctions only those measures that are otherwise 'inconsistent' with the TRIPS Agreement.

Once more, in Article 8(2) of the TRIPS Agreement, member states tacitly concede the existence of practices that have the potential to unreasonably restrain trade. These member states have also collectively agreed that such practices

[36] Consequently, a number of top tier IP law journals including Journal of Intellectual Property Law & Practice published articles which used Article 31 to interpret provisions of TRIPS. See for example, Mike Snodin, 'Pharmaceutical innovations and obligations under TRIPS' (2017) 12(6) Journal of Intellectual Property Law & Practice 489, 491

[37] Olivier Cattaneo, 'The Interpretation of the TRIPS Agreement: Considerations for the WTO Panels and Appellate Body' (2000) 3(1) Journal of World Intellectual Property 627, 645

warrant corrective action.[38] Article 8.2 of the TRIPS Agreement further imposes a stringent consistency requirement on member states. This signifies that there are limitations on the scope of action that member states can take; they cannot enact measures arbitrarily, but instead, their measures must align with the provisions of the TRIPS Agreement. This position within the TRIPS Agreement is crafted to strike an equitable balance between diverse policy objectives.[39] Consequently, a purported competition law measure intended to rectify the abuse of patent rights cannot unduly encroach upon the legitimate rights that a patent holder is entitled to receive from member states under the TRIPS Agreement. In such circumstances, it is important to define 'abuse of patent rights', explore the consistency requirement for the measures adopted to deal with abuse of patent rights, and develop a normative framework for 'appropriate measures' under the TRIPS Agreement.

*a) Defining 'Abuse of Patent Rights'*

The TRIPS Agreement does not explicitly define what constitutes an abuse of intellectual property rights, thereby affording member states the discretion to interpret and implement these terms in accordance with their domestic legislation. However, it is worth noting that Article 2(1) of the TRIPS Agreement imposes an obligation on member states to adhere to the provisions of the Paris Convention,[40] specifically Articles 1 through 12, and Article 19 of the Paris Convention for the Protection of Industrial Property. Within the Paris Convention, Article 5A(2) contains the phrase 'abuse of intellectual property rights' and explicitly states that the failure to work a patented invention is considered an abuse of patent rights.[41]

Furthermore, according to the Oxford English Dictionary, 'abuse' is defined as 'improper usage' or 'a corrupt practice or custom.'[42] When we consider the term 'improper,' it denotes actions that are not in alignment with truth, fact, reason, or

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[38] UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge University Press 2005) 546

[39] Thomas Cottier and Pierre Veron, *Concise International and European IP Law: TRIPS, Paris Convention, European Enforcement and Transfer of Technology* (2nd ed, Netherlands: Kluwer Law International 2011) 33

[40] Paris Convention for Protection of Industrial Property of 20 March 1883', as revised in Brussels on 14 December 1900, in Washington on 2 June 1911, at The Hague on 6 November 1925, in London on 2 June 1934, in Lisbon on 31 October 1958 and in Stockholm on 14 July 1967

[41] Article 5A(2) of the Paris Convention states that "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work".

[42] 'abuse, n.' (*OED Online*, OUP March 2023) <https://www.oed.com/view/Entry/821?rskey=hP2mQi&result=1> accessed April 08, 2023

established rules.[43] On the other hand, when 'corrupt' is used as an adjective, it signifies a state changed from its natural or sound condition.[44] Therefore, adopting a comprehensive perspective, 'abuse of patent rights' can be understood as the utilization of patent rights in a manner that deviates from established truths, facts, reason, or rules, or employs patent rights in a form altered from their natural state.

Given that the fundamental purpose of patent rights is to contribute to the advancement of technological innovation, the transfer and dissemination of technology, and to the mutual benefit of both technology creators and users, all while promoting social and economic well-being and maintaining a balance of rights and obligations, it follows that abuse of patent rights can manifest in various ways. These include practices such as excessive pricing, restrictive clauses in licensing agreements, refusal to license, resale price maintenance, price discrimination, mandatory package licensing, and other actions that contravene these fundamental objectives and principles.[45]

*b) Setting the Boundary: The Consistency Requirement*

Article 8(2) of the TRIPS Agreement grants member states the authority to adopt 'appropriate measures'to counteract the abuse of patent rights. Consequently, member states have the prerogative to enact legislation aimed at addressing patent abuses stemming from the exclusive rights granted to patent holders. However, these measures must not run counter to the member states' obligations under the TRIPS Agreement. In other words, the 'appropriate measures' must align with the requirements and provisions of the TRIPS Agreement, ensuring they remain consistent with its stipulations.[46]

The authority of member states to enact appropriate measures is subject to the condition that these measures must align with the TRIPS Agreement, which serves as a constraint on their sovereign authority to craft their own remedies.[47] This limitation has two key dimensions. Firstly, it raises the question of whether the TRIPS consistency requirement exclusively applies to the remedies designed to address the abuse of patent rights. Alternatively, it can be interpreted as a more general requirement that pertains to substantive rules as well. However,

[43] 'improper, adj.' (*OED Online*, OUP March 2023) <https://www.oed.com/view/Entry/92817?rskey=S77dn3&result=1#eid> accessed April 08, 2023

[44] 'corrupt, adj.' (*OED Online,* OUP March 2023) <https://www.oed.com/view/Entry/42034?rskey=nZz3bF&result=1#eid> accessed April 08, 2023

[45] Hiroko Yamane, 'Competition Analyses of Licensing Agreements: Considerations for Developing Countries under TRIPS' (Discussion Paper, ICTSD Innovation, Technology and Intellectual Property, Geneva: International Centre for Trade and Sustainable Development 2014) 39

[46] Also see, Tú Thanh Nguyãễn, *Competition Law, Technology Transfer and the TRIPS Agreement: Implications for Developing Countries* (UK: Edward Elgar Publishing 2010) 48

[47] UNCTAD-ICTSD (n 38) 553

irrespective of the specific dimension, if the measures adopted undermine the fundamental rights of a patent owner, they would contravene the international obligations of the member state under the TRIPS Agreement.

Now, it is crucial to discern the basic rights emanating from the grant of a patent that 'appropriate measures' must respect. The TRIPS Agreement bestows upon the patent holder exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing the same product or process.[48] Nonetheless, the TRIPS Agreement itself acknowledges that these rights can be constrained in accordance with the provisions set forth in Articles 30, 31, and 40 of the Agreement. Consequently, curtailing the rights of a patent holder under Article 28 can be deemed TRIPS consistent if such curtailment aligns with the requirements articulated in Articles 30, 31, and 40 and satisfies the TRIPS consistency mandate. Furthermore, these provisions necessitate interpretation in light of the principles enshrined in Articles 7 and 8 of the TRIPS Agreement.

Notably, the position of law regarding how the TRIPS consistency requirement in Article 8(2) can be satisfied has not been definitively clarified by any WTO dispute settlement panels or Appellate Body reports.[49] Nevertheless, scholars and experts in the field of TRIPS have offered varying opinions and interpretations of the consistency requirements under the agreement. Frederick Abbott has argued that "competition law should not be used as a disguised mechanism for undermining the basic rights accorded under it."[50] In his view, the TRIPS Agreement should not be leveraged to erode the fundamental rights conferred by the Agreement.

On the other hand, Daniel Gervais contends that the TRIPS consistency requirement in Article 8(2) can be fulfilled by drawing upon the operational provisions outlined in Arts. 31 and 40 of the Agreement.[51] According to Gervais, these operational provisions provide a framework for adhering to the TRIPS consistency mandate. Thomas Cottier and Pierre Véron share a similar perspective to Daniel Gervais and argue that the TRIPS Agreement offers a framework for exploiting policy space and flexibilities through its operational provisions.[52] They emphasize that the operational aspects of the agreement provide guidance for

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48 TRIPS Agreement, Art 28

49 Wei Zhuang, 'Interpreting Competition-Related Flexibilities in the TRIPS Agreement for Facilitating Innovation and Transfer of ESTs' in *Intellectual Property Rights and Climate Change: Interpreting the TRIPS Agreement for Environmentally Sound Technologies* (Cambridge University Press 2017) 311-345

50 Frederick M. Abbott, 'Are the Competition Rules in the WTO TRIPS Agreement Adequate?' (2003) 7(3) Journal of International Economic Law 687–703, 692

51 Daniel Gervais (n 10) 240

52 Thomas Cottier and Pierre Véron (n 39) 32

member states to navigate the TRIPS consistency requirement.

In response to the arguments presented by scholars like Daniel Gervais, Carlos Correa posits that the TRIPS consistency requirement can be met by taking into account socio-economic welfare considerations in accordance with the preamble, Articles 7, and 8(1) of the TRIPS Agreement.[53] He suggests that assessing TRIPS consistency should factor in the broader principles and objectives outlined in these provisions. Abdulqawi A. Yusuf advances the viewpoint that the TRIPS consistency requirement should be evaluated against the objectives and principles enshrined in the preamble, Articles 7, and 8 of the TRIPS Agreement.[54] Yusuf goes a step further by advocating for an 'overall consistency' approach.[55] He asserts that even if certain measures are inconsistent with specific TRIPS standards, their overall consistency with the principles and objectives of the Agreement should be taken into consideration.

Henning Grosse Ruse-Khan meticulously evaluates these arguments, taking into account Art. 31(3) of the Vienna Convention on the Law of Treaties, Articles 7 and 8 of the TRIPS Agreement, and the Doha Declaration on the TRIPS Agreement and Public Health. His conclusion is that members have "no right to act inconsistently with specific TRIPS obligations."[56] This suggests a more stringent interpretation of the TRIPS consistency requirement, emphasizing adherence to specific TRIPS obligations as the paramount consideration.

The measures that member states are authorized to undertake to counteract the abuse of patent rights must align with the TRIPS Agreement, and as such, competition law provisions that systematically nullify the essential elements of patent rights are not consistent with the TRIPS Agreement.[57] Consequently, any blanket prohibition on restrictive clauses in licensing agreements, without due consideration of circumstantial factors and qualifications, would be deemed inconsistent with the TRIPS Agreement. This underscores the need for such measures to be carefully crafted and applied in a manner that respects and upholds the principles and objectives of the TRIPS Agreement.

In conclusion, a domestic competition legal framework must align with the objectives and principles set forth in the TRIPS Agreement. The negotiating

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[53] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press 2007) 110

[54] Abdulqawi A. Yusuf, 'TRIPS: Background, Principles and General Provisions' in Correa and Abdulqawi (eds.), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, New York: Kluwer Law International 2008) 3–21, 14

[55] ibid

[56] Henning Grosse Ruse-Khan (n 31) 452

[57] UNCTAD-ICTSD (n 38) 553

history of the TRIPS Agreement reveals that the final text of the Agreement strikes a balance between the 'No Consistency'[58] requirement and the 'No Derogation'[59] obligation of member states.[60] Consequently, member states possess significant regulatory authority to formulate their domestic competition law regime, provided that such derogations are consistent with the TRIPS consistency requirement. This means that the curtailment of patent rights is permissible when these rights have been abused, and measures have been implemented in accordance with the provisions of Articles 31 and 40 of the TRIPS Agreement, interpreted in light of Articles 7 and 8 of the Agreement. Additionally, member states cannot derogate from their National Treatment obligation[61] or Most Favored Nation (MFN) treatment obligation[62], ensuring that their competition law framework remains within the bounds of their TRIPS commitments.

*c) Appropriate Measures*

A plain reading of the Article 5A(2) of the Paris Convention indicates that compulsory licensing is the singular remedy that may be prescribed to prevent abuse of patent rights. This provision underscores the importance of compulsory licensing as a mechanism to address abuses of patent rights, particularly within the framework of the Paris Convention. It states:

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.[63]

It is important to clarify that Article 5A of the Paris Convention does indeed prescribe another measure in addition to compulsory licensing, which is the forfeiture of a patent.[64] This signifies that the Paris Convention offers national legislatures two potential remedies for addressing abuses of patent rights. However, it is crucial to note that the subsequent provisions, specifically Articles

[58] 'Status of Work in the Negotiating Group: Chairman's Report to the GNG' (Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, 23 July 1990) GATT Doc. MTN.GNG/NG11/W/76, Art. 8B.4

[59] 'Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations' (Multilateral Trade Negotiations, The Uruguay Round, 3 December 1990) GATT Doc. MTN. TNC/W/35/Rev.1, Article 8.2

[60] Beatriz Conde Gallego, 'Intellectual Property Rights and Competition Policy' in Correa (ed.), *Research Handbook on the Protection of Intellectual Property under WTO Rules: Intellectual Property in the WTO, Vol. I* (UK: Edward Elgar Publishing 2010) 226–65, 237.

[61] TRIPS Agreement, Art. 3

[62] ibid, Art. 4

[63] Paris Convention for the Protection of Intellectual Property 1967, Art. 5A(2)

[64] ibid, Art. 5A(3)

5A(3) and 5A(4), provide detailed procedures and rights for patent holders in connection with these remedies, ensuring that the application of such measures is guided by a defined process and that patent holders' rights are duly safeguarded.

Article 5A(4) of the Paris Convention introduces a specific precondition related to the timing of taking a legislative measure in response to the failure to work or insufficient working of a patent. It stipulates that a compulsory license may not be sought on the grounds of failure to work or insufficient working before the expiration of a specific period, typically four years from the date of filing the patent application or three years from the date of the patent's grant, depending on which period expires later.[65] This condition grants the patent holder approximately three to four years to commence working a patent before a compulsory license can be pursued under the obligations of Article 5A of the Paris Convention, which aligns with Article 2(1) of the TRIPS Agreement.

Similarly, no measure related to the forfeiture of a patent can be taken before the expiration of two years from the grant of the first compulsory license of the patent.[66] In essence, these conditions establish a timeframe within which the domestic patent/competition interface may offer various legal remedies, providing a structured and time-bound framework for addressing the failure to work a patent and related issues. Moreover, TRIPS provisions do not prevent jurisdictions from implementing further actions. It also does not require a specific institutional structure (such as a singular authority or multiple regulatory bodies).[67] In addition, competition authorities are not restricted from granting different types of remedies including Fair, Reasonable and Non-discriminatory (FRAND) licensing for standard essential patents (SEPs), monetary fines etc.[68]

### 3. Patent/Competition Interface in TRIPS

Compulsory licensing represents an exceptional measure that restricts the rights of a patent owner, acknowledging the primacy of public interest concerns over the private rights of the patent holder.[69] Through compulsory licensing, access to essential medicines can become more affordable. It has been recognized, even in articles opposing the concept of compulsory licensing, that "the existence

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65 ibid, Art. 5A(4)

66 ibid, Art. 5A(3)

67 South Centre, 'TRIPS Flexibilities and the Use of Competition Laws' < https://ipaccessmeds.southcentre.int/wp-content/uploads/2021/07/Competition-and-Access-to-Medicines.pdf> accessed 19 December 2023

68 South Centre and IDEC, 'Conference on Fair and Equitable Pricing in Health: Competition Law and Access to Medicines' (December 2020) Recordings available here: https://www.youtube.com/playlist?list=PLZdHFQBFVjThTBeKtmswACPeSAoaqzMbq

69 UNCTAD-ICTSD (n 38) 461

of compulsory licensing as a legal right likely exerts a generalized downward pressure on global medicine prices."[70]

Although no latest data is available as to the use of competition law to curb anti-competitive practices of a patent holder, an empirical research conducted by Deere in 2009 revealed that globally, twenty-four countries have resorted to compulsory licensing as a remedy for addressing anticompetitive practices.[71] For instance, countries like Brazil[72] and Thailand[73] have utilized compulsory licensing to ensure the affordability of antiretroviral medications for HIV/AIDS treatment. Even in the United States, competition authorities have invoked compulsory licensing to rectify anticompetitive practices related to the exercise of intellectual property rights.[74] These examples underscore the broad utility and impact of compulsory licensing in promoting fair access to critical medicines and countering anticompetitive behavior.

Millions of lives have been preserved to date through the provision of compulsory licensing, highlighting the crucial role such mechanisms play in public health.[75] This is why international law permits what may be seen as a temporary utilization of intellectual property rights. The TRIPS Agreement grants member states the authority to authorize third-party manufacturers to produce patented medicines,[76] with the understanding that "the right holder shall be paid adequate remuneration" as compensation for this use. [77]

Article 31 of the TRIPS Agreement addresses compulsory licensing, focusing on the rules and procedures associated with this mechanism. While it does not extensively specify the grounds for issuing compulsory licenses, it instead outlines the procedures and conditions that governments are expected to follow

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[70] Reed F. Beall, Randall Kuhn and Amir Attaran, 'Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement' (2015) 34 Health Affairs 493, 498

[71] Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (OUP 2009) 83

[72] Jane Galvão, 'Access to Antiretroviral Drugs in Brazil' (2002) 360 The Lancet 1862-65

[73] Robert Steinbrook, 'Thailand and the Compulsory Licensing of Efavirenz' (2007) 356(6) New England Journal of Medicine 544-546

[74] Carlos M. Correa (n 14) 35–57, 50

[75] Petra Moser and Alessandra Voena, 'Does Compulsory Licensing Hurt Innovation?' (Stanford Institute for Economic Policy Research Policy Brief, November 2010) <https://siepr.stanford.edu/publications/policy-brief/does-compulsory-licensing-hurt-innovation> accessed 26 April 2023; On morality issue of compulsory licensing see, Margo A. Bagley, 'The Morality of Compulsory Licensing as an Access to Medicines Tool' (2018) 102 Minnesota Law Review 2463

[76] TRIPS Agreement, Article 31(b)

[77] ibid, Article 31(h)

when invoking compulsory licensing. This provision provides the framework for the proper implementation of compulsory licensing, ensuring that it is carried out in a fair and controlled manner.

Article 31(b) of the TRIPS Agreement sets forth a requirement for prior negotiation between the party seeking a compulsory license of a patent and the patent holder. The granting of a compulsory license can only proceed if the patent holder does not agree to voluntarily license the patent under "reasonable commercial terms and conditions" within a "reasonable period of time," as stipulated in this provision. Additionally, Article 31(f) of the TRIPS Agreement mandates that an order for a compulsory license of a patent must primarily serve to meet the domestic needs of the country granting the license. Initially, Article 31 of the TRIPS Agreement limited countries from using compulsory licenses to manufacture medicines for export, putting countries that lacked the capacity to produce necessary drugs within their borders at a disadvantage.[78] However, the requirement to predominantly serve domestic needs was waived for pharmaceutical products with the incorporation of Article 31bis.[79]

Importantly, TRIPS requires member states to authorize such use on a case-by-case basis,[80] taking into account the individual merits of the situation and ensuring that the patent holder receives adequate remuneration in consideration of the economic value of the authorization.[81] This framework allows for flexibility and adaptability in addressing public health needs while still respecting intellectual property rights.

### A. Higher Status of Market Competition

Article 31(k) of the TRIPS Agreement serves as an exception to the provisions outlined in Articles 31(b) and 31(f). It grants governments an exceptional power to address situations where the patent holder is involved in anticompetitive practices. This provision empowers governments to take action through compulsory licensing to remedy instances of anticompetitive behavior on the part of the patent holder. The provision is as follows:

> 31 (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount

[78] Jerome H. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 Journal of Law, Medicine and Ethics 247, 248

[79] Sapna Kumar, 'Compulsory Licensing of Patents During Pandemics' (2022) 54(1) Connecticut Law Review 57, 64

[80] TRIPS Agreement, Art. 31(a)

[81] ibid, Art. 31(h)

> of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

Article 31(k) of the TRIPS Agreement introduces a distinct provision, allowing for the grant of compulsory licenses without adhering to the usual requirements of prior negotiation (Article 31(b)) and the need for predominantly serving domestic needs (Article 31(f)). However, this exception is conditional upon the identification of anticompetitive practices through a judicial or administrative process. This process also plays a crucial role in determining the remuneration amount associated with the compulsory licensing.

Notably, the TRIPS Agreement does not explicitly define the terms- "judicial or administrative process" providing member states with the flexibility to formulate their policies and standards when addressing anticompetitive practices by a patent holder. This flexibility becomes advantageous when considering remedies other than compulsory licensing or patent forfeiture, especially since the competition scrutiny process is often protracted.[82] The sanction to assess the anticompetitive nature of a practice through an administrative body streamlines the decision-making process, reducing the time required to implement alternative remedies in critical situations.

A determination of the anticompetitive nature of a practice related to the exercise of patent rights grants the member state the flexibility to establish the terms of a compulsory license. In particular, identifying anticompetitive practices by a patent holder lowers the barriers for granting a compulsory license, bypassing the usual requirements outlined in Articles 31(b) and 31(f) of the TRIPS Agreement. This finding provides the member state with the ability to determine the terms and conditions of the compulsory license, allowing for a more streamlined process in cases involving anticompetitive practices.

In contrast, when seeking a compulsory license for reasons unrelated to anticompetitive practices, the requirement of prior negotiation poses a substantial barrier. Negotiating reasonable terms and conditions can be challenging, as it is a subjective and vague criterion. Vu Van Le points out two such reported instances:[83] *firstly,* during the Indian compulsory licensing process in 2012, the patent owner sought a royalty rate of 15%, whereas the licensee's proposed offer

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[82] Shirin Syed, 'Incorporation of competition-related TRIPS flexibilities in the domestic law: A case study of India' (2019) Journal of the World Intellectual Property 2

[83] Vu Van Le, 'Compulsory Licensing of Patented Pharmaceuticals in the Developing World. A Legitimate or Illegitimate Way to Enhance the Access to Medicines?' (Unpublished PhD Thesis, Bangor University 2018) 121 <https://research.bangor.ac.uk/portal/files/22474531/2018_Le_VVA_PhD.pdf> accessed 26 April 2023

intellectual property rights have an adverse effect on trade.[89] Additionally, there is no responsibility imposed on intellectual property holders to refrain from acting in an anticompetitive manner, as TRIPS does not impose obligations on private parties. However, this provision is not merely a statement; it has been argued that member states commit to giving effect to TRIPS provisions under Article 1.1 of the Agreement itself.[90] While not having an effective competition regime may not constitute a breach of the TRIPS Agreement, it is deemed inconsistent with the Agreement. The distinction lies in the legal implications of "breach" versus "inconsistency" with TRIPS, both referring to situations where there is a failure to fulfill an obligation.

Absolutely, without a competition regime to address situations where licensing practices or conditions related to intellectual property rights restrict competition and have an adverse effect on trade, member states would be falling short of giving full effect to Article 1.1 of the TRIPS Agreement. In such a context, the absence of a competition regime would not align with TRIPS consistency. It underlines the significance of having a regulatory framework that can effectively address anticompetitive practices in the realm of intellectual property rights.

### C. Policy Space in Defining 'Anti-Competitive Practice'

The flexibility in determining what constitutes an anticompetitive practice under the TRIPS Agreement is indeed a crucial aspect. It allows member states to tailor their approach based on their unique economic circumstances. This adaptability ensures that the criteria for identifying anticompetitive practices can be shaped in a way that aligns with the specific needs and conditions of each country. It acknowledges the diverse economic landscapes of member states and empowers them to develop standards that best serve their interests.

While a patent holder indeed possesses the right to exclude others from the use, production, and sale of patented products, this entitlement is not absolute.[91] A mere denial of patent licensing does not inherently qualify as anticompetitive behavior. However, this stance transforms into an anticompetitive act, warranting

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[89] Brand and Lehman, 'Section 8: Control of Anti-Competitive Practices in Contractual Licences' in Peter-Tobias Stoll, Jan Busche & Katrin Arend (eds), *WTO—Trade-Related Aspects of Intellectual Property Rights* (Brill 2009) 665

[90] J. Reichman, 'Beyond the Historical Lines of Demarcation: Competition Law, Intellectual Property Rights, And International Trade After the GATT's Uruguay Round' (1993) 20 Brooklyn Journal of International Law 1, 75, 107

[91] Katrin Nyman-Metcalf, Pawan Kumar Dutt and Archil Chochia, 'The Freedom to Conduct Business and the Right to Property: The EU Technology Transfer Block Exemption Regulation and the Relationship between Intellectual Property and Competition Law' in Kerikmäe (ed.), *Protecting Human Rights in the EU: Controversies and Challenges of the Charter of Fundamental Rights* (Germany: Springer 2014) 37–70, 56

compulsory licensing as a remedy, when the patent holder endeavors to establish a monopoly within the relevant market. Notably, the TRIPS Agreement refrains from explicitly delineating what constitutes a refusal to license as an anticompetitive activity. Member states navigate this by resorting to indigenous assessments or importing doctrines into their legal frameworks to ascertain the anticompetitive nature of a practice. For instance, the United States and the European Union frequently employ the essential facilities doctrine to evaluate whether a specific refusal to license amounts to anticompetitive conduct.[92] In essence, member states enjoy considerable policy latitude to formulate their criteria for applying the essential facility doctrine within either competition law or patent law. As previously argued, it is imperative for members to consider the objectives and principles articulated in Articles 7 and 8 of the TRIPS while integrating TRIPS obligations into their domestic legal frameworks.

Member states have frequently employed compulsory licenses to address anticompetitive practices, such as the refusal to license.[93] While patent holders retain the right to refuse dealings under certain conditions, they may abuse the monopoly conferred by patent rights through practices like excessively pricing patented products. The UN General Assembly has outlined potentially anticompetitive practices in the *Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices*.[94] This document characterizes restrictive business practices as actions or behaviors by enterprises that, through the abuse or acquisition and abuse of a dominant market position, restrict market access or unduly restrain competition, adversely affecting international trade, particularly in developing countries.[95] A dominant position of market power, as per the same document, is a situation where an enterprise, either independently or in collaboration with a few others, controls the relevant market for a specific good or service.[96] Excessive pricing resulting from a monopoly granted by patent rights aligns with the definition of a dominant position of market power. An illustrative example is Sofosbuvir, priced at $84,000 for a 12-week treatment, while generic versions are available for around $100.[97] Exploiting their dominant market position, patent holders impose these exorbitant costs on consumers,

[92] See for details, Mariateresa Maggiolino, *Intellectual Property and Antitrust: A Comparative Economic Analysis of US and EU Law* (UK: Edward Elgar Publishing 2011) 147

[93] For an overview see, Beatriz Conde Gallego (n 60) 226–65, 258

[94] UNCTAD, 'The Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices' (United Nations 2000, TD/RBP/CONF/10/Rev.2) <https://unctad.org/system/files/official-document/tdrbpconf10r2.en.pdf> accessed 09 April 2023

[95] ibid, 10

[96] ibid

[97] Abbey Meller and Hauwa Ahmed, 'How Big Pharma Reaps Profits While Hurting Everyday Americans' (*Center for American Progress*, 30 August 2019) <https://www.americanprogress.org/article/big-pharma-reaps-profits-hurting-everyday-americans/> accessed 26 April 2023

establishing a barrier to affordable medicines, constituting an anticompetitive abuse of dominant position in the relevant market.

Revisiting the earlier discussion on "defining abuse of patent rights," it is worth noting that Article 5A(2) of the Paris Convention identifies the failure to work a patent as constituting an abuse of patent rights. Consequently, this scenario may prompt the involvement of competition authorities to authorize compulsory licenses, subject to the conditions outlined in Articles 5A(3) and 5A(4) of the Paris Convention.

Exploring the intricacies of the TRIPS Agreement, Article 40(1) recognizes the detrimental effects of certain licensing practices. Simultaneously, Article 40(2) instructs member states to delineate in their domestic laws the instances that may amount to an abuse of patent rights. Furthermore, Article 40(2) offers guidance on shaping the competition regime. The language of Article 40(2) explicitly indicates the non-exhaustive nature of the list of anticompetitive practices it provides. It empowers member states to take appropriate measures against practices, including but not limited to, 'exclusive grantback conditions, conditions preventing challenges to validity, and coercive package licensing.' This leaves room for member states to identify and address other potentially anticompetitive practices not explicitly listed but deemed so by their legislators.

Examining the evolution of the TRIPS Agreement, it is worth noting that the Brussels draft of the TRIPS Agreement initially included an extensive list of anticompetitive practices. This list encompassed various elements such as grant-back conditions, challenges to validity, exclusive dealing, restrictions on research, limitations on personnel use, price fixing, restrictions on adaptation, exclusive sales or representation agreements, tying arrangements, export restrictions, patent pooling or cross-licensing agreements, restrictions on publicity, and obligations persisting after the expiration of industrial property rights.[98] In the transition from the Brussels draft to the final version of the TRIPS Agreement, the initial comprehensive list of anticompetitive practices was notably condensed. The question arises as to whether member states are legally empowered to include the omitted practices in their domestic legislation. The TRIPS Agreement, while not explicitly addressing this question, upholds the regulatory authority of member states to formulate their competition rules and policies, provided they align with the Agreement's provisions. As long as the overarching condition outlined in the first sentence of Article 40(2) of the TRIPS—addressing the 'abuse of intellectual property rights having an adverse effect on competition in the relevant market'—is met, member states possess the freedom to integrate these practices into their domestic legal frameworks.

[98] Daniel Gervais (n 10) 189

## D. Standard of Competition Review: Per Se or Rule of Reason

As discussed above, Article 40(1) mandates the member states of the TRIPS Agreement to have a domestic competition law regime. Thomas Cheng argues that it is in the interest of developing countries to pursue a *per se*[99] scrutiny of alleged anticompetitive practices, because most often they do not have the resources to engage in *rule of reason*[100] based economic analysis.[101] Frederick Abbott argues[102] that the member states have the sovereign authority to legislate that archetypical competition law cases such as absolute territorial protection for distributors, price fixing, or quantitative restriction constitute *per se* violation of competition in the relevant market. However, the wording in Article 40(2) is puzzling. Because a closer look at Article 40 reveals that it does suggest application of a *rule of reason*-based competition scrutiny on a case-by-case basis. But in a literal reading it seems that abuse of intellectual property rights is a *per se* 'particular case' within the meaning of this article.

In navigating the terrain of competition scrutiny, the TRIPS Agreement provides a guideline. If a member state includes in its legislation that administrative or judicial authorities may consider either compulsory license or forfeiture of patent as a remedy, TRIPS suggests that 'such authorization should be assessed on an individual merit basis, inviting a rule of reason analysis'.[103] However, if a member state prescribes any other remedy for consideration, the state retains sovereign authority and can even mandate a per se scrutiny of alleged anticompetitive practices. Thus, the flexibility extends to the member states in defining the standards for competition scrutiny.

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[99] *Per se* is one kind of competition analysis that determines legality of agreements or actions of enterprises. Under this rule, some practices are presumed to violate competition law without any other consideration.

[100] *Rule of reason* is another kind of competition analysis to determine legality of agreements or actions of enterprises. Under this rule, before concluding whether an agreement breaches antitrust laws, courts scrutinize both the favorable and unfavorable impacts of the agreement. To reach their verdict, courts analyze various factors, including the agreement's business objective, the market influence of the parties involved, the level of competition in the applicable market, and other market conditions.

[101] Thomas K. Cheng, *Competition Law in Developing Countries* (Oxford University Press 2020) ch 9. Also see, Amber Darr, Thomas K. Cheng, 'Competition Law in Developing Countries, Oxford: Oxford University Press, 2020, xii+580 pp, hb £80.00' (2020) 84 The Modern Law Review 662-666

[102] F. Abbott, 'Are the Competition Rules in the WTO TRIPs Agreement Adequate?' (2004) 7 Journal of International Economic Law 687, 692

[103] TRIPS Agreement, Art. 31(a)

## 4. Conclusion

Member states have the leeway to delineate what constitutes 'anti-competitive' conduct. Competition law is designed to foster marketplace competition and mitigate the emergence of monopolies or anticompetitive behavior detrimental to consumers. At first glance, patent law and competition law might appear to be in conflict, as a patent holder by virtue of their patent enjoys an exclusive right to manufacture and sell their product.[104] However, this exclusivity can potentially culminate in a monopoly in the absence of comparable competitors offering similar products. It is worth noting that patents are increasingly wielded as strategic assets to shape competitive conditions, rather than as defensive tools to protect research and development outcomes.[105] In contrast, competition law seeks to prevent such monopolistic tendencies by ensuring opportunities for other enterprises to enter the market and compete. Professor Fox has argued that the silence of international law on this matter aligns with the interests of developing countries, contending that they would be better served by developing and enforcing their domestic competition laws.[106]

In navigating the extent of flexibility in addressing competition-related matters within the TRIPS Agreement, taking into Account the Principles and Objectives of the Agreement, this article concludes that that certain practices related to the use of patent rights may unreasonably restrain trade, offers developing countries a strategic toolset. Noting that articles 8(2) and 7 are at the forefront of TRIPS interpretation and implementation, the obligation to interpret TRIPS in light of these articles, combined with the consistency requirement, underscores the pivotal role they play in shaping domestic competition law frameworks. This interpretative framework, rooted in good faith and aligned with the text, object, and purpose of the Agreement, provides developing countries with vital policy space.

While the TRIPS Agreement lacks an overt provision explicitly mandating the establishment of a competition regime at the domestic level, this article concludes that article 40 compels member states to have a substantive legal framework to counteract anticompetitive licensing practices. The flexibility inherent in this

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[104] For a debate on the issue, see Ioannis Lianos, 'Competition Law and Intellectual Property Rights: Is the Property Rights' Approach Right?' (2006) 8 Cambridge Yearbook of European Legal Studies 153

[105] Vuyisile Hobololo, 'Strategic Patenting of Pharmaceutical Inventions and the Public's Right to Access Medicines: The South African Context' (2015) 16 African Journal of Information and Communication 78; also see Brian Whitehead, Stuart Jackson, and Richard Kempner, 'Managing generic competition and patent strategies in the pharmaceutical industry' (2008) 3(4) Journal of Intellectual Property Law & Practice 226–235

[106] Eleanor M. Fox, 'Trade, Competition, and Intellectual Property--TRIPS and its Antitrust Counterparts' (1996) 29(3) Vanderbilt Journal of Transnational Law 481

provision allows for diverse approaches, with the mandate to prescribe appropriate measures that may extend beyond the listed practices.

Furthermore, the TRIPS Agreement stipulates that any measures designed to counteract anticompetitive practices must adhere to TRIPS-consistent standards. Consequently, this article demonstrated that the limitations imposed on competition measures must ensure their compliance with the TRIPS Agreement. It also points out the wide policy space for the member states, within the TRIPS Agreement, to define 'anti-competitive practices' that may even trump the patent rights of the patent holder. Moreover, the agreement also enables the member states to design their own standard of competition review (*per se* or *rule of reason*) to assess what constitutes 'anti-competitive practices' in exploiting patent rights by the respective patent holder. Developing countries, armed with the TRIPS flexibilities, can navigate this delicate policy space to forge a path that fosters innovation, protects public health, and nurtures a competitive market landscape.