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Using the flexibilities of Article 30 *TRIPS* to implement patent exceptions in pursuit of Sustainable Development Goal 3

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Abstract

Despite over 25 years passing since *TRIPS* entered into force, the full potential of the patent exceptions provision under Article 30 *TRIPS* (Article 30) is yet to be realised. The hesitation by developing states to implement new patent exceptions in their domestic laws has presented a barrier to reconciling the tension between protecting patent rights and achieving access to essential medicines for all as committed by states under Sustainable Development Goal 3 (SDG 3). This article addresses the uncertainty of the interpretation of Article 30 through a doctrinal analysis of treaty interpretation rules and the recent *Australia-Tobacco Plain Packaging* decisions. It proposes an original interpretation of Article 30 that permits public interest considerations, and uses this interpretation to justify a proposed stockpiling exception for pandemic and epidemic preparedness aimed at facilitating access to essential medicines to achieve SDG 3. Accordingly, developing states should feel more confident about implementing patent exceptions tailored to their public interest needs in pursuit of SDG 3.

KEYWORDS

access to medicines, Article 30 TRIPS, patent exceptions, public health, Sustainable Development Goal 3, TRIPS flexibilities

1 | INTRODUCTION

The World Trade Organisation's (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights*[1] (*TRIPS*) has been criticised for its inability to balance the public interest needs of developing states against the protection of intellectual property rights (IPRs) desired by developed states.[2] Developing states, international bodies and academics question whether exclusive patent rights stifle social development in developing states by excessively restricting their ability to gain access to essential medicines.[3] Access to essential medicines has been acknowledged by all United Nations states as necessary for social development through Sustainable Development Goal 3 (SDG 3) to 'ensure healthy lives and promote well-being for all at all ages'.[4] SDG 3 has been recognised as 'an important vehicle for realising the right to health'[5] enshrined in Article 12 of the *International Covenant on Economic, Social and Cultural Rights*, which includes the core obligation of states to provide access to essential medicines.[6] Furthermore, WTO Members addressing the effect of patents on increasing the price of medicines during the HIV/AIDS crisis acknowledged in the Doha Declaration on TRIPS and Public Health (Doha Declaration) that states can use *TRIPS* flexibilities to the fullest to address access issues.[7]

TRIPS flexibilities allow states to tailor their intellectual property (IP) policy in a manner conducive to their domestic needs,[8] thereby respecting the policy space left to states to implement *TRIPS* under Article 1(1) and Article 8(1) *TRIPS*.[9] Patent exceptions are an important example of *TRIPS* flexibilities, existing at Article 30 (general exceptions) and Articles 31 and 31*bis* (compulsory licensing) *TRIPS*.[10] These provisions allow third parties to use protected subject matter in certain circumstances regardless of any authorisation granted by the rights holder.[11] This article investigates the potential use of the general exceptions provision of Article 30 and the flexibility of its terms to limit the negative impacts of patents on access to medicines and social development in developing states.

Article 30 has many broad and ambiguous terms, posing a challenge for interpretation, however, also providing flexibility in interpretation and implementation.[12] Presently, states have insufficient guidance from the WTO Dispute Settlement Body (WTO DSB) on the scope of Article 30. The provision has only been partially interpreted once in *Canada-Patents*,[13] where a WTO DSB Panel erroneously failed to interpret its terms in light of their context and Articles 7 and 8 *TRIPS*, as required by the *Vienna Convention on the Law of Treaties* (*VCLT*).[14] Unfortunately, this limited interpretation has stifled the full potential of Article 30, causing a chilling effect on developing states implementing new patent exceptions.[15]

The WTO DSB's approach has however recently shifted in the *Australia-Tobacco Plain Packaging* decisions *(Australia-TPP (No. 1 and No. 2))*[16] where Articles 7 and 8 were applied to interpret the term 'unjustifiably' in the special measures provisions on trade marks under Article 20 *TRIPS*.[17] The Panel found that public interest objectives stated in Article 8(1), including public health, are legitimate objectives permitting encumbrance on trade mark use.[18] As Articles 7 and 8 assist in interpreting all *TRIPS* provisions,[19] the decisions have opened the door for public health objectives, such as increasing access to essential medicines to justify patent exceptions.[20] Additionally, the context of the terms of Article 30 includes the *TRIPS* preamble, which directly references 'development objectives'[21] and the *General Agreement on Tariffs and Trade 1994 (GATT 1994)* preamble, which directly references the 'objective of sustainable development'.[22] These direct references to development make SDG 3 particularly useful for justifying patent exceptions. As such, this new guidance reveals the potential for the flexibility of Article 30 to strike an appropriate balance between patent rights and the public interests in access to essential medicines.

This article makes three important contributions. Firstly, it proposes an original interpretation of Article 30 applying these interpretive sources and precedents. Secondly, it adopts a novel approach to justifying patent exceptions through development arguments in pursuit of SDG 3. Thirdly, it proposes a hypothetical stockpiling exception for pandemic and epidemic preparedness, assisting developing states to gain greater access to patented essential medicines to achieve SDG 3. Section 2 explains how the *TRIPS* patent regime affects access to essential medicines in developing states and why Article 30 can address the unbalanced effects of patents. Section 3 explores the interpretive sources that inform an understanding of Article 30, including Articles 7 and 8, the Doha

Declaration and *Australia-TPP (No. 1 and No. 2)*. Section 4 applies these interpretive sources and proposes an original interpretation of Article 30 focused on a balancing assessment of both the patent holder's interests and the public interest. Finally, the proposed interpretation is used to justify a stockpiling exception for panedmic and epidemic preparedness to encourage developing states to implement new and more ambitious patent exceptions. This article concludes that patent exceptions are a powerful IP policy tool that states should feel more confident implementing in their domestic laws, particularly where such exceptions are tailored to increasing access to essential medicines to achieve SDG 3.

2 | *TRIPS* PATENT REGIME

This article adopts the WTO's approach to classifying 'developing' states, whereby states announce themselves as developed or developing.[23] The majority of WTO Members are developing states, broadly being those states 'with low levels of income and standards of living'.[24] Developing states can be further categorised into least-developed countries (LDCs) constituting the poorest countries in the world, with the highest poverty levels.[25] This article does not consider LDCs as 'developing' states as their transition period for implementing the *TRIPS* patent provisions extends until 2034.[26]

2.1 | Patents, access to essential medicines and social development

The *TRIPS* requirement that patents cover all inventions, including pharmaceuticals and confer exclusive rights to holders for at least 20 years,[27] significantly increased the standards of patent protection and enforcement in developing states.[28] Patents can impede developing states' ability to achieve social development and access to affordable medicines because the monopoly granted increases the costs of medicines by eliminating competition of generics and hindering follow-on innovation.[29] Previous studies conclude that 'the introduction of patent regimes in middle and low-income developing countries will result in price increases between 12% and 200%, which is highly likely to have an impact on effective access to medicines in these countries'.[30]

Patent monopolies are commonly justified by incentive theory, which rationalises patents as the most effective means of encouraging inventions and innovation, which are necessary for development.[31] Proponents of this theory argue that patents can assist social development by creating 'incentives that are needed to induce people to produce particular objects beneficial to society' such as medicines.[32] However, the WTO has acknowledged that 'empirical studies find evidence of both positive and negative effects of patents on innovation' and that 'patents play a limited role in providing incentives to develop new medicines for "neglected diseases" or "diseases of the poor" where there are small markets'.[33] As such, the appropriateness of incentive theory justifying pharmaceutical patents in developing states is questionable.[34]

The Committee on Economic, Social, and Cultural Rights articulated the link between patents and access to essential medicines through its interpretation of the right to health.[35] General Comment No. 24 states that 'parties should ensure that IPRs do not lead to denial or restriction of everyone's access to essential medicines necessary for the enjoyment of the right to health'.[36] State implementation of domestic IP policy that affects patent rights to fulfil obligations under the right to health is likely a legitimate measure in pursuit of public health objectives under *TRIPS*.[37] However, because *TRIPS* does not explicitly acknowledge human rights,[38] and the WTO DSB as a specialist trade body has historically been cautious to integrate external norms, states may face difficulties in relying on the right to health in WTO DSB proceedings.[39] The absent discussion on human rights in *Australia-TPP (No. 1 and No. 2)* supports this proposition.[40]

Accordingly, this article addresses the issue of access to essential medicines as critical to states' commitments under SDG 3.[41] This policy agenda includes 'to achieve access to safe, effective, quality and affordable essential

medicines and vaccines for all'[42] and to 'provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration'.[43] A development approach is preferred over a human rights approach for three reasons. Firstly, implementing IP policy in pursuit of 'development objectives' is addressed explicitly in the *TRIPS* preamble[44] and implementing trade policy in pursuit of 'sustainable development' is specifically addressed in the *GATT 1994* preamble.[45] The benefit of using development arguments to justify IP policy includes that sustainable and social development are internal norms of the WTO system and can support existing human rights arguments without relying on external norms. Second, for IP policy to facilitate development in developing states, it has been recognised that such laws should 'be integrated into national development strategies and policies'.[46] While developing states have different development strategies, the United Nations 2030 Sustainable Development Agenda applies to all states and can be relied on by all developing states.[47] Third, SDG 3.b directly acknowledges the Doha Declaration and using *TRIPS* 'flexibilities to protect public health, and, in particular, provide access to medicines for all'.[48] The WTO has recently said that 'SDG 3 itself recognises the international IP system as a practical tool of public policy, acknowledges the need for policy flexibilities and expressly provides scope for diverse regulatory approaches at the national level'.[49] SDG 3 thereby supports using *TRIPS* flexibilities, including patent exceptions to assist access to essential medicines.

2.2 | Why Article 30 can address the unbalanced effects of patents

The exclusive rights conferred by patents are not absolute and are limited through *TRIPS* via general exceptions and compulsory licencing rules. Since the Doha Declaration and the recommendations of the United Nations Secretary-General's High-Level Panel Report on Access to Medicines, the TRIPS Council has focused on using compulsory licensing to achieve greater access to essential medicines.[50] To date, the compulsory licensing regime permitted by the Article 31*bis* amendment has had limited effectiveness and uptake.[51] This is due to burdensome procedural requirements, which increase production costs and prolong negotiations, making the process economically unfeasible for generic companies and practically unattainable for patients.[52] As such, further attention should be given to the alternate general exceptions provision under Article 30 and the inherent flexibility of its terms.

Article 30 provides:

> Members may provide *limited exceptions* to the exclusive rights conferred by a patent, provided that such exceptions do not *unreasonably conflict with a normal exploitation* of the patent and do not *unreasonably prejudice the legitimate interests of the patent owner*, taking account of the *legitimate interests of third parties*.[53]

Exceptions carve out from the exclusive rights of patent owners specific purposes and forms of use that serve important individual and collective interests.[54] This allows third parties to use subject matter protected under Article 28 *TRIPS* in certain circumstances regardless of any authorisation granted by the right holders and protects them from patent infringement claims.[55] Exceptions therefore offer an opportunity to balance a patent holder's economic interests with societal interests of access to patented products and can be used to achieve greater access to patented medicines.[56]

Several pre-existing patent exceptions facilitate access to medicines, however, they are limited in scope and have varied implementation by developing states.[57] For example, the 'regulatory review exception' or 'Bolar exception', permits the use of a patented invention to obtain regulatory approval,[58] thereby increasing access to generic medicines by allowing generics to sell medicines as soon as it comes off-patent without needing to wait years for regulatory approval.[59] Furthermore, the 'research exception' and the 'private and non-commercial use exception' both aimed at facilitating follow-on innovation,[60] permit third parties to use a patented invention for research purposes,[61] and permit certain acts done for private and non-commercial purposes during the patent term.[62]

However, the limited scope of these established exceptions means that each do not increase public access to patented medicines or facilitate generic entry during the patent term. These pre-existing exceptions are insufficient to address the negative impact of patents on access to essential medicines, and more ambitious exceptions are required to achieve SDG 3. Calls for greater use of patent exceptions were made in the landmark Report of the Commission on Intellectual Property Rights which recommended that 'developing countries should provide broadest possible exceptions to patent rights'.[63] Furthermore, the Expert Report of the World Intellectual Property Organisation Standing Committee on the Law of Patents (WIPO SCP) has also recognised that 'careful thought should be given to broader use of exceptions' because they are an 'important avenue for calibrating national patent policy'.[64]

2.3 | Why Article 30 has been underutilised

This article argues that patent exceptions have not been fully explored due to a lack of understanding of Article 30 and its scope. States have limited guidance on Article 30 as the provision has only been partially interpreted once by a WTO DSB Panel in *Canada-Patents*.[65] The decision involved a complaint brought by the European Communities against Canada, regarding the compatibility of two exceptions in Canadian patent law with Article 30.[66] The first 'regulatory exception' allowed competitors to make, construct, use or sell a patented drug to gain regulatory approval by the competent agency in Canada or elsewhere.[67] The second 'stockpiling exception' allowed competitors to manufacture and stockpile a patented drug for 6 months before the patent expiry date.[68] The Panel found the regulatory exception compliant, yet the stockpiling exception non-compliant for not being 'limited'.[69]

The Panel's conclusion that Article 30 contains a strict cumulative three-step test[70] has been criticised by Kur as not fully serving the inherent flexibilities of Article 30.[71] Despite Article 30 having multiple broad and ambiguous terms requiring interpretation, including 'unreasonably conflict', 'normal exploitation', 'unreasonably prejudice', 'legitimate interests', and 'third parties',[72] the Panel's assessment focused on whether the exceptions were 'limited'.[73] The Panel concluded that the term 'limited exception' enabled only a 'narrow curtailment of the legal rights' of a patent holder.[74] The Panel's narrow interpretation of 'limited' being a quantitative assessment, devoid of normative considerations (including reasons justifying the exception) artificially constrained the scope of Article 30.[75] As recognised in the WIPO SCP Expert Report, the Panel's finding 'on the notion of "limited" may operate to deprive member countries of the real potential offered by the use of exceptions' and 'in [their] view, this would be regrettable'.[76]

Furthermore, because the requirement for the exception to be 'limited' was the first step of the Panel's three-step test, failure to satisfy this criterion meant that an exception was incompatible and assessment against the subsequent two steps was unnecessary.[77] Importantly, the third step, which requires a balancing assessment of the interests of the patent owner and third parties was side-lined and not assessed.[78] As such, the Panel found it unnecessary to interpret all of the terms of Article 30 and the interpretation of the following terms therefore remains uncertain:[79]

1. What amounts to 'unreasonable conflict?'[80]
2. What constitutes 'prejudice' or 'unreasonable' prejudice to the legitimate interests of the patent holder?[81]
3. Who are relevant 'third parties?'[82]
4. What constitutes the 'legitimate interest' of these third parties?[83]

Additionally, while the Panel did correctly acknowledge that the object and purpose of *TRIPS* are expressed in Articles 7 and 8,[84] it erroneously did not apply them to interpret the broad terms of Article 30 as required by the *VCLT*.[85]

Canada-Patents has been extensively criticised over the last 20 years.[86] Given that the Report was not appealed to the Appellate Body (AB), it only binds parties to the dispute and the doctrine of *stare decisis* does not apply to the WTO DSB, a broader concept of the terms in Article 30 or a different approach can be adopted.[87] There are cogent

reasons why a future Panel and the AB should not adopt the same interpretation, primarily because the interpretation of the provision has evolved in light of the Doha Declaration and *Australia-TPP (No. 1 and No. 2)*, and their guidance on Articles 7 and 8.[88] The remaining discussion will focus on a complete understanding of Article 30 in light of these interpretive sources, allowing states to realise its full potential and implement more ambitious patent exceptions.

3 | INTERPRETIVE SOURCES FOR ARTICLE 30

3.1 | Articles 7 and 8

Articles 7 and 8 are the object and purpose provisions of *TRIPS* and were negotiated by developing states to afford flexibilities against the mandatory IP standards imposed by *TRIPS*.[89] Their content, therefore, represents the intentions of developing states and 'provides objective clues as to how ambiguous terms of *TRIPS* are to be interpreted',[90] making them important for interpreting Article 30.[91] Both Articles are an essential source of flexibility that WTO Members should draw upon when interpreting and implementing *TRIPS* to achieve balanced protection of IPRs.[92]

Article 7 termed 'objectives' states that:

> 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*.[93]

Article 7 affirms that *TRIPS* was not intended to protect IPRs as an end in itself and that IP protection alone will not achieve welfare gains.[94] Instead, *TRIPS* calls for a balancing of (1) incentivising 'technological innovation' with the (2) 'transfer and dissemination of technology' by taking account of (3) the interests of users and producers to technical knowledge and (4) WTO Member's rights and obligations.[95] Article 7 essentially encourages interpreting *TRIPS* provisions in a manner proportional to both social and economic welfare and aimed at the benefit of society as a whole.[96] Accordingly, Yu recognises that Article 7 is integral to 'paving the way for the development of future exceptions, which can be used to restore the balance of the international IP system'.[97]

Article 8(1) termed 'principles' states that:

> Members may, in formulating or amending their laws and regulations, adopt measures *necessary to protect public health and nutrition*, and to promote *the public interests in sectors of vital importance to their socio-economic and technological development*, provided that such measures are consistent with the provisions of this agreement.[98]

Article 8(1) gives states autonomy to adopt public policy measures to protect societal interests, thereby recognising states' ability to legitimately tailor their IP systems to their development level and needs.[99] Furthermore, because states can determine what constitutes 'the public interests in sectors of vital importance', states have significant deference to define the content and scope of measures they adopt.[100] Although debate exists regarding the effect of the consistency requirement in constraining the scope of measures permitted, this uncertainty has arguably been resolved through the Doha Declaration and *Australia-TPP (No. 1 and No. 2)*, which will be explored below.[101]

Therefore, Articles 7 and 8 have been recognised as a 'guiding light' that must be used to interpret other *TRIPS* provisions and as a 'bridge' that links IP with other public interest concerns.[102] The guiding light function derives primarily from the *VCLT* and has been further supported by the Doha Declaration and *Australia–TPP (No. 1 and No. 2)*.

3.2 | The *VCLT*

Central in providing security and predictability to the WTO trading system is the WTO DSB's clarification of provisions of WTO Agreements, 'in accordance with customary rules of interpretation of public international law'.[103] It is well recognised by the WTO DSB that 'customary rules of interpretation' are enshrined in Articles 31 and 32 *VCLT* despite not all WTO Members having ratified the *VCLT*.[104] Article 31 *VCLT* establishes that the general rule of interpretation is that 'a treaty shall be interpreted in good faith in accordance with the *ordinary meaning* to be given to the *terms of the treaty in their context* and in light of its *object and purpose*'.[105] Before *Australia-TPP (No. 1 and No. 2)*, the WTO DSB incorrectly side-lined the role of the context and the object and purpose when interpreting *TRIPS* provisions, and its decisions were marked by over-reliance on the ordinary meaning of a term as informed by dictionary definitions.[106]

The context of the terms of *TRIPS* includes inter alia, the *TRIPS* preamble[107] and the *GATT 1994* preamble,[108] to which *TRIPS* is annexed.[109] Firstly, the *TRIPS* preamble 'recognises the underlying *public policy objectives* of national systems for the protection of IP, including *development and technological objectives*', which legitimises measures that affect IP protection and pursue development objectives.[110] The *TRIPS* preamble also recognises 'the special needs of LDCs in respect of the *maximum flexibilities* in the *domestic implementation of laws and regulations* to enable them to create a *sound and viable technological base*'.[111] This statement acknowledges that flexibility at the implementation level is essential for developing domestic technological bases necessary for development and without engaging *TRIPS* flexibilities to the maximum extent, LDCs will not realise these objectives.

Additionally, the *GATT 1994* preamble provides that the central aim of the WTO is:

> raising standards of living…expanding trade in goods and services…allowing for the optimal use of the world's resources in accordance with the *objective of sustainable development*…in a manner consistent with [states] *needs and concerns* at *different levels of economic development*.[112]

This context affirms that the terms of *TRIPS* should be interpreted to achieve a balance of social and economic interests in pursuit of sustainable development by reference to states' different development levels. The preamble of both agreements provides that measures in pursuit of development objectives are legitimate and respects state autonomy to assess public policy interests.[113] The Doha Declaration confirmed this approach to interpretation in the context of WTO Members protecting public health when regulating domestic IP regimes.[114] Importantly, the Doha Declaration was a critical turning point in the history of *TRIPS* and the role of Articles 7 and 8 as transversal interpretation tools.

3.3 | The Doha Declaration

The Doha Declaration was borne out of the public health emergency of the HIV/AIDS crisis where developing states had limited access to antiretroviral drugs.[115] At the African Group's request, the TRIPS Council convened a special session on access to medicines, which ultimately yielded the adoption of the Doha Declaration by a consensus decision of WTO Members.[116] The operational provisions of the Doha Declaration, which aid in the interpretation of *TRIPS* can be summarised as:

1. *TRIPS* 'does not and should not prevent WTO Members from taking measures to protect public health'.[117]
2. *TRIPS* 'can and should be interpreted and implemented in a manner supportive of the WTO Member's right to protect public health and, in particular to promote access to medicines for all'.[118]
3. WTO Members have the right to use *TRIPS* flexibilities to the fullest, which include:

a. Interpreting each *TRIPS* provision 'in light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles'.[119]
b. The right to determine what 'constitutes a national emergency or other circumstances of extreme urgency', acknowledging that public health crises can be both.[120]

The Doha Declaration confirms that addressing public policy concerns, including public health, is realised through interpretation and implementation of *TRIPS*.[121] Specifically, it identifies that WTO states have a right to interpret each *TRIPS* provision in light of Articles 7 and 8, which advocate balancing the interests stated therein. Furthermore, it empowers states to use *TRIPS* flexibilities to deal with public policy concerns at the implementation level.[122]

The Doha Declaration has been deemed a 'subsequent agreement' of WTO Members under Article 31(3)(a) *VCLT*, which provides general guidance on interpreting all *TRIPS* provisions.[123] Therefore, while the compliance clause in Article 8(1) prima facie appears to restrict the scope of measures states can impose in pursuit of public policy objectives,[124] the Doha Declaration reconciles that *TRIPS* does not conflict with public health objectives because it must be interpreted to permit these concerns.[125] Furthermore, while the Doha Declaration recognises that Articles 7 and 8 are relevant to interpreting all *TRIPS* provisions, Ruse-Khan argues that they are of significant utility in interpreting provisions that 'contain broad and open legal concepts and/or relate to exceptions of exclusive rights'.[126] This hypothesis was tested in *Australia-TPP (No. 1 and No. 2)*, where the WTO DSB Panel and AB were tasked with interpreting the broad term 'unjustifiably' in Article 20.[127] These decisions provide a turning point in WTO jurisprudence as they are the first decisions to meaningfully engage with Articles 7 and 8 to interpret *TRIPS* flexibilities.[128]

3.4 | *Australia-TPP (No. 1 and No. 2)*

Australia-TPP (No. 1 and No. 2) involved a complaint against Australia, alleging that Australia's tobacco plain-packaging legislation violated *TRIPS*.[129] Focusing on how the decisions guide interpretation of *TRIPS* flexibilities, this analysis will only examine the decisions in relation to the alleged violation of Article 20.[130] The Australian legislation impacts trade mark rights used on cigarette and cigar packaging by requiring word marks to be in a prescribed size, font, colour, and set position (TPP Measures).[131] This was alleged to violate Article 20,[132] which provides that 'the use of a trademark in the course of trade shall not be *unjustifiably encumbered* by special requirements'.[133] The Panel had to interpret the meaning of 'special requirements',[134] 'encumber',[135] 'use of a trademark in the course of trade'[136] and 'unjustifiably',[137] and apply these interpretations to the TPP Measures. The Panel found and the AB upheld that the TPP Measures did amount to special requirements that encumbered the use of a trade mark in the course of trade,[138] however, that it did not so do unjustifiably, thus being *TRIPS* compliant.[139]

3.4.1 | Application of Articles 7 and 8 to interpret Article 20

The Panel's interpretation of the term 'unjustifiably' sets out the WTO DSB's approach to interpreting broad or ambiguous terms in *TRIPS* provisions. The Panel stated that it must interpret the 'ordinary meaning of unjustifiably in its context and in light of the object and purpose of the provision and the Agreement' citing Article 31 *VCLT*. [140] The Panel found that because 'unjustifiably' refers to the ability to provide 'good reason for the relevant action', and Article 20 is silent as to what constitutes legitimate reasons, guidance should be sought from the preamble and Articles 7 and 8.[141] The Panel articulated these provisions' normative value to be:

> Article 7 reflects the intention of *establishing and maintaining a balance* between the *societal objectives* mentioned therein. Article 8(1), for its part, makes clear that the provisions of the *TRIPS*

> Agreement are not intended to prevent the adoption, by Members, of laws and regulations pursuing certain *legitimate objectives*.[142]

The Panel then provided an approach, which the AB upheld, that is to be undertaken on a case-by-case basis to assess the conformity of the balance reached between the interests involved.[143] This approach requires consideration of three factors being:

(1) the nature and extent of the encumbrance resulting from the special requirements, bearing in mind the legitimate interest of the trademark owner …
(2) the reasons for which the special requirements are applied, including any societal interests they are intended to safeguard; and
(3) whether these reasons provide sufficient support for the resulting encumbrance.[144]

In determining factor (2) the Panel used Article 8(1) to identify legitimate reasons, including the expressly recognised societal interest of public health.[145] The Panel also observed that the Doha Declaration emphasised the importance of public health as a legitimate policy concern.[146] Consequently, in determining factor (3) the Panel assessed the gravity of the public health concerns of tobacco consumption that underly the TPP Measures against the encumbrance on trade mark use.[147] The Panel concluded that because the TPP Measures 'are capable of and in fact do contribute to Australia's objective of improving public health.... [this] provides sufficient support for the application of the resulting encumbrances on use of trade marks'.[148] Notably, the Panel and AB did not question the balancing exercise undertaken by Australia, acknowledging Australia's autonomy in determining its public policy measures.[149]

3.4.2 | The usefulness of *Australia-TPP (No. 1 and No. 2)* for other IPRs

Australia-TPP (No. 1 and No. 2) confirm that Articles 7 and 8 are important transversal interpretation tools for *TRIPS* provisions, particularly *TRIPS* flexibilities.[150] While the decisions only examine Article 20, which relates to trade marks, because the Panel's approach relied on Articles 7 and 8, which assist in interpreting all *TRIPS* provisions,[151] its reasoning can usefully extend to other IPRs and other *TRIPS* flexibilities, including the exception provisions under Articles 13, 17, 26(2) and 30 *TRIPS*.[152] This begs the question, how can *Australia-TPP (No. 1 and No. 2)* assist in interpreting Article 30? Can the approach of balancing interests found in Article 8(1) to determine whether a special measure is unjustified in Article 20 be adapted to determine whether a patent exception is unreasonable in Article 30? The AB observed that in addition to Article 20, measures seeking to protect health encompasses a range of measures, including patent exceptions under Article 30.[153] This confirms that Article 8(1) also justifies public health measures taken under Article 30 and therefore must play an important role in its interpretation.

4 | A PROPOSED INTERPRETATION AND FUTURE USE OF ARTICLE 30

Article 30 contains several broad and ambiguous terms, including 'unreasonably conflict' and 'unreasonably prejudice' which have never been interpreted by the WTO DSB.[154] This has led to an excessively constrained interpretation of Article 30, having a chilling effect on developing states implementing new patent exceptions.[155] The primary aim in clarifying the interpretation of Article 30 is to instil confidence in states of the legality of patent exceptions implemented in pursuit of important public policy objectives such as public health and access to medicines in pursuit of SDG 3.

4.1 | The weighing and balancing assessment in Article 30

An interpretation of Article 30 informed by Articles 7 and 8 makes evident that striking an appropriate balance between the legitimate interests of patent owners and the right of WTO Members to adopt measures for the protection of certain societal interests is the essence of the exception provision.[156] The three-step test in *Canada-Patents* which side-lines a balancing assessment of these competing interests to the third-step, where it can be unassessed, therefore does not conform to Articles 7 and 8 and should not be accepted as the correct approach to interpreting Article 30.[157] Rather, there is significant support that the correct approach is to consider the provision as an 'indivisible entirety' requiring a 'comprehensive overall assessment' with the balancing assessment playing the central role.[158] In accordance with the Panel and AB's conclusion in *Australia-TPP (No. 1 and No. 2)*, that the locus of the weighing and balancing assessment is the term 'unjustifiably' in Article 20, similarly, the locus of the balancing assessment is the term 'unreasonably' in Article 30.[159] Therefore, the Panel's approach to interpreting 'unjustifiably' in Article 20 should be applied to clarify the meaning of 'unreasonably' in Article 30.

The interpretive approach of the Panel is to determine the ordinary meaning of the terms firstly by reference to a dictionary definition and where further clarification is required by reference to Articles 7 and 8 and the context of *TRIPS*, including the preamble and the Doha Declaration.[160] The Panel, in determining the ordinary meaning of 'unjustifiably' relied on the definition of 'justifiable' being 'the action of or result of showing something to be just, right, or reasonable' and that 'justified' means 'based on good reason'.[161] Similarly, the definition of 'unreasonable' is 'an action not guided by, or based upon, reason, good sense, or sound judgement; unjustifiable'.[162] These two terms are closely linked and, as the Panel expressed, refer to the 'ability to provide good reason for the relevant action that is reasonable, in the sense that it provides sufficient support for that action'.[163] The relevant action that requires good reason in Article 20 is 'encumbered' while in Article 30 is 'conflict' and 'prejudice'.[164] Thus, there may be circumstances in which good reason exists to sufficiently support the application of 'conflict with the normal exploitation of the patent' and of 'prejudice to the legitimate interests of the patent owner'.[165] To determine whether sufficient support exists, the weighing and balancing assessment as set out by the Panel with reference to Article 20 can and should be adapted to the specific terms of Article 30 and applied.[166]

Whether the normal exploitation of a patent is unreasonably conflicted and whether the legitimate interests of the patent owner are unreasonably prejudiced, therefore requires consideration of the following three factors:

(1) the nature and extent of the conflict with the normal exploitation of the patent resulting from the exception, bearing in mind the nature and extent of the prejudice caused to the legitimate interest of the patent owner in exploiting their patent in the market and thereby allowing the patent to fulfil its intended function;
(2) the reasons for which the exception is applied, including societal interests they intend to safeguard, bearing in mind the legitimate interests of third parties; and
(3) whether the reasons provide sufficient support for the resulting conflict and prejudice.

Despite Article 30 referencing 'unreasonably' twice, the balancing assessment should only be carried out once because the provision should be treated as an 'indivisible entirety'.[167] Fortunately, the first factor put forward by the Panel sufficiently engages both the effect on the IPR and the owner's legitimate interests.[168] This is consistent with the approach of considering the provision as a whole and removes any need to repeat the balancing assessment. Ultimately, this three-factor consideration truly reflects a comprehensive overall assessment of Article 30 whereby the effect on the patent right, the patent owner, and third parties are assessed by reference to a weighing and balancing exercise.

4.1.1 | The nature and extent of the conflict and prejudice

The first consideration will depend on the exception in question and the specific patents or types of patents affected. However, some general issues to consider should include that the patent system's intended function is to 'prevent market failure from failing to produce technical knowledge at adequate levels'.[169] Thus, 'normal exploitation' will cover use required to rectify market failure and thereby should not include interference by groups that are not a part of the consumer market, such as philanthropic organisations or research institutes using patents for humanitarian or research purposes.[170] Furthermore, as patent rights are a negative right to exclude others from market access, the 'legitimate interests' of the patent holder must 'go no further than the right to monetise a given market opportunity without interference by others'.[171] As such, it should not extend to the entitlement of 'patentees to be compensated for their efforts or to obtain any given return on their investment'.[172] Importantly, as was the case in *Australia-TPP (No. 1 and No. 2)*, even where the nature and extent of the action are 'far-reaching', this may still be reasonable in the circumstances.[173]

4.1.2 | The reasons for the exception

The reasons for the exception will also depend on the purpose of the exception. However, the sources that reveal legitimate reasons permitted under Article 30 will include Articles 7 and 8(1), the Doha Declaration, and the preambles of *TRIPS* and *GATT 1994*.[174] As Article 30 is, similarly to Article 20, silent on the types of reasons that sufficiently support the application of conflict with the normal exploitation of a patent or the application of prejudice to the legitimate interests of the patent holder, guidance should be sought from Article 8(1) and the context of *TRIPS*.[175] Therefore, legitimate reasons under Article 30 must include 'public health, nutrition and measures that promote the public interests in sectors of vital importance to their socioeconomic and technological development'.[176] Article 8(1)'s reference to socioeconomic development, the direct reference to development in the *TRIPS* preamble, and sustainable development in the *GATT 1994* preamble also identify development objectives as legitimate reasons. The intersection of public health objectives and development objectives in SDG 3 to provide access to essential medicines for all, therefore makes SDG 3 very helpful in supporting exceptions. Furthermore, these sources also aid in determining who relevant third parties are and what constitutes their legitimate interests.[177]

4.1.3 | Whether the reasons provide sufficient support

While the Panel and AB in *Australia-TPP (No. 1 and No. 2)* did not specifically clarify what is required for 'sufficient support' to be established, both held that more than a rational connection is needed, however, it does not require that the measure be necessary.[178] As such, the balancing exercise simply involves determining whether the policy reasons for implementing a patent exception determined in factor (2) has at least equal or more weight than the extent of the resulting conflict on the normal exploitation of the patent and prejudice to the patent owner's legitimate interests determined in factor (1).[179] This balancing exercise is evident in the Panel's findings that the public health objective of reducing tobacco consumption is important and that because the measures would in fact, contribute to achieving that objective, this was substantial enough to prevail over the far-reaching encumbrance on trade marks use caused by the TPP Measures.[180] The Panel's assessment provides assurance that exceptions implemented in pursuit of legitimate public health objectives, that are objectively likely to or will in fact, contribute to achieving that objective will on a balancing assessment, be sufficient to prevail over the conflict and prejudice caused, even where the action is far-reaching.[181]

This renewed approach to interpreting Article 30 entails an overall assessment focused on weighing and balancing competing interests and affords a broader scope of permissible exceptions.[182] While the precedents of *Australia-TPP (No. 1 and No. 2)* means that states should feel more confident to enact exceptions in pursuit of important public policy objectives, how to do so regarding patent exceptions remains uncharted. A nuanced approach will be needed based on the state, their development level, and the relevant public interest objective. However, to inspire states to explore further exceptions, this article proposes a potential stockpiling exception for pandemic and epidemic preparedness to increase access to essential medicines to achieve SDG 3.

4.2 | A proposed stockpiling exception for pandemic preparedness to achieve SDG 3

The global spread of Covid-19 (SARS-CoV-2) and associated shortages of medicines, personal protective equipment, and ventilators have caused states to re-evaluate their pandemic preparedness, including stockpiling measures.[183] The United States, Australia, United Kingdom, Canada, Israel, and 12 other European countries have expanded stockpiles of medicines, including antibiotics, antivirals, and vaccines.[184] However, stockpiling for developing countries is currently unfeasible due to the costs of acquiring patented medicines and is impractical due to a lack of domestic manufacturing capacity.[185] Consequently, the World Health Organisation maintains global vaccine stockpiles for Ebola, cholera, smallpox, meningococcal and yellow fever vaccines.[186] While these stockpiles are enormously helpful for the developing world, they only assist in preventing five diseases, and the present supply is insufficient for global demand.[187] For example, the present stockpile of the Ebola vaccine is 6890 doses, and it will take around 2–3 years to reach the recommended level of 500,000 doses.[188] As such, it is critical that developing states build domestic stockpiles tailored to their needs.

The absence of stockpiles in developing states weakens their ability to respond to future public health emergencies. Developing states should investigate a general patent exception permitting stockpiling of patented medicines for pandemic or epidemic preparedness to address problems with stockpiling and assist access to essential medicines for all as committed under SDG 3.[189] The proposed stockpiling exception would permit a state to acquire patented medicines for stockpiles from generic suppliers, either through domestic manufacturers or importation from an international manufacturer. [190] The state acquiring the medicines would pay a marginal cost of the patented medicine to the generic manufacturer at the time of supply.[191] Additionally, negotiated compensation for the patent owner could be included, with payment conditional on the actual use of the supplied medicines.[192]

This exception allows developing states to properly prepare for pandemics and epidemics by acquiring essential medicines at sufficient levels and at a reduced cost.[193] This system has several advantages, including that developing states would not have to pay the patent holder for stockpiled medicines should they expire before use, thereby reducing the risk of acquiring such medicines. Furthermore, the exception creates a safe harbour for generic manufacturers, thereby incentivising generic companies to invest in developing countries and establish local manufacturing capacity. Previous studies confirm that 'representatives of the generic industry have indicated their interest in investing in local production sites in developing countries, particularly in Africa, provided the latter implement, to the fullest extent, available *TRIPS* flexibilities'.[194] With increased competition, innovator companies would be pressured to match costs with generics, increasing the negotiating power of developing states when building stockpiles and driving down prices.[195] This patent exception makes stockpiling of medicines by developing states economically feasible and practically possible and should be considered for future use.

The efforts of developed states to stockpile the patented drug Remdesivir is a recent example of stockpiling to increase access to medicines and reveals the inequality in access for developing states. Remdesivir is an antiviral drug approved in various jurisdictions as a treatment for Covid-19 patients hospitalised with severe respiratory illness.[196] Remdesivir has been stockpiled by 36 European countries, with all states cumulatively purchasing more than 640,000 doses paying €2070 per course.[197] Similarly, the United States has stockpiled 500,000 doses paying

US$2340 per course.[198] Such costs are prohibitive for developing states. This is one example where the stockpiling exception would decrease costs and increase access in the future for developing states.

Furthermore, many health experts reflect that states should have stockpiled broad-spectrum antivirals in preparation for a coronavirus pandemic, given the emergence of two other deadly coronavirus' in the 21st century, being SARS (SARS-CoV) and MERS (MERS-CoV).[199] Had policymakers followed warnings by health experts to stockpile broad-spectrum antivirals after the SARS outbreak in 2003, states would have been better positioned to respond to the Covid-19 pandemic.[200] The world is now learning from this missed opportunity. Presently, antiviral stockpiling is not feasible for developing countries because of the high costs of these drugs.[201] Studies have shown that to develop a cost-effective strategy for developing states to stockpile antivirals, almost all of the costs would need to be subsidised or that costs may be reduced through increased generic antivirals.[202] The stockpiling exception could play a key role in assisting developing states to build sufficient stockpiles of broad-spectrum antivirals, which are now a primary focus of states.[203]

Unfortunately, developing states will continue to be disproportionately plagued by epidemic and pandemic diseases.[204] Unless developing states address accessibility and affordability to essential medicines as part of their national patent policy, their ability to fulfil their commitments under SDG 3 is limited. As such, developing states should seriously consider using this watershed moment to implement patent exceptions tailored to their domestic needs to increase access to essential medicines in pursuit of SDG 3.[205] This is an opportunity developing states cannot afford to miss.

5 | CONCLUSION

The interpretation of Article 30 proposed in this article should make developing states feel more confident to implement patent exceptions tailored to their development objectives, particularly regarding public health and access to medicines in pursuit of SDG 3. The proposed interpretation is informed by various interpretive sources of WTO law, including the *VCLT*, the Doha Declaration and *Australia-TPP (No. 1 and No. 2)*. These three sources confirm that Articles 7 and 8 play an essential role in interpreting the broad terms in Article 30. The proposed interpretation of Article 30 views the term 'unreasonably' as the locus of a weighing and balancing assessment capable of striking the appropriate balance between patent owner's interests and public interests to address the negative impact of patents in developing states. By focusing on a weighing and balancing assessment, this interpretation broadens the scope of permissible exceptions in pursuit of important public interest objectives.

Australia-TPP (No. 1 and No. 2) also confirm that the objectives stated in Articles 7 and 8 reveal legitimate societal interests that may justify affecting IPRs. These certainly include, but are not limited to, public health, nutrition, and the public interests in sectors of vital importance to states' socioeconomic and technological development. Additionally, legitimate societal interests can be derived from the context of Article 30, including the preamble of *TRIPS* and *GATT 1994*, which recognise development and sustainable development objectives. As public health, development, and sustainable development are internal norms of the WTO, the legitimacy of implementing exceptions affecting patent rights in pursuit of these measures is undeniable.

The commitment of states to achieve access to essential medicines for all under SDG 3 intersects the objectives of public health and development, making exceptions in pursuit of SDG 3 legitimate. As such, this article proposes a stockpiling exception for pandemic and epidemic preparedness intended to assist developing states to achieve access to essential patented medicines in pursuit of SDG 3. The intention of proposing an exception is to inspire developing states to implement more ambitious exceptions in their domestic laws. Ultimately, developing states should feel emboldened to implement patent exceptions as they are an important tool for IP policy calibration capable of addressing the negative impact of patents on the realisation of access to essential medicines and social development in developing states.

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ENDNOTES

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[148] Ibid [7.2604]; *Australia-TPP No. 2* (n 16) [6.632].

[149] *Australia-TPP No. 1* (n 16) [7.2604]; *Australia-TPP No. 2* (n 16) [6.647], [6.695], [6.697]; Ruse-Khan, 'Proportionality and Balancing' (n 12) 120b.

[150] Thamara Romero (n 94) 5; Wilkinson (n 38) 388.

[151] *Australia-TPP No. 1* (n 16) [7.2402]–[7.2406], [7.2411]; *Australia-TPP No. 2* (n 16) [6.658]; *Doha Declaration* (n 7) [5(a)].

[152] Rochel (n 2) 23; Ruse-Khan, 'Proportionality and Balancing' (n 12) 7.

[153] *Australia-TPP No. 2* (n 16) [6.649].

[154] *TRIPS* (n 1) art 30.

[155] *WIPO SCP Expert Report* (n 15) 71; Garrison (n 15) 40.

[156] *Australia-TPP No. 1* (n 16) [7.2429].

[157] Geiger and Desaunettes-Barbero (n 12) 40–42.

[158] Lamping et al. (n 54) 15; Geiger and Desaunettes-Barbero (n 12) 41–42; Kur (n 71) 340.

[159] Mitchell and Samlidis (n 130) 13.

[160] *Australia-TPP No. 1* (n 16) [7.2393], [7.1822]; *Australia-TPP No. 2* (n 16) [6.719].

[161] *Australia-TPP No. 1* (n 16) [7.2394].

[162] *Oxford English Dictionary* (online at 23 January 2022) 'unreasonable' (adj, def 3a-b).

[163] *Australia-TPP No. 1* (n 16) [7.2395].

[164] Ibid.

[165] Ibid [7.2396].

[166] Ibid [7.2430].

[167] Lamping et al. (n 54) 15; Geiger and Desaunettes-Barbero (n 12) 41–42; Kur (n 71) 340.

[168] *Australia-TPP No. 1* (n 16) [7.2430]-[7.2431]; *Australia-TPP No. 2* (n 16) [6.651].

[169] Lamping et al. (n 54) 3.

[170] Ibid 15; Rodrigues (n 11) 102.

[171] Lamping et al. (n 54) 3.

[172] Ibid.

[173] *Australia-TPP No. 1* (n 16) [7.2557], [7.2569]; *Australia-TPP No. 2* (n 16) [6.675], [6.697].

[174] *Australia-TPP No. 1* (n 16) [7.2586]–[7.2589].

[175] Ibid [7.2396]–[7.2401]; *Australia-TPP No. 2* (n 16) [6.649].

[176] *TRIPS* (n 1) art 8(1).

[177] Geiger and Desaunettes-Barbero (n 12) 38.

[178] Mitchell and Samlidis (n 130) 13.

[179] Ibid; Voon (n 130) 183; *Australia-TPP No. 1* (n 16) [7.2598]; *Australia-TPP No. 2* (n 16) [6.653]–[6.655].

[180] Mitchell and Samlidis (n 130) 13.

[181] *Australia-TPP No. 1* (n 16) [7.2557], [7.2569]; *Australia-TPP No. 2* (n 16) [6.675], [6.697].

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[190] Ibid.

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[204] Madhav et al. (n 185) 16–22.

[205] Dolgin (n 196) 340–341.

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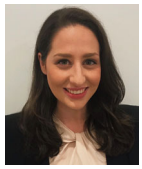

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