5

Revisiting the TRIPS' Flexibilities

This chapter addresses how the reframed interpretation of the TRIPS' foundations can be used as a guiding light to interpret further TRIPS' norms and, in Chapter 6, the broader international IP regime.

Aligned with the overall goal of this work, our reflections focus on the norms that instantiate and operationalise the internal balance of the TRIPS. On the side of developing economies, these norms enable States to craft IP regulations aligned with their self-determined policy decisions. For developed economies, the argument recalls their responsibility in interpreting the TRIPS as normative framework able (and meant) to integrate under-represented interests (e.g., of users, the broader public, trade partners, and so forth).

This chapter is structured into four sections with the first section specifying the contours of a republican interpretation of limitations and exceptions norms (L&E) as relational. The second section applies this argument on TRIPS' exceptions norms (three-step test of Articles 13 and 30 of TRIPS), the third with compulsory licences (Article 31 of TRIPS), and the fourth with technology transfer and technical assistance (Articles 66–67 of TRIPS). All these sections aim to show the relevance and impact of the republican-sufficientarian reframing defended in this work.

The scope of this book precludes dealing with every TRIPS norm, though the reframing of the foundational norms could potentially deploy an impact on virtually every norm. As the general introduction has laid out, the primary focus is on patent, with a minor examination of copyright. Furthermore, this work does not address enforcement-related TRIPS norms (Part III TRIPS, Article 41 ff) nor the issue of national exhaustion (Article 6 of TRIPS).[1] The Doha Declaration has already addressed this provision in paragraph 5, which states that the effect of

[1] For general comments, Pires de Carvalho (2014), 139 ff; Taubman, Wager and Watal (2020), 20–22; Correa (2020b), 71 ff; Cottier (2022).

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the norm was to leave each member free to establish its own regime for exhaustion without challenge. Previous reflections on self-determination could indeed be used to defend this reading.[2]

5.1 Interpretation of TRIPS' Flexibilities

This section addresses the interpretative challenges of norms described as TRIPS' 'flexibilities'. As mentioned in Chapter 4, these flexibilities are defined as a set of norms entailed by the TRIPS that allow a margin of appreciation for the Member States in fulfilling the obligations foreseen by the treaty.[3]

Among these flexibilities, this section focuses on the subgroup of L&E. The interpretation of L&E raises two different sets of challenges: the identification of L&E as such and their interpretation. From a republican perspective, both types of challenges represent a potential risk of domination. If one does not adopt a careful approach to identifying L&E, the risk of domination is double: first on the characterisation of specific norms as L&E and second on the specific interpretative methods chosen to account for them. In that sense, the identification and interpretation of L&E can reinforce the power imbalances found in the TRIPS' negotiation process and as reflected in the TRIPS text.

The section is organised into three parts: the identification of L&E, interpretation of L&E, and the challenges of using these L&E when it comes to national IP legislation.

5.1.1 Identification of L&E

As Qureshi argues in his theory of interpretation of exceptions in WTO law, the characterisation of a norm as an exception is itself controversial.[4] The fact that a norm is titled as an exception or a limitation does not necessarily give us useful information about its functions. The functional approach presented in the first subsection explains that this characterisation should mainly depend upon the relations between a

[2] For a critical reading, Pires de Carvalho (2014), 148 ff.

[3] For this definition, see High-Level Panel on Access to Medicines. See the TRIPS Flexibilities database prepared by the network Medicines Law & Policy (documenting the use by Member States of these flexibilities). http://tripsflexibilities.medicineslawandpolicy.org (consulted 15 June 2025).

[4] Qureshi (2015).

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specific norm and the objectives of a treaty (or a specific part of the treaty).[5] The second subsection highlights the relevance of L&E as relational norms.

5.1.1.1 A Functional Approach to Defining Limitations and Exceptions

The starting point of the reflection is to submit that the characterisation of a norm as L&E is a functional question. As Dinwoodie and Dreyfuss argue, in dealing with the international IP acquis, the category of 'limitations' could be reserved for norms that limit the subject matter of IP.[6] Limitation norms restrict the realm of intellectual creations that can be protected. Article 27 of TRIPS, though not labelled as a limitation, is an example of a subject matter delimitation.[7]

The characterisation of a norm as an 'exception' is more complex because the functions of different exception norms can be more diverse.[8] As Qureshi proposes, identifying a norm as an exception 'is a manner of giving legitimacy to a departure from a rule that is in a relationship with it. An exception authorizes a departure for a specific purpose under certain conditions'.[9] An exception cannot be defined alone; it is always a relational definition. It needs to be found in the context of a relation with a distinct norm (called the 'rule' in Qureshi's account). This relational approach hence requires interpretation of the other relational norm (the rule) and the types of normative relations between the two.[10] These two points need to be addressed against the background of the object and purpose of the treaty.

An exception can fulfil different paradigmatic functions in relation to the rule. According to Qureshi, exceptions can serve

[5] For further references, Christie and Wright (2014), 420–421.
[6] Dinwoodie and Dreyfuss (2012), 184.
[7] The CJEU has clarified the definitions of limitations and exceptions in (C-457/11 to C-460/11) *Verwertungsgesellschaft Wort (VG Wort)* v. *Kyocera and Others* (C-457/11) and Canon Deutschland GmbH (C-458/11) and Fujitsu Technology Solutions GmbH (C-459/11) and *Hewlett-Packard GmbH (C-460/11)* v. *Verwertungsgesellschaft Wort (VG Wort)* (27 June 2013), § 34–40. The Court describes the core idea of limitation (in copyright) as '(. . .) to exclude, from the material scope of that provision, any right for the rightholders to authorise reproduction of their protected works or other subject-matter'.
[8] For a distinction between external exceptions (such as those of Article 8 of TRIPS) and internal exceptions (such as those of Article 31 of TRIPS), Pires de Carvalho (2014), 393 ff.
[9] Qureshi (2015), 167.
[10] Qureshi (2015), 151.

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> to bridge general rules to a set of specific agendas and thus enable the melding of different objectives; to integrate the agreement into the rest of the international order; to facilitate co-existence with a set of other objectives; to facilitate the trumping of other objectives; to circumnavigate conflicts arising from obstacles, emergencies, and temporary and/or new developments; and, finally, for practical reasons to facilitate the implementation of the rule.[11]

This list prevents any initial analysis of the relationship between a rule and an exception as characterised by opposition and conflict.

Two examples illustrate this point, the first referring to the case of an exception encapsulating a WTO objective. As Qureshi notes, the AB acknowledged in *EC-Tariff Preferences* that 'WTO objectives may well be pursued through measures taken under provisions characterized as exceptions.'[12] It gives the example of the optimal use of the world's resources, one of the objectives entailed by the Preamble to the WTO and found in Article XX of GATT.

The second example aims to illustrate the normative work required. Qureshi uses an analogy with special and differential treatment (S&D) norms. Such norms often take the form of an exception (to a general rule, during a certain time), which nevertheless reflects an important aspect of the WTO. Indeed, for developing countries, S&D norms appear central to the general deal they accepted. In the context of the TRIPS, for instance, this importance is underlined by the Doha Declaration. As for exceptions, S&D norms cannot be properly interpreted without understanding them in a relational account with the rule they refer to and without clarifying their importance considering the object and purpose of the treaty as a whole (the TRIPS and/or the WTO). In that respect, the AB clarified in *China – Raw Materials* that 'we understand the WTO Agreement, as a whole, to reflect the balance struck by WTO Members between trade and non-trade-related concerns'.[13]

This approach also allows us to distinguish the exception from associated concepts such as the 'proviso', 'exemption', or 'waiver'. Following Qureshi, a proviso limits or qualifies the scope of the rule to which it is addressed[14] while an exemption or limitation excludes a specific class of elements from the operation of the rule (as for the

[11] Qureshi (2015), 135–136.
[12] Appellate Body Report, *EC – Tariff Preferences,* paras. 94 and 95.
[13] Appellate Body Report, *China – Raw Materials*, para. 306.
[14] Qureshi (2015), 136 ff.

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limitation defined earlier). A waiver is informed by the mandate from which it originates.[15]

5.1.1.2 The Importance of Exceptions as Relational Norms

Evaluating exceptions as relational norms necessitates an analysis of both the underlying rule and the nature of their normative relationship, taking into account the objectives and purposes of TRIPS as articulated in its foundational principles. This approach aligns with the proposals discussed in TRIPS scholarship that consider the exceptions as emanations of access rights considerations. For instance, Dinwoodie and Dreyfuss argue that exceptions 'must be conceived affirmatively, as the rights of consumers, competitors, intermediaries, and follow-on innovators'.[16] Geiger has proposed focusing on users' rights: 'Limitations and exceptions would not only result in mere defences, but also in subjective rights of equal value to exclusive rights.'[17] These proposals rely on a relational understanding of the interface between the exception and 'their' rules.

An important implication of this approach is to refuse to systematically consider the exception to be of less importance than the rule. An exception could be less important than a rule, but it need not necessarily be the case. The exception norm can appear as a fully legitimate counter-norm that protects crucial interests from the rule. This approach could pave the way for Yu's argument which states that 'a strong case that exceptions and limitations in the TRIPS Agreement should be treated as importantly as the rights provided in the Agreement, an argument which commentators have made with respect to exceptions and limitations in the domestic intellectual property system'.[18]

Overall, the identification and qualification of a norm as an exception (and to a lesser extent of a limitation) requires a functional approach, which itself requires the identification and qualification of the rule and the qualification of the normative relations between the exception and the rule. All these steps must consider the object and purpose of the treaty. Public policy interests are not external to the IP system but are in fact its foundations (societal parameters of Article 7 of TRIPS) and should, as such, be an integral part of the qualification of the relations

[15] Panel Report, *US – Sugar Waiver (GATT)*, paras. 3.33, 5.9; and Appellate Body Report, *EC – Bananas*, paras. 381 and 382.
[16] Dinwoodie and Dreyfuss (2015), 160.
[17] Geiger (2016), 89 ff. See further Elkin-Koren (2017).
[18] Yu (2009), 1007.

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between rule and exception and of the determination of the applicable standard of interpretation.

5.1.2 *Interpretation of L&E*

Based on this relational approach to characterising an exception and, to a lesser extent, a limitation, one can turn to the task of interpretation, starting with what could be called a traditional understanding of exceptions. As explained earlier, the exception is often considered less important than the rule. Because the exception's function is to limit a rule considered as the normative priority, the exception is claimed to be interpreted in a narrow manner. This traditional understanding represents exactly the double domination pattern described earlier (on both the identification as L&E and the interpretation).

Following the formula '*exceptio est strictissimae applicationis*', numerous cases were decided based on a narrow interpretation of an exception, reflecting both an international practice and a practice within the WTO specifically.[19] For instance, in *EC – Bananas I*, the Panel recalled that 'the burden of proof was on the party invoking an Article XI:2 exception, and that such exceptions were to be interpreted narrowly'.[20]

The point is not to deny that exceptions could be legitimately interpreted in a narrow way, but rather to argue that this is by no means natural. This restrictive interpretation approach must be justified based on a qualification of an L&E in relation to its rule in the context of the object and purpose of the treaty.[21]

In this context, the decision taken in *EC – Hormones* appeared as a change of course. The AB stated that

> merely characterizing a treaty provision as an "exception" does not by itself justify a "stricter" or "narrower" interpretation of that provision that would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in the light of the treaty's object and purpose or, in other words, by applying the normal rules of treaty interpretation.[22]

This decision recalls that the narrow interpretation does not 'by itself' follow from the qualification of a norm as an exception. At the same

[19] For references to international, European, and WTO cases, Qureshi (2015), 171–172.
[20] Panel Report, *EC – Bananas,* para. 339.
[21] For the example of AB decisions concerning exceptions meant to protect the environment, Trachtman (2017), 308.
[22] Appellate Body Report, *EC – Hormones*, para. 104.

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time, the *EC – Hormones* decision does not overrule the precedent practice but rather contextualises it as one possibility.[23]

This point is especially important in the context of the TRIPS because the Agreement mainly codifies IP owners' rights and not, for instance, users' rights. In the formal construction of the TRIPS, these latter rights are encapsulated in flexibilities that qualify rules structurally made for IP protection. If these L&E are systematically interpreted in a narrow manner, it introduces a structural bias towards the protection of IP owners over other stakeholders and policy objectives.

As Kur proposes, the interpretation of L&E should not be narrow or strict but instead must be 'correct':

> if the legislative objectives underlying the regulation of intellectual property law are taken seriously, the complex body of rules determining the extent of protection must be given equal weight in each of its parts, meaning that each legal provision, whether constituting a claim or a defence, must be interpreted in accordance with the aim and purpose expressed therein.[24]

This argument calls for not only qualifying a norm as L&E based on a thorough analysis, but also to determine the level of interpretative scrutiny required to address it. This determination is arguably related to the determination of a standard of review.[25] As the AB argues in *EC – Hormones,* a standard of review must reflect the balance established in an Agreement: 'To adopt a standard of review not clearly rooted in the text of the SPS Agreement itself, may well amount to changing that finely drawn balance; and neither a panel nor the Appellate Body is authorized to do so.'[26]

As for the interpretation of exceptions and limitations norms, this requirement of preserving a 'finely drawn balance' again shines a light on the importance of the foundational norms of the TRIPS as a crucial resource to elucidate the context, object, and purpose of the Agreement. It furthermore implies that the republican-sufficientarian reading of these foundational norms will tend to see as 'correct' an interpretation that gives Member States an important margin of appreciation in their competence to achieve their public policy objectives (based on their right to self-determination).[27]

[23] Qureshi (2015), 176.
[24] Kur (2011), 213.
[25] See infra on accountability (Ch. 2.1.2.1.).
[26] Appellate Body Report, *EC – Hormones*, para. 115.
[27] Kur (2016), 139.

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This point connects this reading to arguments based on human rights and national regulatory autonomy. Geiger, for instance, has argued that the principle of restrictive interpretation of exceptions could not be justified under a system based on fundamental rights. He mentions case law of the Court of Justice of the European Union (CJEU), for instance *Denkmyn* on copyright, to illustrate the importance that the Court has given to the purposive and effective interpretation of exceptions. On national regulatory autonomy, Okediji mentions the importance of interpreting exceptions with a view towards preserving the capacity of States to pursue their national interests.[28] Both the human rights- and national autonomy-based arguments are key parts of the reframing proposed here and will hence be systematically referred to in the interpretation of TRIPS' L&E.

This purposive and functional approach also explains why the interpretation of L&E can evolve over time. Whether an exception is permissible or not depends on changing circumstances necessitating interpretation considering the foundational norms of the TRIPS.[29] As the Panel in *US-110(5)* puts it, exceptions are not 'frozen in time'. Evolving markets and consumer preferences might change the interpretation of copyright exceptions.[30]

5.1.3 *Challenge of Using L&E in National Legislation*

It is important to highlight a further and different type of challenge, especially for less powerful States. Even if recognised and qualified in a relational manner, L&E norms are still difficult to utilise in the process of crafting national legislation. The normatively precarious or unclear nature, function, and scope of these L&E can be seen as a threat to weaker States that cannot bear the costs (or even the prospects) of aggressive trade policy or retaliation through dispute settlement procedures.[31] In that context, domination is exercised through the capacity to threaten States that might be willing to use the TRIPS' L&E.

For our present argument, this risk of domination is not only a 'Realpolitik' scenario but is also intrinsically linked to the conceptualisation and interpretation of L&E norms. In addition to global political

[28] UNCTAD (2005), 694; Okediji (2017), 476 ff.
[29] Qureshi (2015), 154.
[30] Panel Report, *US – 110*(5) *Copyright,* paras. 6.59 and 6.187.
[31] See *infra* for this discussion in the context of bilateral trade policy (Ch. 6.2.3.2.).

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dynamics, weaker States fight an uphill battle in arguing against the traditional approach to L&E's interpretation. As Sekala and co-authors hold, 'although countries from the Global South have the option of engaging TRIPS flexibilities in the absence of a general waiver, they often do not do so because the process of using these flexibilities is often stacked against them, reproducing neocolonial dynamics'.[32]

As a complement to the qualification and interpretation of L&E proposed earlier, there are two further paths worth exploring to diminish the risks of domination. Firstly, the path of mandatory exceptions could address the capacity of weaker States to concretely use exception norms. As Okediji argues, 'mandatory limitations and exceptions for developing and least developing countries play a crucial role in supporting the free flow of knowledge goods to support development',[33] also pointing out how this strategy must go hand in hand with a strategy of strengthening the relevant reporting mechanisms.[34] States are required to report how they operationalise these L&E through domestic legislation by analogy to human rights compliance mechanisms. I will address the example of the Marrakesh Treaty and the mandatory exceptions it prescribes later.[35]

Secondly, short of mandatory L&E, it is possible to support States in interpreting and operationalising existing non-mandatory L&E. Guidelines that explain best practices for domestic legislation can potentially provide weaker States resources on promising interpretations.[36] Okediji argues that 'such tools can help formalize customs and practices that, although widely practiced, lack legal certainty and thus are less helpful as evidence of alternative policy approaches to regulating creative industries'.[37] As soft law instruments, these guidelines encourage legal experimentation by showing the palette of diverse possibilities for interpreting and enacting specific TRIPS' obligations.[38] As Gervais mentions, the IP offices of powerful economic nations also try to set standards by attempting to transform their submission guidelines and the associated definitions into largely accepted benchmarks.[39] According to the

[32] Sekalala, Forman, Hodgson, Mulumba, Namyalo-Ganafa and Meier (2021), 4.
[33] Okediji (2018), 65.
[34] Okediji (2018), 64–65.
[35] *Infra* (Ch. 6.1.).
[36] UNCTAD (2005), 694.
[37] Okediji (2017), 477.
[38] Recommendations by Special Rapporteurs might be understood in a similar way. See, for instance, the measures mentioned by Grover (2009), § 27.
[39] Gervais (2014b), 547.

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double-path structure of this work, these soft law instruments lie at the juncture of a renewed interpretation and policy instrument.

5.2 Exceptions in TRIPS

This section deals with exceptions in the TRIPS, both regarding patent and copyright, and focuses on the so-called three-step test structure found in Articles 13, 17, 26.2, and 30 of TRIPS. The interpretation of these norms requires considering the qualification of norms as exceptions.

The section discusses structural questions of the three-step analysis before analysing the three-step test in patent and copyright. The general objective is to provide guidance for an interpretation aligned with the previous reconstruction of the TRIPS' foundations.

5.2.1 The Structure of the Three-Step Analysis

Articles 13, 17, 26.2, and 30 of TRIPS all display a similar structure consisting of three steps to evaluate whether a measure qualifies as an exception.[40] Before analysing the patent and copyright exceptions in more detail, this subsection addresses common structural points, firstly addressing why the interpretation of the three-step test must be contextual before secondly discussing the cumulative or holistic interpretation of the steps and thirdly clarifying the standard of interpretation.

5.2.1.1 Contextual Interpretation

The three-step provisions entail concepts that require significant interpretative work. Terms such as 'unreasonably', 'normal exploitation', and 'legitimate interests' require interpreters to engage with different approaches to ascertain the meaning of these norms. In *Plain Packaging*, the Panel had to interpret 'unjustifiably' as found in Article 20 of TRIPS. The approach taken by the Panel in its interpretation of Article 20 of TRIPS can be called contextual in two different senses.[41] It must be informed by the object and purpose of the treaty, and it must qualify the rule-exception relations.

[40] Three-step tests are also to be found in other international instruments such as the Berne Convention, the WIPO Copyright Treaty, and the WIPO Performances and Phonograms Treaty. For a comparative evaluation, Christie and Wright (2014).

[41] Panel Report, *Australia – Plain Packaging,* para. 7.2405.

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On the one hand, the interpretation broadly contextualises the TRIPS in accordance with the VCLT by considering the object and purpose of the provision and the agreement.[42] The Panel starts with a dictionary-based definition of 'unjustifiably', defined by reference 'to the ability to provide a "justification" or "good reason" for the relevant action or situation that is reasonable in the sense that it provides sufficient support for that action or situation'.[43] Going further, the Panel pays attention to Articles 7, 8, and the Preamble of TRIPS.[44] As the AB confirmed, the interpretation must consider Article 8 of TRIPS and its requirement to give Member States enough policy space to pursue their national priorities.[45]

On the other hand, the interpretation is contextual because, according to the Panel, the content of Article 20 of TRIPS must be interpreted in light of the general norm related to trademark. As explained earlier, the interpretation of the exception requires a qualification of both the general norm and of the normative relation with the exception norm. In that sense, Articles 15 and 16 of TRIPS (about the subject matter and rights conferred by trademark) must be interpreted and their relations to Article 17 (exceptions) and Article 20 (other requirements) qualified.[46] The general norms (here Articles 15 and 16 of TRIPS) must be interpreted as part of the more general context of the TRIPS and its objectives. On this specific point, Frankel critiques the cautiousness of Panels in considering the importance of national policy objectives as part of this relation between a general norm and its exception(s).[47]

5.2.1.2 Cumulative Interpretation and Order of Interpretation

The interpretation of the three-step test raises the question of the relationship between each of the steps. The first question is whether the three steps are cumulative or whether they represent an analytical whole to be considered holistically. The second question is whether the ordering of the different steps is relevant.

[42] Panel Report, *Australia – Plain Packaging,* para. 7.2393.
[43] Panel Report, *Australia – Plain Packaging,* para. 7.2398–2404. Mitchell and Samlidis (2021), 1016.
[44] Panel Report, *Australia – Plain Packaging,* para. 7.2405.
[45] Appellate Body Report, *Australia – Plain Packaging,* para. 6.658.
[46] Panel Report, *Australia – Plain Packaging,* para. 7.2427.
[47] Frankel (2021), 93.

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In a much-criticised interpretation, the Panel in *Canada – Patent Protection of Pharmaceutical* Products argued that the three steps should be viewed as cumulative.[48] The Panel added that each condition must be presumed to mean something different from the other two. This view has been adopted in further cases and defended in TRIPS' commentaries.[49]

In the same decision, the Panel addressed the second question, in effect, the order of listing of the steps. It considered how the order must be respected: an exception can fulfil the first condition while failing to fulfil the second. The syntax of Article 30 is taken as evidence of the Russian-doll structure of the steps, where each step represents a further condition to be fulfilled.[50]

Scholars have challenged this interpretation in two main ways, firstly, by arguing that the three-step test should not be considered as a set of three cumulative conditions, but rather as an analytical whole in which all three conditions should be duly considered. Secondly, authors have claimed that the list of ordering was not fundamentally relevant as the three conditions should be considered together as forming a coherent set of conditions.

In supporting the first point, Dinwoodie and Dreyfuss interpret the international IP acquis as built around the idea of balance.[51] The interests and stakeholders stated by the TRIPS' foundations (such as Articles 7 and 8 of TRIPS) are relevant for the three-step test and constitute the parameters of this balance. The idea of striking a balance makes it clear that every step of the test has specific relevance with respect to specific stakeholders, and that it is by considering all these elements together that actors can ensure the integrity of the balance.[52]

Furthermore, the idea of balance strives for equilibrium among the three steps. The formulation of the exception articles does not reveal the ambition to qualify one step as a priority or more important than the other. The fact that this clear priority-setting formulation does not exist can be taken as evidence that the three steps should be considered equally important.[53] On the contrary, as Hugenholtz and Okediji put it,

[48] Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, para. 7.20.
[49] See also Panel Report, *US – 110(5) Copyright*, para. 6.97. In the literature, Beas Rodrigues (2012), 156; Pires de Carvalho (2014), 378 ff; Taubman, Wager and Watal (2020), 118.
[50] Panel Report, *Canada – Patent Protection of Pharmaceutical* Products, para. 7.21.
[51] Dinwoodie and Dreyfuss (2015), 154.
[52] Wright (2009), 609–610.
[53] Geiger, Gervais and Senftleben (2014), 585.

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a cumulative reading would imply that the first and second steps must be interpreted more liberally in order for the third step to remain relevant.[54]

To adopt a cumulative and sequential approach would imply prioritising the first step(s) unduly. Interests of third parties – which are crucial to the legitimacy of the IP regime – are mentioned in the last step.[55] This is problematic because the assessment process does not even consider them. Steps 1 and 2 are already decisive and the assessment stops before reaching Step 3, thus implying that the assessment does not consider a part of the exception that is a crucial counterbalancing mechanism with respect to the interest of the IP-owners.[56] This explains why Geiger has argued that, assuming that the three steps are an analytical whole, we should start with the third step, thereby making sure that the interests of third parties are duly considered.

In a republican perspective, the three steps must be considered together as a tool to safeguard the balance of the TRIPS. The interpretation of the test must hence consider all three steps to ensure the integration of all relevant interests.[57] This clearly speaks against assuming a cumulative and an order-of-listing approach (which often will stop at the first step). The test should be considered as a holistic analytical tool. The republican dimension focuses on the requirement to identify and consider all the relevant interests of stakeholders.

5.2.1.3 Standard of Interpretation

The third structural remark on the three-step test concerns the standard of interpretation. As explained earlier, exceptions must be interpreted in a way that considers the normative relation between the general norm and the exceptions. An exception that is meant to protect access for the broader public (such as the third step of the test) does not necessitate narrow interpretation. It rather commands a potentially broad interpretation. As shall be argued later on copyright, this interpretation must make room for user interests, understood as being as important as the IP owners' interests. This norm is meant to protect an interest that is a crucial part of the TRIPS' overall balance.[58]

[54] Hugenholtz and Okediji (2008), 21.
[55] Apart from the copyright exception in TRIPS (Article 13) in which they are not directly mentioned.
[56] Wright (2009), 617 ff.
[57] Geiger, Hilty, Griffiths and Suthersanen (2010), 120.
[58] Geiger (2011), 288.

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The standard of interpretation entails further assumptions that also depend on the qualification of the overall international IP regime and its objectives. The different Panels have focused strongly on the protection of proprietary interests in their reading of the three-step test. For instance, they have focused on determining whether an exception could be limited to small diminutions of the full exploitation of the relevant IPRs. By choosing this reading, the Panels assume that IPR protection is the default option and that exceptions to it must be kept narrow.

As Kur holds, exceptions should not be treated as 'islands in a sea of exclusivity' but, to the contrary, as part of the sea of availability in which exclusivity islands are granted.[59] This metaphor highlights the requirement to clearly identify the general objectives of the TRIPS and the corresponding standard of interpretation applicable to IPRs and norms of exceptions. As Helfer and co-authors explain in their commentary on the Marrakesh Treaty, 'exceptions and limitations that are consistent with the three-step test are thus not merely permissible restrictions on copyright; they are affirmative expressions of government policy that embody socially desirable and salutary objectives, including the realisation of a range of internationally protected human rights'.[60] As Kapczynski recalls, this relates to a public domain narrative – the sea of availability is the public domain, and every exclusivity right should be justified against this background.[61] The interpretation of the three-step test must acknowledge the relevance of these societal goals underlying the whole TRIPS. This view is a direct implication of the access default position argued for in Chapter 4.[62]

5.2.2 *Three-Step Test of Article 30 of TRIPS*

Article 30 of TRIPS establishes three criteria that must be met to qualify as an exception: (1) the exception must be 'limited', (2) the exception must not 'unreasonably conflict with normal exploitation of the patent', and (3) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'. The objective of this subsection, then, is to provide a

[59] Kur (2009), 333.
[60] Helfer, Land, Okediji and Reichman (2017), 68–69.
[61] Kapczynski (2010), 30 ff.
[62] *Infra* (Ch. 4.2.3.2.).

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republican-sufficientarian account of these three criteria by addressing each condition before considering recognised exceptions.

Note that the tripartite structure of Article 30 of TRIPS could already be put into question. The previous structure in three parts is the one chosen by the parties and the Panel in *Canada – Patent Protection of Pharmaceutical Products*.[63] Alternatively, one could argue that the final part of Article 30 ('taking account of the legitimate interests of third parties') must apply to the second and third conditions.[64]

5.2.2.1 First Condition: Article 30

The first condition ('limited exception') is a telling example of the requirement to interpret exceptions in a way that does justice to the general norm they refer to. In *Canada – Patent Protection of Pharmaceutical Products*, both the EU and the Panel interpret 'limited' as a reinforcing parameter. As the Panel puts it, 'the word "exception" by itself connotes a limited derogation, an understanding which is reinforced by the qualification "limited"'.[65] As for the determination of the meaning of 'limited', the Panel concludes that a limited exception should only represent a 'small diminution of the rights in question'.[66] It applies this understanding to the stockpiling exception claimed by Canada and concludes that 'it was clear to the Panel that an exception which results in a substantial curtailment of this dimension cannot be considered a "limited exception" within the meaning of Article 30 of the Agreement'.[67] Even if one assumes the understanding of 'limited' chosen by the Panel, it remains unclear what degree of curtailment is unacceptable or, in other words, what 'substantial' means in the Panel's quote.[68]

But above all, the Panel's understanding of 'limited' and its general qualification of exceptions appear misleading. As explained earlier, exceptions should not *per se* be interpreted in a narrow way, quite the contrary when their function is to secure important interests in the context of a balancing exercise. As Zhuang argues, the Panel's interpretation contradicts the interpretative principle of *in dubio mitius*, under which in case of ambiguity, that 'meaning is to be preferred which is less

[63] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.20.
[64] Malbon, Lawson and Davison (2014), 478.
[65] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.30.
[66] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.30. See also Panel Report, *EC – Trademark/GI*, para. 7.650.
[67] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.36.
[68] For this criticism, Howse (2000), 498; Kur (2009); Beas Rodrigues (2012), 92–93.

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onerous to the party assuming an obligation'.[69] If this first step is considered as part of a cumulative reading of Article 30 of TRIPS (as done by the Panel), the challenge is aggravated because the interpretation of 'limited' would represent the whole discussion on (un)reasonable conflict and prejudice. The second and third conditions would be subsumed into the first which would be about, eventually, the acceptability of the exception defined in economic terms.[70]

Furthermore, understood in the context of the curtailment of a patent (as a quantitative parameter of it), the Panel's notion of 'limited' relies upon an opposition between the patent and potential exceptions: first the patent, and only in a second time the exceptions. But as Chapter 4 indicates, at its very core the justification of IPR relies upon societal interests. The interpretation chosen by the Panel makes it structurally impossible for Member States to consider the societal interests protected by Articles 7 and 8 of TRIPS as an intrinsic part of the IP regime.

There is another understanding of limited that would make more sense in the context of the three-step test. 'Limited' is best understood as a condition of delimitation, in contrast to a general or open-ended exception.[71] This has been the position held by Canada in *Canada – Patent Protection of Pharmaceutical Products*.[72] As Correa explains it, this understanding can integrate boundaries related to the acts involved, the purpose, the outcome, the person, or the duration of the exception.[73] This understanding does not assume the pre-existence of justified IPRs (without considering societal interests); it only focuses on the delimited character of the exception.

5.2.2.2 Second Condition: Article 30

The second condition refers to an exception which would 'unreasonably conflict with normal exploitation of the patent'. In *Canada – Patent Protection of Pharmaceutical Products,* the Panel qualifies the

[69] Zhuang (2017), 266. Referring to Appellate Body Report, *EC – Hormones,* footnote 154. In general on this principle, Fahner (2021).

[70] Beas Rodrigues (2012), 99–100. Referring to case law on Article XX of GATT and the distinction between 'limited exceptions' and the impact of the exception on trade. For instance, Appellate Body Report, *US – Shrimp,* para. 157. For a similar criticism regarding the copyright's case law, Senftleben (2004), 152.

[71] Howse (2000), 496; Zhuang (2017), 265–266.

[72] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* pp. 76–77.

[73] Correa (2020b), 299. Some dimensions of delimitation are addressed by the Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.37.

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'exploitation' as a commercial activity in which the patent owners employ their exclusive patent rights to extract economic value from their patent.[74] Exploitation is hence primarily defined as the economic use by the patent owners. The Panel further distinguishes between two understandings of 'normal', the first being empirical-descriptive (by reference to a specific market/context and what the patent owner could realistically expect) and the second being normative (what is owed to a patent owner in a more dynamic sense[75]). According to the Panel, the word 'normal' is used in Article 30 of TRIPS in a way that combines the two meanings.

The concepts of this second condition of Article 30 of TRIPS are excellent examples of the requirement to adopt the interpretative approach argued for in this work. These concepts cannot be properly understood – in the sense of the VCLT – without considering Articles 7 and 8 of TRIPS. Note that the Panel acknowledges the importance of patent as 'inducement to innovation'.[76]

However, the Panel only goes halfway, not considering the further objectives underlying the patent regime in the TRIPS. All the objectives described in Articles 7 and 8 of TRIPS qualify 'normal exploitation'. This required interpretation is not an argument situated at the same level as the empirical versus normative understanding of 'normal'. Though the argument appears more clearly with a normative understanding (in which all relevant stakeholders in light of the principles of Articles 7 and 8 of TRIPS must be considered to determine what is due to a patent owner), it is also relevant for an empirical understanding. Here also, the scope of analysis must extend beyond the most direct economic interests of the patent owner to consider the relevant stakeholders *in concreto*. Both normatively and empirically, the main requirement of the republican-sufficientarian approach is to give its due to the content of Articles 7 and 8 of TRIPS and, with it, to follow the requirement to consider relevant stakeholders.

Once normal exploitation is defined, exceptions must not provoke an 'unreasonable' conflict. First, the term is used twice, as part of the second and third conditions of Article 30 of TRIPS. The presence of the term is

[74] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.54.

[75] For instance, by considering the 'normal' exploitation given technological developments or market opportunities. See below on copyright for further reflections on technologies.

[76] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.55. Howse (2000), 499.

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itself significant as it shows the ambition of the drafters to distinguish between conflicts that can be reasonable and those that cannot. This delimitation indicates that some conflicts with normal exploitation can be labelled as 'reasonable'.

Second, the use of '(un)reasonable' here indicates that the exception should have identifiable grounds.[77] It must be justified based on an interest that is known and, going further, recognised as justified. This work's reflections on Article 8 of TRIPS can arguably be used for that purpose. This condition eliminates conflicts that are unreasonable because they have no clearly justified grounds.

Third, the word 'reasonably' highlights that there must be a normative relation between the grounds used as justification and the conflict with normal exploitation (second condition) or the prejudice of the patent owner's right (third condition). The objective is to exclude a situation in which justifiable grounds (e.g., health policy) would justify every potential exception slightly related to it. In such scenarios, the grounds are justified, but the relationship between the exception and the impact of the exception on normal exploitation or the legitimate interests of the patent owner is not adequate.

In *Canada – Patent Protection of Pharmaceutical Products,* the Panel does not provide an interpretation of this use of 'unreasonable'. In *US – Section 110(5)* (a copyright case), the Panel interprets the concept of 'do not unreasonably prejudice' (such as entailed by Article 13 of TRIPS). The Panel seems to assume that the level of prejudice measured by financial impact can be a way to try to draw a line between reasonable and unreasonable. It concludes that 'a prejudice to the legitimate interests of rights holders reaches an unreasonable level if an exception or limitation causes or has the potential to cause an unreasonable loss of income to the copyright owner'.[78] However, this reflection bears rather on the object of inquiry (the loss of income as the definition of prejudice) rather than on the level (reasonable or not), as 'reasonable' is here clearly used in a circular way (unreasonable prejudice = unreasonable loss).

Another way to try to draw the line would be to pinpoint lower and upper limits. In quantitative terms, a lower limit could be a conflict/prejudice deemed reasonable unless the economic interests of the IPR owner are completely negated. To deprive an IPR owner of all their

[77] Beas and Hestermeyer defend a similar idea, but consider it as part of the criterion 'limited'. Hestermeyer (2007), 236; Beas Rodrigues (2012), 98.

[78] Panel Report, *US – 110*(5) *Copyright,* para. 6.229.

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economic interests would fail to be reasonable. An upper limit could be proportionality.[79] The conflict would then be required to be reasonable in the sense of proportionality, which would set a higher standard that not all exceptions would fulfil, though they prove not to conflict unreasonably. However, as we shall discuss later in the case of copyright exception, the interpretation of the 'reasonable' test as a proportionality test can be significant for two types of reasons. Firstly, proportionality forces us to identify relevant interests and to normatively qualify them in relation to each other. Secondly, proportionality represents a well-known standard to conduct this normative qualification.

In the framing defended in this work, 'reasonable' is best defined with respect to Articles 7 and 8 of TRIPS. As per Correa, the interpretation of 'unreasonable' depends upon the conception 'of the role and objectives of the patent system'.[80] Clearly linking the interpretation of 'unreasonable' and the justification of IPR also explains why different Member States may come to different understandings.

Interestingly, the finding of the AB in *Plain Packaging* can be drawn upon on this point. In interpreting Article 20 of TRIPS, mainly the notion of 'unjustifiably encumbered',[81] the AB links the definition of 'unjustifiably' with the degree of regulatory autonomy that Member States arguably possess in imposing special requirements on trademarks.[82] It writes that 'accordingly, we understand that a Member that imposes encumbrances on the use of trademarks through special requirements must be able to provide a reasonable explanation of how an objective pursued by introducing special requirements warranted the resulting encumbrances'.[83] In order to specify the type of reasons that States might use, the AB confirms the findings of the Panel on the linkage between 'unjustifiably' and Article 8 of TRIPS.[84]

[79] Beas considers only a test of necessity. Beas Rodrigues (2012), 103.

[80] Correa (2020b), 301.

[81] Article 20 of TRIPS reads as follows: 'The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.'

[82] Appellate Body Report, *Australia – Plain Packaging,* para. 6.647.

[83] Appellate Body Report, *Australia – Plain Packaging,* para. 6.651.

[84] Appellate Body Report, *Australia – Plain Packaging,* para. 6.649. Note that the Panel and the AB also choose an argumentative strategy trying to identify higher standards that

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Overall, the interpretation of 'unjustifiably' must be linked with the interpretation of 'unreasonable'. Firstly, 'unreasonable' is arguably best understood along the first dimension mentioned later: the existence of identifiable and justifiable grounds for Member States to enact a limited (in the sense of delineated) exception. Secondly, the dimension of non-excessiveness of the conflict/prejudice should be defined along the requirement to consider all relevant interests and the requirement to not completely negate any of them.

5.2.2.3 Third Condition: Article 30

The third condition refers to the phrase, 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'. It has two main parts: the legitimate interests of the patent owner and the necessity to avoid 'unreasonable prejudice'. It has a similar structure as the second condition: something valuable (the legitimate interests) should not unreasonably be negatively affected.

For the 'unreasonable prejudice', similar reflections as above apply. Prejudice can be defined as connoting damage, harm, or injury.[85] The prejudice is not unreasonable if it is justified based on legitimate grounds (such as those mentioned in the context of Article 8 of TRIPS) and if the relation between the exception and the prejudice is adequate.

The definition of 'legitimate interests' has been subject to controversy. To equate 'legitimate interests' with 'legal rights' (as the EC in *Canada – Patent Protection of Pharmaceutical Products* claims) appears problematic in an exception clause and does not clearly align with the second part of this third condition (the legitimate interests of third parties).[86] In *Canada – Patent Protection of Pharmaceutical Products*, the Panel clearly rejects this equation, trying to define legitimate interests 'as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms'.[87] Furthermore, the Panel seems to consider the

should not be conflated with 'unjustifiably' (focus of the distinction is on the higher standard of necessity). See Appellate Body Report, *Australia – Plain Packaging,* para. 6.655.

[85] See in the context of the interpretation of Article 13 of TRIPS, Panel Report, *US – 110*(5) *Copyright,* para. 6.225.

[86] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.68.

[87] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.68. Also in also Panel Report, *EC – Trademark/GI*, para. 7.663.

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international consensus (or lack thereof) on what constitutes a legitimate interest to be a useful benchmark.[88]

In trying to more clearly define why it chooses this interpretation of 'legitimate interests', the Panel looks to the case of an exception considered justified (the exception for scientific experimentation) and illustrates the meaning of 'legitimate'.[89] This general approach by the Panel aligns with the argument that this work proposes: Articles 7 and 8 of TRIPS must inform interpretative work on concepts such as 'legitimate interests'.[90] Legitimate interests are those justified as part of the balance that justifies IP in the first place. Intellectual property rights cannot be defined as absolute property rights. As Howse argues, this would result in a structural silencing of competing social and economic interests found in the IP justification matrix.[91]

As for patent owners, the interests of third parties must be defined according to our interpretation of Articles 7 and 8 of TRIPS, including the right to science framework presented previously. As Chapter 4 has argued, these types of interests must be understood as part of the same justification matrix. The ordering is not primarily economic property interests and secondarily public access exceptions. Both are parts of the same justification matrix and must be considered in a consistent manner. The question of who qualifies as third parties with legitimate interests can be answered based on the account of the TRIPS' foundations. Third parties include at least competitors in a broad sense, researchers, consumers, and the public at large which, as part of a right to science framework, is a crucial element of any justification of the TRIPS.[92] It is important not to limit the list of relevant third parties (and their legitimate interests) to an exclusively economic understanding of the relevance of the TRIPS.[93]

Table 5.1 presents an overview of the arguments made.

[88] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.82.
[89] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.69.
[90] Canada and third-party participants in the case *Canada – Patent Protection of Pharmaceutical Products* have argued in this way. Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.67.
[91] Howse (2000), 501.
[92] For a similar list, Hilty and Lamping (2014), 15.
[93] Haugen (2008b), 357. Beas makes this point in his interpretation of the case law on trademark rights in TRIPS. Beas Rodrigues (2012), 111–112. Also, according to the Panel Report, *EC – Trademark/GI*, consumers should be included in the definition of 'third parties' for the purpose of Article 17 of TRIPS (paras. 7.675–7.681).

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Table 5.1 *Article 30 of TRIPS*

Schematic overview of Article 30 of TRIPS' interpretation based on the republican-sufficientarian framework

1st step

Is the exception clearly delimited (e.g., by defining the acts involved, the purpose, the outcome, the person, or the duration)?

2nd step

Is the interference caused by the exception reasonable, in effect, (1) does it have grounds and (2) does it not excessively impact the normal exploitation of patents?

At (1) Is the exception justified by grounds that can be identified in light of Articles 7 or 8 of TRIPS?
At (2) (a) Qualify the normal exploitation in light of Articles 7 and 8 (incl. societal objectives of patent protection)
(b) Does the exception have an excessive impact on this normal exploitation? 'Excessive' is to be defined by combining the identified grounds and the effect on normal exploitation. Explore the availability of alternative measures capable of achieving the same objectives.

3rd step

— Identify the legitimate interests at stake (republican objective to ensure all stakeholders' interests are identified and sufficientarian objective to identify especially relevant interests)
— Identify the contributions of the exception to the goals of the TRIPS in light of Articles 7 and 8 (taking into account the different stakeholders)
— Identify the prejudices caused by the exception
— Address the reasonableness of the prejudice

(a) Is the exception justified by grounds which can be identified in light of Articles 7 or 8 of TRIPS?
(b) What impact does the exception have on the prejudice and on third parties? Can we argue that this overall impact is reasonable from a quantitative perspective? Explore the availability of alternative measures capable of achieving the same objectives.

5.2.2.4 Recognised Exceptions

Overall, Article 30 should be interpreted as a conceptual and analytical whole, meaning that the three conditions must be duly considered as part

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of a holistic tool. Correctly understood and applied, Article 30 of TRIPS gives States sufficient room to adopt justified exceptions in accordance with their TRIPS' obligations.

To test this general approach, I will briefly consider the exceptions generally considered to pass the three-step test.[94] The drafters of the TRIPS renounced the use of a list of exceptions. In a negotiation working document, the Chairman mentioned exceptions that were considered to pass the test, including rights based on prior use, acts done privately and for non-commercial purposes, acts done for experimental purposes, and preparation in a pharmacy in accordance with a prescription.[95] In *Canada – Patent Protection of Pharmaceutical Products,* the Panel considered why an exemplative list was not chosen and concluded that it 'was abandoned in favour of a more general authorization following the outlines of the present Article 30. The negotiating records of the TRIPS Agreement give no explanation of the reason for this decision.'[96]

Following Correa, exceptions meant to pass the three-step test must be identified through a comparative law approach. At least six exceptions could arguably qualify: importation of a product that has been put on the market elsewhere by the patentee, acts done privately for non-commercial purposes or on a non-commercial scale, using the invention for research and experimentation and for teaching purposes, seeking regulatory approval for marketing of a product before the expiry of the patent (Bolar exception), preparation of medicines for individual cases according to a prescription, and use of the invention by a third party who started/undertook *bona fide* preparatory acts before the application for the patent (or its publication).[97]

Let us briefly address two exceptions for the sake of illustration. The experimental use exception – which does not require the authorisation of the patent owner – is significant for promotion and dissemination of scientific knowledge. Both as part of a mechanism to test an invention (e.g., whether it works and whether its functioning has been sufficiently disclosed) and as part of a broader scientific endeavour (using the disclosed information for further research), this type of exception is a key expression of the societal objective to foster innovation. As such, it is

[94] For the perspective of developing countries, Garrison (2006).
[95] Chairman of the Negotiating Group, Status of Work in the Negotiating Group – Chairman's Report, 23 July 1990, MTN.GNG/NG11/W/76, Part III, Section 5, paragraph 2.2.
[96] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.70.
[97] Kur (2016), 142; Correa (2020b), 296.

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an essential justification for the granting of patent rights in the first place. As Zhuang argues, the promotion of ESTs through a strong experimental exception could be a promising avenue.[98]

The same kind of argument applies to the Bolar exception, named after a case involving a pharmaceutical company called Bolar.[99] In this case, a US court denied the right of Bolar to start the FDA approval process before the expiry of a patent held by Roche. After this case, the relevant US law was changed to allow for the right to start procedures before the expiry of the patent. The key rationale is to foster the public good by ensuring that consumers get access to generic drugs as soon as possible. The Bolar-exception constellation is one of the leading questions addressed by the Panel in *Canada – Patent Protection of Pharmaceutical Products*. To recall, the regulatory review exception of this dispute was found compatible with Article 30 of TRIPS (while the stockpiling exception was not).[100]

Drawing upon the image used by Kur, this exception recalls that a patent is an island of exclusivity in an ocean of availability and access.[101] The patent should not be used to prevent competitors from producing generics and initiating regulatory procedures before its expiration. This would be costly for the broader public in terms of access to drugs. In exchange, the patent term of the initial drug can be extended. Interestingly, this question is addressed as an issue of 'welfare'. If understood as argued for in Chapter 4 (as part of Article 7 of TRIPS), social and economic welfare should prioritise those who have not reached a sufficientarian threshold. In that sense, the Bolar exception should be linked with strong consideration of the justice obligations of States, expressed through the human rights obligations they must fulfil.

Understood as part of a republican-sufficientarian understanding of a State's obligations, States not only have the right to use Article 30 of TRIPS to formulate exceptions but also have the obligation to do so. This

[98] Zhuang (2017), 273.

[99] *Roche Products Inc.* v. *Bolar Pharmaceutical Co.*, 733 F.2d 858 (1984). Regulatory review exceptions remain an important item on the TRIPS' agenda. See, for instance, the discussion in Minutes of the Meeting, Council of the TRIPS, 27 February 2018, IP/C/M/88/Add.1, para. 369: 'The Bolar provision is one of the key tools to ensure an efficient and balanced patent system by safeguarding against the artificial extension of patent protection. It is a very useful health-related patent flexibility for promoting public health objectives and maintaining dynamic competition between companies.' On the Bolar exception, Straus (2014).

[100] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.39 ff.

[101] Kur (2009).

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obligation is grounded in both TRIPS internal consistency (giving the stakeholders mentioned by Articles 7 and 8 of TRIPS their due) and general justice obligation (both domestic and global justice).

5.2.3 *Lessons from Article 13 of TRIPS*

Article 13 of TRIPS establishes three criteria that must be met in order to qualify for an exception/limitation in copyright: (1) the exception/limitation must be confined to certain special cases, (2) which do not conflict with a normal exploitation of the work, and (3) which do not unreasonably prejudice the legitimate interests of the right holder.

Overall, reflections on Article 13 of TRIPS make comparable points as to the patent's analysis but add more reflection on the importance of integrating the users' perspective because of the practices made possible by digital technologies. Our reflections outline a standard to interpret Article 13 of TRIPS in a way compatible with self-determination, the obligations of justice that Member States have with respect to their population, and the protection of the interests of copyrights holders.[102]

Three lessons learnt are important for the present argument: the importance of societal objectives, the focus on economic benefits, and the relevance of users' rights.

5.2.3.1 The Importance of Societal Objectives

Firstly, the interpretation of Article 13 of TRIPS requires a qualification of the underlying societal objectives pursued by copyright protection in particular and by IPR in general. These objectives, as part of the justification matrix of copyright protection, are crucial resources in giving meaning to concepts such as 'legitimate' or 'unreasonable'.[103] As the objective is to secure a flexible three-step test,[104] this also means the requirement to respect the integrity of the TRIPS as incorporating a rich justification matrix.[105]

For instance, in discussing the 'special' character of the case (first criterion), the Panel has used it synonymously with a minor exception, especially from the point of view of the number of potential beneficiaries

[102] This standard shares commonalities with Okediji's reading of Article 13 in light of the ambition to preserve room for fair use approaches. Okediji (2000), 168ff.
[103] This implies a reinforcement of users' rights, Oriakhogba (2023), 24 ff.
[104] Hilty, Geiger and Griffiths (2008), 491.
[105] Okediji (2000), 169–170.

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and the corresponding impact on the rights holders.[106] In this context, the Panel's ambition to set aside legitimacy reflections on why an exception is formulated (i.e., its underlying policy objectives) is problematic.[107] The qualification of the word 'special' is not only about being narrow in its scope and reach. It requires considering the grounds for the exception, mainly to know whether the exception could be linked to policy objectives as those of Articles 7 and 8 of TRIPS.[108] As Senftleben puts it, 'a limitation that rests on a rational justificatory basis making its adoption plausible constitutes a special case in the sense of the three-step test'.[109] The question should hence be transformed into 'how limited' a special case is, and this 'how' question necessarily integrates reflections on the 'why'.[110]

5.2.3.2 Shifting Away from the Economic Benefits

Secondly, integrating these foundations implies moving away from the focus on the economic benefits of the rights holders. This is indeed an important parameter to consider, but, contrary to the Panel's interpretation in *US – Section 110(5)*, it is neither an exclusive nor a primary one. For instance, the Panel interprets 'normal exploitation' as including the forms of exploitation that currently generate significant or tangible revenue.[111] In addition, it also includes forms of exploitation which, with a certain degree of likelihood and plausibility, could be economically important. This focus on potential sources of revenues might indeed be problematic in the context of evolving technological means of diffusion.[112] Namely, it is almost impossible to exclude the possibility that specific uses will not, in the future, become venues for economic gains.[113]

As Beas proposes, this second step can be reconstructed along distinct premises.[114] Firstly, this second step needs to clarify which market – whether actual or potential[115] – is at stake. From the perspective of our

[106] Panel Report, *US – 110*(5) *Copyright*, para. 6.112. Geiger, Gervais and Senftleben (2014), 593.
[107] Gervais (2008), 26–27.
[108] Beas Rodrigues (2012), 129.
[109] Senftleben (2004), 287.
[110] Kur (2011), 227.
[111] Panel Report, *US – 110*(5) *Copyright*, para. 6.180.
[112] Geiger (2011), 296–297.
[113] Beas Rodrigues (2012), 125.
[114] Beas Rodrigues (2012), 131.
[115] Actual markets are easy to measure, potential/prospective markets less so. The predictability of these markets is hence crucial. Gervais (2008), 30–31.

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reflections on global justice, this focus on markets allows for a differentiated view, according to the purchasing power of the distinct audiences. The second premise is about giving a meaning to 'normal' by focusing on the way the majority of rights holders use their rights. The third premise concerns the relationship between what is considered 'normal exploitation' and the underlying justification for copyright. As for the previous patent discussion, one first needs to define what justifies copyright protection in the first place before turning to the qualification of specific uses as 'normal'. This reflection necessarily brings back the idea of balancing between different objectives inherently present in the justification matrix of copyright.[116] As Kur argues, 'from this perspective, "normalcy" becomes a relative notion stretching over a range of differentiated options. Instead of pinpointing one specific result, it establishes the general framework for a gradual measurement to be undertaken in light of the strength and urgency of the legal motives underlying the rule at stake'.[117]

Overall, the focus on economic losses explains why the issue of compensation is relevant.[118] If compensation is paid to the rights holders, the exception at stake is more likely to be considered compatible with the third step of the test.[119] This option raises the question of which compensation should be considered equitable. Unsurprisingly, this question must be considered via underlying policy objectives of the TRIPS. Compensation is hence equitable if it conserves the incentives crystallised in TRIPS (such as creation and dissemination of new works) and if it is adequate given the economic capacity of the users and the objectives pursued by the exception.[120] In terms of global justice, both questions must be approached very differently if examining the adequacy of the TRIPS with an exception in a developed economy (as in *US – Section 110(5)*), or if looking at the situation in developing economies where purchasing power is very limited. Potential prejudice logically appears less significant, then, because the audiences at stake do not represent a major stream of revenue.[121]

[116] See also Senftleben (2014), 9 ff.
[117] Kur (2011), 229.
[118] As Senftleben explains it, 'the payment of equitable remuneration was regarded as a factor capable of tipping the scales in favour of a finding of compliance with the three-step test' Senftleben (2021), 94.
[119] Hugenholtz and Okediji (2008), 19. For an example, Beiter (2020), 248.
[120] Beas Rodrigues (2012), 134.
[121] Foster (2020), 383.

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5.2.3.3 The Relevance of Users' Rights

Thirdly, a republican-sufficientarian perspective on the foundations of the TRIPS requires considering the situations of specific users[122] who, with the objective of securing non-domination, appear to justify exceptions.[123] As discussed in the context of the Marrakesh Treaty later, users with specific disabilities have a strong claim to access relevant content because of the risks to their capacity to prevent domination.[124]

Beyond this access modality aligned with our previous reflections on human rights, the republican approach also mandates a broader approach to users' rights.[125] In a right to science framework, the access to knowledge, or more broadly to cultural material, is a precondition for active and critical citizenship.[126] This entails an educational rationale (elevating individuals to a level of competence required for citizenship), but also a participation rationale (allowing individuals to share cultural practices and materials for the purpose of critically addressing policy questions).

As Elkin-Koren argues, this general approach gains importance in a context characterised by the omnipresence of digital technologies and practices.[127] Similarly, digital technologies have deeply reshaped the creation, diffusion, and consumption processes of cultural creations (understood broadly). In brief, we need to consider 'users and usage as inputs into a creative process rather than recipients of outputs from creative processes. This broader understanding of the way cultural works are created and shared recognizes the dynamic, interactive, and diffused nature of creative processes.'[128]

Firstly, the user rights argument proposed by Elkin-Koren presupposes and further reinforces an interpretation of the TRIPS' foundations considering all relevant interests and stakeholders. The main contribution to this interpretative discourse is to shift from the idea that exceptions are

[122] For an overview, Gervais (2008), 20. With respect to critical literature on copyright, this is where reflections on how to revise copyright to achieve a certain ideal of justice can be factored in. For instance, informational justice by Hoeren (2018).
[123] This point might justify the special treatment of 'personal use' types of exceptions. See Litman and Samuelson (2010), 1229–1230.
[124] *Infra* (Ch. 6.1.1.).
[125] For an influential contribution popularising this concept, Patterson and Lindberg (1992).
[126] Oriakhogba (2023), 93 ff.
[127] Elkin-Koren (2017).
[128] Elkin-Koren (2017), 145.

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always secondary in comparison to owners' rights considered of primary importance.[129] Secondly, this argument makes clear that a holistic reading of copyright foundations not only changes the interpretation of exceptions, but also of rights, especially in the context of technological evolution.[130]

5.3 Compulsory Licence

Compulsory licensing has been a disputed issue in the history of IP rights.[131] The corresponding provisions in the TRIPS' patent section, Article 31 and, since its entry into force in 2017, the amendment Article 31*bis*, have also been among the most debated issues during TRIPS negotiations. This issue has also been especially prominent in the public health debates around the HIV crisis and the more recent COVID-19 pandemic.[132] As we shall discuss later, the absence of drug manufacturing capacity is still a burning issue for developing economies.

The topic has been the focus of a large and rich literature that cannot be systematically considered here. I focus instead on the changes and adaptations that a republican-sufficientarian approach calls for in the interpretation of Articles 31 and 31*bis* of TRIPS. This work proposes, on the one hand, to clarify the conditions of the use of compulsory licences in favour of the weakest parties (developing economies at risk of suffering domination) and, on the other, to reinforce the capacity of these parties to concretely make use of this possibility. An important point will be to assess to what extent we could draw upon the situation regarding public

[129] This explains why copyright exceptions must not be interpreted in a restricted way. For a Canadian decision explicitly adopting this user rights approach, *Supreme Court of Canada, CCH Canadian Ltd.* v. *Law Society of Upper Canada*, (2004), 1 S.C.R. 339, S.C.C. 13.

[130] Elkin-Koren mentions the following examples among the already recognised exceptions: consumer sovereignty, freedom of information, and freedom of expression and rights such as personal use, learning and educational use, breathing space for creation by user-authors, and rights necessary for free speech and a participatory citizenry. Elkin-Koren (2017), 148.

[131] Reichman and Hasenzahl (2003); Reichman (2009); Zhuang (2017), 278 ff.

[132] For an overview of the use of compulsory licences during the COVID-19 crisis, Bonadio and Contardi (2023). According to Article 9 of the Pandemic Agreement (May 2025), States shall develop and implement national and/or regional policies,(. . .) whose provisions may include: (i) licensing and/or sublicensing, particularly to manufacturers of developing countries and for the benefit of developing countries, preferably on a non-exclusive basis; (. . .). WHO Pandemic Agreement, WHA78.1, 20 May 2025.

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health and access to drugs in order to formulate arguments for other situations, such as ESTs.[133]

The first subsection discusses the general approach found in the TRIPS. The second subsection questions the conditions of 'adequate remuneration' (Article 31(h) of TRIPS) while the third subsection addresses the mechanism of Article 31*bis* of TRIPS for States without manufacturing capacity. Based on these reflections, the fourth subsection investigates in which sense the mechanism of Article 31*bis* of TRIPS could be used to address further policy goals by States without sufficient manufacturing capacity, focusing on ESTs in the context of climate change.

5.3.1 *General Approach: Article 31 of TRIPS*

The general structure of Article 31 of TRIPS is the result of hard-fought negotiations.[134] Developed economies with strong innovative industries have resisted the demands by developing economies to have accessible and efficient compulsory licence mechanisms. A compromise was found in the structure of Article 31 of TRIPS. In brief, Member States are free to determine why they use compulsory licences (the grounds) but, when using them, they must respect strict conditions.[135] Overall, these conditions are an expression of the ambition to tighten the margin of action enjoyed by Member States as much as possible. In contrast, in a republican-sufficientarian reading of the TRIPS, these conditions should be interpreted from the perspective of an affirmed right to self-determination serving the objective to fulfil obligations of justice.

As Correa states, the formulation of Article 31 of TRIPS recognises the right of Member States to limit the patent holders' rights using a compulsory licence.[136] Article 31 of TRIPS should be seen as a complement to Article 30 of TRIPS' three-step test. It complements the exception article in dealing with situations of non-limited use, in effect, potentially large commercial use, and in formulating a further crucial condition for the use of this right to compulsory licence: the requirement to provide adequate remuneration. For Taubman, Article 30 of TRIPS is hence about a limited exception to patent rights and Article 31 of TRIPS a remunerated limitation to these rights.[137]

[133] For an overview of the 2000 public health crises and the TRIPS, Reichman (2009).
[134] Reichman and Hasenzahl (2003); Taubman (2008), 932 ff; Zhuang (2017), 280 ff.
[135] UNCTAD (2005), 473; Malbon, Lawson and Davison (2014), 500 ff.
[136] Correa (2020b), 305.
[137] Taubman (2008), 957.

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This right to choose the grounds of Article 31 of TRIPS is a part of the framework on national self-determination. It is a key competence for Member States to be able to define their own obligations (in light, among others, of their human duties and, more generally, of their internal justice obligations) and to act accordingly.[138] In the context of the COVID-19 crisis, Grosse Ruse-Khan provides references to countries such as Germany, Israel, and the United States, which declared in 2020 their willingness to use compulsory licences to secure the supply of drugs important in addressing the pandemic.[139]

As Taubman explains, this is an example of the necessary interaction between domestic law and the international law dimension of the TRIPS.[140] Article 31 of TRIPS specifies conditions that apply to a situation in which a Member State has enacted a domestic law to allow for other uses of the subject matter of a patent without the authorisation of the right holder. This domestic law can empower the government to use a patented invention or to authorise a third party to do so. A public non-commercial use (or government use) is an authorisation by the government for one of its agencies/departments or one of its contractors to exploit a patented invention with a non-commercial purpose.[141] A compulsory licence is usually reserved for an arrangement allowing a third party to use a patented invention.[142] The TRIPS does not distinguish between these two uses.[143]

This right was reiterated in the Doha Declaration. Paragraph 5(b) clearly states that 'each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.[144] Paragraph 5(c) further specifies that Member States have the right to 'determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis,

[138] Hilty and Lamping (2014), 13.
[139] Grosse Ruse-Khan (2020). For an overview of the measures taken by States at the beginning of the COVID-19 crisis, Syam (2020). See also Hoen (2020).
[140] Taubman (2008). For Guan, the detailed obligations linked to compulsory licences represent an illegitimate intrusion of international trade law into domestic law, especially from the perspective of IPRs as private rights. Guan (2016), 417, 437 ff.
[141] UNCTAD (2005), 471; Correa (2020b), 307.
[142] Pires de Carvalho (2014), 388–389.
[143] Malbon, Lawson and Davison (2014), 493 ff.
[144] This point is recalled by Article 11(4) of the WHO Pandemic Agreement, WHA78.1, 20 May 2025.

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malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency'. The diseases mentioned are part of what can represent a national emergency, but they do not exhaust the definition of this concept.[145]

However, this disease reference is important.[146] Firstly, the qualification of a national emergency is significant because it relaxes the requirement to conduct prior negotiations with the patent holder (Article 31(b) of TRIPS). Secondly, the explicit mention of epidemics and long-term challenges as part of a national emergency clearly exclude an exclusive focus on short-term crises. As shall be recalled later, this could be important in the context of climate change.

Regarding public health crises, the Doha Declaration has been a crucial signal sent to States and private companies about the existence of this right both to determine the grounds for a compulsory licence and to use it concretely. This is important, as powerful States put pressure on their trading partners (e.g., through bilateral agreements) to limit the grounds permissible for a compulsory licence[147] and threaten them with retaliation if they make explicit in their domestic law the possibility to use compulsory licences.[148]

Given this freedom to determine the grounds for a compulsory licence, it is possible to cluster two broad categories of compulsory licences.[149] The first is found at the junction of IP law and competition law. It includes the use of compulsory licences for the sake of maintaining a competitive environment as mentioned in Article 31(k) of TRIPS. The second category refers directly to a public policy, such as health policy. Both categories can be considered an integral part of the functioning of the IP system.[150]

5.3.2 *The Requirement of Adequate Remuneration*

As proposed earlier, the distinction between the exceptions of Article 30 of TRIPS and the compulsory licences of Article 31 of TRIPS relies importantly on the obligation to pay 'an adequate remuneration in the

[145] Sunder (2012), 189.
[146] Correa (2020b), 307.
[147] See *infra* our discussion about bilateral trade agreement and TRIPS (Ch. 6.2.1.3.).
[148] Correa (2020b), 309–310.
[149] Correa (2020b), 304. See Hilty and Lamping (2014), 9 ff.
[150] Hilty and Lamping (2014), 9.

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circumstances of each case, taking into account the economic value of the authorization' (Article 31(h) of TRIPS). Patent licences generally involve a royalty. This usage fee can be calculated on different bases, for instance, on the number of units made or sold or on the licensee's income from sales.[151] The discussion on adequate remuneration is mainly about the determination of this royalty.

This provision raises three questions of interpretation: what does adequate remuneration mean? How should we understand the 'circumstances of each case'? How should we understand the requirement to take 'into account the economic value of the authorization', in effect, to consider this parameter as potentially one of many? This third question is addressed in three subsections. The sixth subsection summarises the findings.

5.3.2.1. Definition of Adequacy

The definition of 'adequacy' is crucial for the first question.[152] As Taubman argues, the burden of proof is on the party claiming that a specific remuneration is not adequate.[153] The key question will hence often appear to be the definition of *in*adequate remuneration. In that sense, it is useful to distinguish adequacy from equity. Article 31(h) of TRIPS does not require an equitable remuneration (like in Article 14(4) of TRIPS), but only an adequate one. The ordinary meaning of adequacy is about the capacity of a measure to achieve a specific goal.[154] 'X is adequate for Y' means that X can meet Y. The adequacy does not qualify the measure beyond acknowledging that it is sufficient to meet Y. It is less morally laden than equity.

Nevertheless, it would be false to consider adequacy devoid of any moral dimension. This definition raises the question of what the specific goal is that an adequate remuneration should be able to achieve. The general answer must refer here to the normative foundations of the TRIPS and, more generally, of the IP regime. The adequate remuneration is part of an arbitrage in the context of compulsory licensing, which is itself a crucial normative point of equilibrium in the TRIPS itself. The balance of the TRIPS – its interpretation both through domestic

[151] UNCTAD (2005), 469; Love (2005), 60–61.
[152] For an early contribution, Vaughan (2001), 100 ff.
[153] With reference to the principle 'in dubio mitius' as means to protect the sovereignty of States. Taubman (2008), 952.
[154] Taubman (2008), 952.

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legislation and potentially as part of a WTO dispute settlement – is at stake when it comes to defining the adequacy of the remuneration. The question should hence be addressed by drawing upon the reading of Articles 7 and 8 of TRIPS proposed and the conditions of a regime of intellectual property meant to fulfil societal objectives.[155] With respect to the first question, the parameters of remuneration set by domestic legislation is arguably adequate if these parameters do not disturb the balance that sustains the TRIPS as a general normative framework.

5.3.2.2 The Circumstances of Each Case

As for the second question, an adequate remuneration should be determined 'in the circumstances of each case'. As explained in the context of the definition of the 'normal exploitation' (e.g., Articles 13 and 30 of TRIPS), this task is unavoidably normative. The choice of these parameters and their relative weight with respect to each other reflect normative choices to be made in light of the TRIPS' foundations. In his assessment of national practices, Love notes that 'countries may legitimately arrive at a broad range of royalties, depending on policy choices they make'.[156]

Generally, the objective pursued by a Member State (the rationale for its action) must be considered as part of the circumstances of the case.[157] It seems possible to draw upon the two broad categories of compulsory licences according to their objectives: for the sake of achieving a public policy goal and for the sake of addressing anti-competitive practices.

For the first category of public policy goals, the definition of adequacy should reflect an interpretation of the TRIPS that fully integrates the human rights duties of States. The interpretation of the societal objectives upon which the TRIPS is built (Article 7 of TRIPS) requires factoring in these duties. This is the type of situation considered in the COVID-19-waiver accepted in 2022 during the pandemic: 'Determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines (. . .).'[158]

[155] In that sense, as Love states, 'it is important to note that when a patent right contributes to a lack of access to essential medicines, there is a very high level of dysfunction for an intellectual property regime'. Love (2005), 63.

[156] Love (2005), 19.56–57.

[157] Taubman (2008), 953.

[158] Ministerial Decision on the TRIPS Agreement, 17 June 2022, WT/MIN(22)/30 WT/L/1141, pt. 3(d).

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The second category of anti-competitive practices is specifically addressed by Article 31(k) of TRIPS. This provision specifies that 'the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases'. The use of compulsory licensing aims at restoring conditions of competition in a specific market.[159] As Chapter 4 argues, IPRs could, for instance, be justified because they contribute to social and economic welfare. An anti-competitive practice negates this instrumental justification.[160] The link between IPR and welfare must be restored through compulsory licensing, among other measures. Adequate remuneration is hence definable with respect to the goals of restoring competition (and the instrumental link to social and economic welfare) and, in specific situations, to remedy past abuses by the patent holder. As the UNCTAD resources book proposes, 'the level of compensation may be adjusted to reflect the need to remedy past misconduct and to affirmatively promote the entry of new competitors in the market'.[161] Love's assessment reveals that many countries set royalty at zero for this type of situation.[162]

This first clustering was based upon two general types of circumstances according to the objectives pursued (public policy or anti-competitive practices). The following three subsections address a different clustering along three types of relevant parameters to be considered when determining the circumstances: government-based, product-based, or patent holder-based parameters.[163]

5.3.2.3 Government-Based Parameters

The first group gathers cases in which the government uses the compulsory licence (or the State importing from a third State with manufacturing capacity in an Article 31*bis* regime). Structurally speaking, we could propose a first distinction between States that have *some* resources and those that have no resources at all. This hypothetical distinction is interesting because it forces us to test the different parameters.

[159] Cottier briefly discusses the function of competition policy in the EU innovation policy (rather than improving distribution) and as a means of achieving efficiency in US law. Cottier (2007).
[160] Pires de Carvalho (2014), 184–185.
[161] UNCTAD (2005), 476.
[162] Love (2005), 19-20.
[163] This type of approach is compared by Love to other approaches, Love (2005), 83–84.

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For those without resources, the question of adequacy becomes almost irrelevant: they cannot pay. Such cases include LDCs facing a situation of a public health emergency, as exemplified by Zambia in 2004 and its compulsory licence for an AIDS drug.[164] Let us assume that LDCs desperately need a specific patented drug, but they cannot remunerate the patent holder (leaving the issue of manufacturing capacity aside for the time being). The question here is whether an adequate remuneration could be equal to zero. According to a sufficientarian reading of the TRIPS, this would be acceptable. The remuneration of the patent holder should give way to the priority of an emergency. Moreover, on a different, more pragmatic level, LDCs would not have represented a relevant revenue stream for the patent holder. In that sense, the patent holder does not lose anything (assuming that anti-diversion measures are put in place).

For States with *some* resources (anything different from the assumed zero of the first scenario), adequacy should be minimal but not be zero, largely because the State has the possibility to pay something. This something should be defined according to the capacity of the State to address the situation of emergency while maintaining the value of IPRs as an investment of the patent holders (assuming a general instrumental justification of IPRs).

To define this remuneration, a sufficientarian reading could take an index measuring the level of development of a State as a proxy. The UN human development index could arguably be an example: States with a higher human development score must accept a higher adequate remuneration. In turn, this higher remuneration could be capped because of the other parameters, as discussed later.

The point is to illustrate the rationale at stake: States should define adequacy according to their capacity. The domestic legislation that Canada has chosen (Canada's Access to Medicine Regime) is an example of this approach. In the context of a third country missing manufacturing capacity, the royalty to be paid is calculated according to a formula: 'The lower the ranking on the UNHDI, the lower the prescribed royalty rate will be. (. . ..) Mathematically, the regulatory formula cannot result in a royalty rate more than four percent, a ceiling that is consistent with the

[164] Hestermeyer (2007), 249. More generally, t'Hoen et al. have identified between 2011 and 2016 100 cases of compulsory licences/public non-commercial use on patented medicine. As they note, the vast majority of these cases were part of a day-to-day procurement, without much publicity. t'Hoen, Veraldi, Toebes and Hogerzeil (2018).

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humanitarian and non-commercial considerations that are the foundation of the regime.'[165]

5.3.2.4 Product-Based Parameters and Economic Value

With respect to product-based parameters, the idea is to focus on the patented product at stake. The following features can be considered relevant: the societal value of the product (e.g., therapeutic value), the costs of development of the product, its level of maturity (new invention vs. product which has been on the market for a long period), and its rate of obsolescence. Indeed, the societal value of the patented product is also the justification for the choice to use a compulsory licence.

Investigating the societal value is a way to uncover the costs of the product and who must shoulder them. In turn this estimation can be considered a part of the adequacy standard because it reflects the required investment. A specific question arises in a situation in which public money has covered the required investment (or an important part thereof). Assuming a first case in which the same State provides public money for the development of the patented product and wants to use compulsory licensing, it seems defensible to consider that part of the adequate remuneration has already been paid. The State, through its public support, is considered a part of the R&D necessary to create the patented invention. From the perspective of the justification of IPRs, its investment needs to be valued as part of the patent's development costs.

The question is indeed different if we repeat the same scenario with two States: one State funding R&D for a patented invention and another issuing a compulsory licence. Can the second one claim that part of the investment required is covered by public support (but not *its* public support) and should be discounted from the adequate remuneration?[166] For this argument to hold, we need to assert that any kind of public support (including public money from a different State) has a special quality as part of the justification of IPRs. Indeed, this seems to be the case because of the human rights duties and responsibilities following, among others, from the right to science. Public support used to fund science is a contribution to an ensemble of knowledge which should, as

[165] Website Health Canada, www.canada.ca/en/health-canada/services/canada-access-medicines-regime/companies/application-process/royalty-payments.html (consulted 15 June 2025).

[166] Love discusses the Japanese framework to define adequate remuneration (which considers the relevance of publicly funded research). Love (2005), 69–71.

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per default, be publicly available.[167] Domestically, States that fund research programmes arguably have the duty to make this research available. Furthermore, they have a human rights responsibility to support other States in their capacity to fulfil their human rights duties. To make publicly funded research available can be seen as a way to support less advantaged States in fulfilling their human rights duties. In that sense, it seems appropriate to consider any public support involved in the R&D required for a patented product as a relevant parameter to be duly accounted for in the determination of an adequate remuneration.

A corresponding argument can be made by referring to the responsibilities of private companies. As Chapter 4 argued, these companies have a responsibility to contribute to the achievement of socially desirable goals,[168] which might indeed take the form of requirements/expectations in terms of remuneration in situations of compulsory licence and constitutes the core of the next subsection.[169]

5.3.2.5 Patent Holder-Based Parameters and Economic Value

The third category encompasses patent holder-based parameters, thereby including the 'economic value of the authorisation' of Article 31(h). The use of 'taking into account' makes clear that this economic value is one parameter that shall be factored in but is not exclusive. Furthermore, according to Article 31(d), a compulsory licence is not exclusive. The patent holder can still exploit further economic opportunities.

As the UNCTAD proposes, at least two broad approaches are conceivable.[170] Echoing product-based parameters, the first focuses on the costs involved in developing the product for the patent holder, who could be asked to justify the royalty by providing evidence of the investment it injected into the product development.[171] The adequate remuneration should hence be a contribution to the reimbursement of this investment.

[167] Yu refers to further frameworks to make this argument, namely the 'responsible research and innovation' and the 'global public good'. Both can be accounted for on the basis of the right to science. Yu (2021), 2 ff.

[168] *Infra* (Ch. 4.1.2.1.).

[169] According to Article 9 of the WHO Pandemic Agreement, States should enact provisions dealing with affordable pricing policies (thereby requiring companies to fulfil their human rights responsibilities).

[170] UNCTAD (2005), 476–477; Correa (2020b), 312.

[171] This cost-based approach has important informational costs. Love (2005), 54 ff. In favour of this approach, Shaheed 2015, § 94. For COVID-19 examples of missing

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The second approach centres on a market approach: how much could the patent holder earn with its product on the relevant market?[172] This approach does not focus on the costs of development but on an estimation of commercial opportunities of the product. This position is defended by Pires de Carvalho based on a combined reading of Article 31(h) and Article 44(2) of TRIPS.[173] Notwithstanding the specific justification, the task of evaluating potential gains must consider the specificities of the market at stake: it is not about potential revenues *per se*, but also the plausible revenues in the market Y of State X. For developing States, this paves the way to assess what segments of the domestic population could afford to pay. The example of Thailand using a compulsory licence to make a drug (antiplatelet drug *clopidogrel* against heart disease) available to people who could never afford the drug at market price illustrates the requirement to segment the different markets.[174] As Thai agencies argued, two markets coexist: people covered by State support who can get the drug at a low price and people not covered who can obtain the drug paying the usual market price.[175] The general objective is to shift from a 'low volume–high margin' pricing strategy to a 'high volume–low margin' approach.[176] This strategy indeed requires strict control over the demarcation of the distinct markets.

This market approach echoes former reflection on the 'normal exploitation' of Article 30 of TRIPS. Unsurprisingly, this approach suffers from similar problems, including the priority given to the protection of the commercial interests of the patent holder. We shall avoid considering the full exploitation of commercial interests as the default situation.

This patent holder-based category is also the place to examine the responsibility of private companies to incorporate human rights.

transparency, McMahon (2021), 143 ff. See also Committee on Social, Economic and Cultural Rights, 'Statement on Universal Affordable Vaccination Against COVID-19, International Cooperation and Intellectual Property' (23 April 2021), E/C.12/2021/1.

[172] UNCTAD (2005), 476.; See the methods of valuation of patent mentioned by Love (2005), 52 ff; Malbon, Lawson and Davison (2014), 503. For such an argument, Solovy and Raju (2021), 1200 ff.

[173] According to him, the same criteria used to assess adequate damages must be used to assess adequate remuneration, in effect, the amount of money the patent owner would make if he were commercially exploiting the patent. Pires de Carvalho (2014), 458.

[174] On this example, Thanitcul and Braslow (2013).

[175] The Ministry of Public Health and The National Health Security Office, Thailand: Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand, February 2007, p. 17. Taubman (2008), 956.

[176] Reichman and Abbott (2007), 952–953.

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To account for this responsibility would require distinguishing between different cases of private companies, a reflection which could indeed be part of the 'circumstances of the case'. A start-up firm arguably has a different responsibility than a pharmaceutical giant, though both could be patent holders and need to be paid adequate remuneration. Furthermore, as Correa mentions, the commitment of the patent holders to invest in further R&D could also be considered part of this responsibility.[177] This is, as proposed earlier, to be assessed from the perspective of the societal objectives of the IP regime (importantly the social and economic welfare).

5.3.2.6 A Republican Definition of Adequate Remuneration

Overall, the correct definition of adequate remuneration appears as a combination of these government-based, product-based, and patent holder-based parameters. Taubman argues that, in practice, agreements are found on a scale between 2 and 5 per cent royalties, despite normative disagreement about the exact justification for a specific percentage.[178] In finding a way among these parameters – qualifying them and arbitrating among them – a republican-sufficientarian reading recalls some important principles. Firstly, the definition of this adequacy is a task for the domestic legislator. How to operationalise Article 31(h) of TRIPS is part of the claim of self-determination of every Member State.[179]

Secondly, the determination of an adequate remuneration should not occur with the primary objective of protecting the commercial interests of the patent holders. Rather, the primary objective is to respect the normative foundations of the TRIPS, as expressed in Articles 7 and 8 of TRIPS. Ultimately, the parameters used to define adequate remuneration should be justifiable with respect to the societal objectives that TRIPS aims to realise.

Thirdly, the approach chosen to define adequate remuneration should not itself become a source of potential domination. It should be as clear and predictable as possible, avoiding endless negotiation with the patent holders and the threat of judicial manoeuvres that put pressure on the capacity of States to make use of compulsory licences.[180] This last point

[177] Correa (2020b), 312.
[178] Taubman (2008), 957–958.
[179] Love (2005), 81.
[180] For this point, Love (2005), 58.

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recalls that private companies also have human rights responsibilities and should act accordingly.

5.3.3 *The Mechanism of Article 31*bis *of TRIPS*

The situation of countries without manufacturing capacity has been an important source of concern. According to Article 31(f) of TRIPS, the use of a compulsory licence shall serve 'predominantly for the supply of the domestic market of the Member authorizing such use'.[181] If this is the case, countries without manufacturing capacity would have no opportunity to use such a licence and would need to import the remaining part of what is not predominantly used for the domestic market of a third country with manufacturing capacity.

This situation was acknowledged as being problematic during the HIV-AIDS crisis. Paragraph 6 of the Doha Declaration 'instruct[s] the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002'. After difficult negotiations, this 'expeditious solution' initially took the form of a waiver by the General Council Decision in 2003.[182] This Decision secondly opened the way for the (as of yet) only amendment to the TRIPS: the new Article 31*bis*,[183] which entered into force in 2017 upon acceptance of two-thirds of the WTO membership. The new article sets detailed conditions for a Member State to produce and export pharmaceutical products to an eligible Member State.[184]

Taking a republican-sufficientarian perspective, the present subsection addresses the following points: a general reconstruction of the objectives and functioning of the regime of Article 31*bis* of TRIPS; the identification of diverse risks of domination found in this regime; and a discussion of lessons learnt, not least with respect to further public policy goals, such as mainly ESTs in the context of climate change. Experience with the

[181] On the interpretation of 'predominantly', Hestermeyer (2007), 251; Pires de Carvalho (2014), 417–418; Abbott (2022a), 25 ff.

[182] General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 30 August 2003, WTO Doc WT/L/540 and Corr.1.

[183] The General Council adopted a Protocol Amending the TRIPS on the 6 December 2005. General Council Decision on the Amendment of the TRIPS Agreement, 8 December 2005, WTO Doc WT/L/641.

[184] For general commentaries, Reichman and Abbott (2007), 932 ff; Stoll, Busche and Wiebe (2013), 592–615; Taubman, Wager and Watal (2020), 204 ff; Correa (2020b), 313 ff.

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COVID-19 pandemic offers insight into the challenges and opportunities of Article 31*bis* of TRIPS.

5.3.3.1 General Functioning

Article 31*bis* of TRIPS mainly involves two derogations with respect to Article 31 of TRIPS. The first derogation bears upon Article 31(f) and its requirement to use a compulsory licence predominantly for the supply of the domestic market while the second derogation concerns Article 31(h) and its requirement to provide adequate remuneration. To avoid double remuneration, Article 31*bis*(2) requires remuneration in the exporting Member State. The remuneration should take into account the economic value to the importing Member of the use that has been authorised in the exporting Member. In addition to these two main derogations, Article 31*bis* of TRIPS regulates the required procedural elements in a detailed way.

Overall, the regime of Article 31*bis* of TRIPS is built upon the recognition of the human rights duties of States, especially regarding public health. Member States have the duty to care for their population and should have the right to cooperate with other States in fulfilling their duties. Paragraph 4 of the Doha Declaration has clearly stated that the TRIPS 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'. According to the 'Chairman's Statement' (Chairman of the TRIPS Council) before the adoption of the 2003 Waiver Decision, the mechanism 'should be used in good faith to protect public health and, without prejudice to paragraph 6 of the [Doha] Decision, not be an instrument to pursue industrial or commercial policy objectives'.[185]

For the exporting Member States, the regime that Article 31*bis* of TRIPS put in place enables them to fulfil their human rights responsibilities.[186] They support other Member States (the importing States) in their capacity to fulfil their human rights duties. The general objective of this regime is hence perfectly aligned with a human rights-based interpretation of the normative foundations of the TRIPS. As Igbowke and Tosato argue, Article 31*bis* mechanism embodies 'a solidaristic

[185] Minutes of the Meeting, WTO General Council, 13 November 2003, WT/GC/M/82, para. 29.

[186] For a list of the Member States which have adapted their domestic legislation, www.wto.org/english/tratop_e/trips_e/par6laws_e.htm (consulted 15 June 2025).

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mechanism designed to allow developing countries to benefit from the technological prowess of foreign pharmaceutical industries at affordable prices. Though it is undeniable that Article 31*bis* has not yet borne fruit, the ambitious idea at its core holds great promise.'[187]

Though the general objective of Article 31*bis* of TRIPS appears correct its concrete design has been the object of numerous criticisms, as summarised with the following points.[188] Firstly, the system has been described as too administratively burdensome.[189] The required procedural steps are too demanding and must be fulfilled before the licence can be issued, making the system too inflexible to respond to crises and emergencies.[190] Secondly, the system can be demanding for the exporting Member State and might discourage generic producers from engagement.[191] Among other detrimental economic incentives, the notification of quantities of drugs to be exported to a single Member State and the strict conditions to secure anti-diversion raise important concerns for the companies that need to cover investment and production costs.[192] Thirdly, on a different level, the discussion on Article 31*bis* of TRIPS falls under the general discussion on compulsory licences. In that context, powerful trading partners and/or private companies have reacted aggressively to standard compulsory licences, for instance, in the case of Thailand between 2006 and 2008. These aggressive reactions can have the effect of deterring Member States from making use of their TRIPS-compliant competencies.[193] However, there is evidence that reactions have evolved, also due to public pressure and reputational risks.[194]

Overall, the system has been criticised for failing to deliver its main objective: enabling Member States to fulfil their human rights duties and responsibilities, especially with respect to the right to health and the

[187] Igbokwe and Tosato (2022), 56.
[188] For an overview, Mellino (2010), 1374 ff; Owoeye (2015); Igbokwe and Tosato (2022), 39 ff; Davies (2022), 7 ff. Moreover, Vincent argues that the system is not ready for novel pharmaceutical products that do not rely on a single active ingredient. Challenges for biologics relate to labelling requirements, modes of production and transport, and patient-tailored treatment. Vincent (2020), 24 ff.
[189] Reichman and Abbott (2007), 940 ff. See Grover (2009), § 41.
[190] Paas (2009), 613; Igbokwe and Tosato (2022), 49–50.
[191] Pires de Carvalho (2014), 387; Davies (2022), 8,11.
[192] Reichman and Abbott (2007), 943–944; Joseph (2011), 228–229; Igbokwe and Tosato (2022), 51 ff. The authors refer to pooled procurement strategies used by groups of countries as a potential way to deal with this issue.
[193] Igbokwe and Tosato (2022), 40–42.
[194] Baker (2021), 302–319.

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supply of pharmaceutical products.[195] As discussed in the literature, the interface between Article 31*bis* and Article 39(3) of TRIPS (about the protection of undisclosed data) could worsen the problem.[196] Article 39 (3) of TRIPS offers a 'protection against unfair commercial use', a concept whose contours are still disputed and which complexifies development of generic drugs.[197] The required protection of data as part of a regulatory review could indeed represent a further time-consuming burden for the importing country.[198]

In presenting these criticisms, commentators usually refer to the only (as of yet) existing case (Rwanda and Canada).[199] As part of its Access to Medicine Regime, Canada exported an antiretroviral drug using a compulsory licence to Rwanda in 2007.[200] In 2010, the Canadian generic manufacturer Apotex presented its view on this experience as part of the debate about the reform of the Canadian legal regime on drugs for humanitarian purposes. The company had been critical of the way Canada had implemented its TRIPS' obligations and the burden it had represented for a generic company.[201] Interestingly, Apotex noted that the Canadian regime as built upon Article 31*bis* of TRIPS could not be compared to an efficient mechanism to obtain access to a drug: 'the fact that countries cannot place a simple order or extend a tender for a specific product but have to initiate what is perceived to be a "political" or legal process is in itself intimidating'.[202]

[195] This criticism can be labelled 'ritualism', in effect, institutionalised means for securing regulatory goals while losing focus on achieving the goals or outcomes themselves. For references, Abbas and Riaz (2018), 34 ff.

[196] Vincent (2020), 27 ff. As discussed later, this issue can be made even more problematic through FTAs. See Grosse Ruse-Khan (2020).

[197] For an overview of the doctrinal debate, Spina Alì (2018).

[198] Malbon, Lawson and Davison (2014), 582 ff. With respect to the COVID-19 crisis, Thambisetty, McMahon, McDonagh, Kang and Dutfield (2021), 22.

[199] For references to the attempts by Ghana (2005), Nepal (2008), and Bolivia (2021), Igbokwe and Tosato (2022), 38–39.

[200] For the notification by Rwanda, Rwanda, Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 19 July 2007, Council for TRIPS, WTO Doc. IP/N/9/RWA/1.

[201] For a criticism of the Canadian regime, Lybecker and Fowler (2009); Houston and Beall (2019); Davies (2022), 9–11. For further references of the involved actors, such as MSF, Abbas and Riaz (2018), 40 ff.

[202] Apotex Inc 'Submission to the Standing Committee on Industry, Science and Technology' (26 October 2010) on Bill C-393, an Act to Amend the Patent Act (drugs for international humanitarian purposes) and to make a consequential amendment to another Act.

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Most recently, the challenge to supply all Member States with anti-COVID vaccines has also presented an opportunity to reiterate criticisms about the efficiency of the Article 31*bis* TRIPS regime.[203] In 2020, India and South Africa submitted a waiver of specific IPRs relevant for the sake of ensuring the widest possible supply of pharmaceutical products to cope with COVID-19. In their communication, they underlined that 'a particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31*bis* and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products'.[204] Following opposition by developed economies and difficult negotiations on this waiver proposal, a Ministerial Decision was adopted in June 2022.[205] This decision lays down a waiver regarding some of the provisions of Article 31 of TRIPS.[206] Article 10 of the Pandemic Agreement (titled *Sustainable and geographically diversified local production*) calls on States to 'achieve more equitable geographical distribution and rapid scale-up of the global production of pandemic-related health products and increase sustainable, timely and equitable access to such products'.

Firstly, the requirement of Article 31(f) of TRIPS can be waived, and a Member is allowed to export any proportion of the products manufactured to other Member States. Secondly, the decision calls on Member States to undertake all reasonable efforts to prevent the re-export or diversion of products. This decision has been criticised as a watering down of the initial demands formulated by India and South Africa. It illustrates the difficulty in designing an efficient and easy-to-use system of compulsory licences for States lacking sufficient manufacturing capacity. The COVID-19 crisis has shown that the regulation in force in 2020 – but arguably also that of 2022, considering the waiver accepted – is unable to guarantee the supply of pharmaceutical products to developing States deficient in manufacturing capacity.

[203] Bolivia has notified the TRIPS Council in May 2021 that it wanted to import COVID-19 vaccines. Bolivia Notification of Need to Import Pharmaceutical Products Under the Special Compulsory Licensing System, 11 May 2021, WTO Doc. IP/N/9/BOL/1. For critical assessments, Thambisetty, McMahon, McDonagh, Kang and Dutfield (2021), 14 ff; Zaman (2024), 398.

[204] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Communication from India and South Africa, 2 October 2020, IP/C/W/669.

[205] Ministerial Decision on the TRIPS Agreement, 17 June 2022, WT/MIN(22)/30 WT/L/1141.

[206] For a critical view, Hilty, Batista, Carls, Kim, Lamping and Slowinski (2021).

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5.3.3.2 Risks of Domination

Expressed in a republican framing, the regime created by Article 31*bis* of TRIPS is characterised by numerous risks of domination. Firstly, the general objective of the regime addresses and simultaneously reinforces a risk of domination: a State without sufficient manufacturing capacity is at risk of facing arbitrary interferences by States with manufacturing capacity,[207] the latter of whom can decide to help or not. The same applies to manufacturing companies. Both actors can decide (or refuse) to help without considering the interests of the importing State.

Secondly, the administrative and processual burden required from the importing State could be considered a form of domination. Every step involves a situation of vulnerability in a context of deep uncertainty about the exact expectations and standards of assessment. The risk of being challenged in a judicial proceeding represents a Damocles' sword hanging over the overall process.

Thirdly, this lengthy process prevents the importing Member State from prioritising its public health interest because it cannot act quickly and reactively but is forced to notify further parties whose interests are sometimes very different, if not contradictory. The patent holders' commercial interests are considered important (for instance, through the burdensome requirement to change packaging and take measures to prevent re-exportation and diversion).[208] These requirements can indeed be understood *per se*, but they conflict with public health demands in a situation of scarcity of time and resources.

Overall, one of the risks is to restrict the analysis to the rights enjoyed by States by virtue of the TRIPS, such as the rights protected by Articles 31 and 31*bis* of TRIPS. However, these rights are difficult to draw upon. On the one hand, Member States fear retaliation on the part of powerful trading partners (States), but also private companies (such as pharmaceutical companies).[209] On the other hand, the exercise of these rights can itself be a source of domination because of the administrative and financial burden or legal uncertainty it creates.

[207] As Grosse Ruse-Khan explains it: '(. . .) the key hurdle in all these scenarios is to find countries that have enough approved facilities to produce medicines for us all: not only for its own population, but especially for poor countries with no or little manufacturing capacity'. Grosse Ruse-Khan (2020).

[208] Annex to the TRIPS, pt. 2 and 3.

[209] For the example of the reactions in Brazil and Thailand following compulsory licensing, Reichman and Abbott (2007), 954–956, 980–981.

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C. Four Republican Lessons on Article 31*bis*

In reply to these challenges, the republican approach focuses on the concrete capacity of States to make use of the rights protected by the TRIPS,[210] with four main lessons identified.

The first republican-sufficientarian lesson learned is about the responsibility of the involved actors. Firstly, for the importing States in need of specific pharmaceutical products, an anti-domination strategy could be to pool forces. This strategy appears as the most promising to address negative economic incentives set by Article 31*bis* of TRIPS. In designing a regional pooled approach, the objective would be to standardise processes and increase the quantities to be produced, thereby reducing problems related to scale and uncertainty for the market of a single State.[211] Article 31*bis*(3) of TRIPS foresees such an approach, with the requirement that half of the partners be LDCs.[212] This kind of approach could prove to be a compelling incentive for the pharmaceutical sector (both the patent holder and the potential generic manufacturer), but also in terms of the required technical assistance, transfer of know-how on working a patent, and production of the drug for the developing countries involved in the pooling strategy.[213]

However, beyond the strategies that importing States might adopt, a responsibility-based framing is also relevant for: exporting States (based on the Article 31*bis* mechanism), States designing the general IP protection regime (the WTO membership), and private companies. All have human rights responsibilities to interpret, apply, and, if required, revise the TRIPS in a manner supportive of the capacity of every State to fulfil its human rights duties. Exporting States have the responsibility to support States willing to use the Article 31*bis* mechanism. For that purpose, they need to prepare their domestic legislation, thereby drawing upon best practices from other States.[214] Private companies such as generic manufacturers but also patent holders also have human rights

[210] See Abbas and Riaz (2018), 33.
[211] Reichman and Abbott (2007), 973.
[212] Abbott and Reichman present a fictitious case of twelve African countries adopting this approach. Reichman and Abbott (2007), 974 ff. See t'Hoen, Veraldi, Toebes and Hogerzeil (2018).
[213] Igbokwe and Tosato (2022), 57. See also Article 11(5) of the WHO Pandemic Agreement.
[214] See the comparative analysis by Kampf (2019). For references to the Canadian system and how it could be improved, Davies (2022), 9 ff.

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responsibilities.[215] Finally, the general WTO membership has the human rights responsibility to make sure that interpretation of the current text occurs in a way that supports Member States in their duties. This could be done by formulating interpretative guidance like the Doha Declaration[216] or by revising the TRIPS' text, as was done with the introduction of Article 31*bis* of TRIPS.

Secondly, an important part of this responsibility is about the underlying debate on the requirement of non-discrimination of Article 27(1) of TRIPS. Patents shall be available and patent rights shall be enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.[217] This work's republican framing considers this issue as another example of why States must be given maximum interpretative latitude to define a concept such as 'discrimination'.[218] This issue was central in the *Canada – Pharmaceutical Products* dispute.[219]

Two points directly relate to the interpretative latitude that States should enjoy. Firstly, the Panel has emphasised the justifiability of legislative acts and their specific effects on the enjoyment of patent rights. In that sense, Article 27(1) of TRIPS only prohibits distinctions in patent law concerning the availability and enjoyment of rights, but not in the general policy choices of a State.[220] Secondly, Article 27(1) of TRIPS does not prohibit, in the words of the Panel, 'bona fide exceptions to deal with problems that may exist only in certain product areas'.[221]

In the context of Article 31 of TRIPS,[222] the question could be shifted to the justification of differential treatment between local working

[215] McMahon discusses them by referring to the idea that patent holders exercise a governance function in choosing what to do (or not do) with their patent. McMahon (2021), 143 ff.

[216] Abbott and Reichman emphasise that what is needed to make the regime work is 'willpower, skill and resources'. Reichman and Abbott (2007), 969.

[217] Pires de Carvalho (2014), 248 ff; Correa (2020b), 264.

[218] Lee (2016), 368; Zhuang (2017), 237 ff.

[219] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.94.

[220] Maskus (2010), 20.

[221] Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.92.

[222] The relationship between Article 27(1) of TRIPS (non-discrimination) and Article 31 (compulsory licence) is itself disputed. Panel Report, *Canada – Patent Protection of Pharmaceutical Products,* para. 7.88 ff, especially 7.91: 'In the Panel's view, what was important was that in the rights available under national law, that is to say those resulting from the basic rights and any permissible exceptions to them, the forms of discrimination referred to in Article 27.1 should not be present.' Contrary to this position, Correa (2020b), 274 ff.

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requirements and importation.[223] Member States could hence argue that a local working requirement is, firstly, fully covered by their right to choose the grounds for a compulsory licence and is, secondly, also aligned with their obligations to support their population (as required by Articles 7 and 8 of TRIPS).[224] This line of argumentation has a normative dimension (based on the proposed reading of the TRIPS along human rights duties), but also an empirical one. The State must namely show that the local working requirement is superior to meeting its population's needs with imports, mainly with respect to the transfer effects of know-how/technological capacity. Following Cottier and co-authors, the empirical dimension of the question is about providing justification for a local working requirement being 'beneficial'.[225] Considering Article 7 of TRIPS, the question can be approached as a determination of the social and economic welfare-enhancing effect of the local working requirement. This opens the door to a situated assessment that considers the situation of the country at stake, but also the type of patented invention.

The third lesson learnt underlines the necessary connection between the discussion of Article 31*bis* of TRIPS and the broader issue of providing information and assistance and improving technology transfer.[226] Information and assistance as part of technical cooperation will be addressed later in the discussion of Article 67 of TRIPS. For the time being, it is important to note that the use of Article 31*bis* mechanism requires information about the functioning of the mechanism, but also assistance (technical, legal, and organisational) to concretely enable its use.[227] In the context of the COVID-19 crisis, voluntary licensing and resource-pooling initiatives could be mentioned.[228] In light of our framing, they represent attempts to fulfil States' and private companies' responsibility for human rights.[229]

[223] Taubman speaks of a 'bona fide' intervention. Taubman (2008), 933. See also Cottier, Lalani and Temmerman (2013), 9; Zhuang (2017), 288.

[224] For a similar argumentation, Mercurio and Tyagi (2010).

[225] For a list of economic parameters to be factored in the assessment of the justification, Cottier, Lalani and Temmerman (2013), 18 ff.

[226] Matthews (2005), 423 ff; Erfani, Binagwaho, Jalloh, Yunus, Farmer and Kerry (2021), 1838 ff.

[227] For an analysis of the Canada/Rwanda experience, Davies (2022), 8.

[228] Open Covid Pledge, and the World Health Organization's (WHO) Covid Technology Access Pool (C-TAP). McMahon (2021), 146 ff. On similar established schemes, such as GAVI, Bostyn (2020), 260 ff; Thambisetty, McMahon, McDonagh, Kang and Dutfield (2021), 12 ff.

[229] Contreras, Eisen, Ganz, Lemley, Molloy, Peters and Tietze (2020).

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Furthermore, technology transfer, as required by Article 7 and by Article 66 of TRIPS, is an important contribution to addressing risks of domination. Clearly, the *raison d'être* of Article 31*bis* of TRIPS (missing supply of drugs in developing countries) should and could be addressed in the first place by improving the manufacturing capacity of developing States. As discussed in Chapter 4 regarding the access modality of human rights, the responsibility of affluent States is not only to fairly distribute existing goods (such as drugs), but also to provide support in a more infrastructural sense. The long-term objective of capacity building is recognised in the TRIPS' Annex.[230] Today, this capacity is very unevenly distributed, resulting in situations of domination between the States requiring drugs and those able to manufacture them.[231] As shown based on the right to science, affluent States have a responsibility to help others build their capacity to conduct scientific research and produce scientific benefits and applications. Improving this capacity addresses the primary source of problems, thus reducing pressure on the Article 31*bis* mechanism.[232]

As Abbott and Reichman described, almost euphorically, 'over time, this network of mutual assistance could grow into a formidable self-help production system, which could exert pressure on patentees everywhere to price discriminate on a "high-volume–low-margin" basis in developing countries generally'.[233]

The fourth lesson learnt somehow paradoxically calls attention to other avenues than Article 31*bis* of TRIPS that have been identified to address the problem of missing manufacturing capacity for pharmaceutical products. Two are worth mentioning as they could play a role in the subsequent discussion on further policy goals.[234] Firstly, recourse to an exception in the sense of Article 30 of TRIPS is conceivable.[235] If Articles 30 and 31 of TRIPS are thought of together as forming a whole, the recourse to Article 30 of TRIPS would mean no obligation of adequate remuneration or prior negotiation. Indeed, it would require fulfilling the

[230] TRIPS Annex, § 6.
[231] For UNCTAD's analysis with respect to the COVID-19 crisis, https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries (consulted 15 June 2025).
[232] Vincent (2020), 33 ff; Correa (2020a), 3.
[233] Reichman and Abbott (2007), 977.
[234] McManis and Contreras (2014), 113–114.
[235] Drahos (2007), 21–22; Reichman and Abbott (2007), 956–957, 986; Abbott (2022a), 33 ff.

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cumulative conditions of Article 30 of TRIPS which, as shown earlier, prove demanding. However, the key rationale is that an exception-based export does not harm the domestic market and, depending on the conditions of the importing State (assuming that it is a developing economy), the argument about 'normal exploitation' could be made. If the developing economy's market does not represent an important revenue stream (or indeed any at all for LDCs), then a 'normal exploitation' condition could be interpreted as being fulfilled. The Doha Declaration and the human rights responsibilities of States to support other States can be used as normative foundations for this argument.

The second option is to use anti-competitive policy to justify the export of patented pharmaceutical products.[236] In the hypothetical situation in which a patent holder prevents the export of its patented drug to a developing country, it might be thinkable for the exporting State to address the situation using its domestic competition policy and, on that basis, force the export of the drug. Both Article 8(2) and Article 31(k) of TRIPS enable Member States to adopt appropriate measures to prevent the abuse of IPRs and address anti-competitive practices.[237] The determination of a domestic competition law remains firmly in each Member State's hands, as protected by the carve-out of Article 40(2) of TRIPS.[238] Cottier describes this as a significant triangle in which trade regulation (TRIPS), competition law (domestic law), and human rights converge.[239] The main question relates to the domestic competition law that needs to regulate this type of situation. Eventually, it also questions the objectives of domestic competition law, ranging, for instance, from innovation policy to consumer protection to distributive goals. Each of these parameters is one piece of a complex regulatory framework that every Member State needs to define for its own purposes.

The important insight is to recognise that the TRIPS leaves open a venue, though for exceptional circumstances, to use competition law as a means of justifying an easier export of important drugs. The argument provides a further opportunity for human rights responsibilities to positively affect trade law through the route of domestic competition law.[240]

[236] Matthews (2005), 422 ff; Abbott (2022a), 32 ff.
[237] Hutchison (2006), 534–535.
[238] Abbott (2005), 286–287. For a discussion of the EU practice, Bostyn (2020), 267 ff.
[239] For this argument, Cottier (2007), 184 ff.
[240] Abbott (2005), 289 ff.

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Indeed, the argument is strengthened if the patented product at stake is an essential drug.[241]

This responsibility is reinforced by a clear position taken on public health challenges as constituting a shared global concern (such as in the Doha Declaration or in the Pandemic Agreement). Expressed in the republican framing, this recognition means that Member States have human rights responsibilities to support other States in addressing challenges that are qualified as a shared global issue. As the next subsection addresses, the same argumentative structure applies to further challenges recognised as representing a common global concern.

5.3.4 *Exporting Patented Technologies to Address Further Policy Goals*

One of the crucial questions raised by the Article 31*bis* mechanism is the extension of the States' responsibility beyond pharmaceutical products and, more generally, beyond public health concerns. Structurally, the issue that Article 31*bis* of TRIPS is meant to address (missing manufacturing capacity) is relevant beyond public health.[242] This subsection addresses different strategies: a broad interpretation of health, the use of compulsory licensing in the context of climate change policy, the opportunity of a new 'Doha Declaration', and the specific features of structural technological domination.

5.3.4.1 Broad Interpretation of Health

Public health arguably constitutes a starting point to address further health-related threats. However, the text of Article 31*bis* of TRIPS (referring to the definitions entailed in the Annex) clearly restricts the mechanism to pharmaceutical products. Interpretative opportunities are to be found in the Doha Declaration, which is not focused on pharmaceutical products. Indeed, its Paragraph 4 mentions public health and, only by using the term 'in particular', promotes access to medicines for all. This paragraph recalls that the TRIPS does not and should not prevent Member States from interpreting the phrase 'taking measures to protect public health' broadly. With respect to the use of compulsory licences, paragraph 5(2) of the Doha Declaration clearly states that 'each member has the right to grant compulsory licenses and the freedom to determine

[241] Abbott (2005), 293.
[242] McManis and Contreras (2014), 115 ff.

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the grounds upon which such licenses are granted'. This statement – which does not create new rights but only clarifies the TRIPS' text – opens up synergies in thinking about the impact on public health of further public policies, such as climate change. If it can be shown that, for instance, climate change has a detrimental effect on public health, Member States would have the competence to use the flexibilities foreseen by the TRIPS.

5.3.4.2 Compulsory Licences and Climate Change

However, the argument should even go beyond this strategy of a broad interpretation of public health. As explained previously, nothing in Article 31 of TRIPS limits the grounds that Member States can refer to in order to issue compulsory licences. Expressed formally, State X needs the supply of patented invention Y to address public policy challenge Z. The public policy challenge Z must not be a public health challenge. If the State X can fulfil the conditions prescribed by Article 31 of TRIPS, it could then use compulsory licensing.

The main extension discussed concerns ESTs in addressing climate change.[243] Climate change and its implications represent a threat to many rights discussed in the previous chapters, most importantly the human right to life, to health, and to food.[244] A human rights-based interpretation of the TRIPS indeed reinforces the case for the use of compulsory licensing in the context of EST.

The argument raises several issues. Firstly, a compulsory licence should not be misinterpreted as an exclusive solution; rather, it could be one of the actions taken by a government to face a public policy crisis. In that sense, whether there might be other ways to transfer knowledge more efficiently to developing countries is indeed a complementary path.[245]

Secondly, the use of a compulsory licence assumes that the conditions of Article 31 of TRIPS are fulfilled. Importantly, as argued earlier, the fact that the climate change crisis is, in the short term, not as acute as an

[243] Maskus and Okediji (2010); McManis and Contreras (2014), 130 ff; Zhuang (2017), 300 ff; Abbe Brown (2020), 814 ff. ESTs are used here as a short-hand. Other concepts include green technologies, decarbonisation technologies, and energy technologies. On these definitions, McInerney (2011), 452.

[244] Special Rapporteur J. Knox, 'Report of the Special Rapporteur on the Issue of Human Rights Obligations Relating to the Enjoyment of a Safe, Clean, Healthy and Sustainable Environment', 2016, A/HRC/31/52 (cited as Knox 2016).

[245] See the scepticism of Maitra (2009), 10 ff.

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epidemic as COVID-19 does not prevent States from using Article 31 of TRIPS.

Thirdly, it might be argued that compulsory licences on ESTs will not be able to have similar effects as for pharmaceutical products. Differences between these industries – including the complexity of the patented goods at stake, but also the know-how necessary to work the patent – make ESTs less appropriate for compulsory licences.[246] As Watson and co-authors argue, compulsory licensing should hence be put in the broader context of an efficient technology transfer scheme.[247] However, these potential counterarguments are mainly empirical. They describe a potential difference between distinct industries and provide implications for the potential benefits of using compulsory licences.[248] However, they do not constitute legal or normative arguments against the possibility of this use.

Fourthly, political risks can stand in the way of compulsory licences on ESTs. As for access to drugs when the TRIPS entered into force, opposition arose from private patent holders and the States in which they are based (mainly developed economies). As mentioned earlier, they will try to use soft or hard pressure and retaliation measures to prevent States from using compulsory licences.

Fifthly, States without manufacturing capacity face an additional difficulty: they need States able and willing to export ESTs that they cannot produce to them. In facing this challenge, States without sufficient manufacturing capacity could focus on a renewed interpretation of Article 31(f) of TRIPS. The objective is to adopt an interpretation that allows supporting Member States to export patented ESTs under a compulsory licence. The COVID-19 waiver adopted in the summer of 2022 could indeed be taken as evidence of the possibility to relax the strict interpretation of Article 31(f) of TRIPS.[249] Further inspiration for this argumentation can be found in discussions that were held before the decision on Paragraph 6. As Hestermeyer argues, for instance, the right to health can be used to favour an interpretation of 'predominantly' for the internal market based on the State's intent. The percentage of

[246] Fair (2010), 39–40; Ni (2015), 712; Machnicka (2016), 430 ff.
[247] Watson, MacKerron, Ockwell and Wang (2007), 7.
[248] Although they are often associated with arguments recalling that IPRs in general are a better way to encourage technology transfer. See Lane (2011), 63 ff.
[249] See Paragraph 3(b) of the Ministerial Decision on the TRIPS Agreement, 17 June 2022, WT/MIN(22)/30 WT/L/1141.

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production being exported would not be decisive here, but rather the primary intent of the exporting Member State.[250] This strategy needs to draw upon human rights duties of both the importing State and the exporting State. Human rights provisions which could be linked to climate change and, more specifically, to the empirical impact of the patented ESTs could be used as justification for a renewed interpretation of Article 31(f) of TRIPS.

5.3.4.3 The Opportunity of a Renewed 'Doha Declaration'

However, this strategy creates important risks of domination for the importing State. First, it takes risks on its own count (retaliation). Second, it is fully dependent upon the support of a State with manufacturing capacity. This exporting State, in turn, also takes a risk for not being compliant with Article 31(f) of TRIPS. To address this multidimensional risk, and more generally to reiterate support for the flexibilities entailed by Article 31 of TRIPS, WTO Member States could decide to provide interpretative guidance for compulsory licence in the form of a Declaration on TRIPS and climate change.[251]

As with the Doha Declaration, such a Declaration would need to cover two distinct parts. Firstly, it needs to reaffirm the flexibilities entailed by the TRIPS. This is especially important for the right of Member States to define grounds for the use of compulsory licences. This Declaration does not need to create new rights, but only to reaffirm the existing ones and protect the concrete capacity of States to use them. Secondly, it needs to address specifically the situation of States without sufficient manufacturing capacity. It could, for instance, partially waive the obligation of Article 31(f) of TRIPS. The main objective would be to provide a political backup for Member States making use of compulsory licences in a context similar to that of Article 31*bis*.[252] Indeed, this political backup could extend or focus on further alternative venues, such as those briefly presented earlier (e.g., Article 30 and Article 31(k) of TRIPS).

This renewed 'Doha Declaration' has already been proposed in different fora. At the UNFCCC (United Nations Framework Convention on Climate Change) Conference of the Parties of 2007 in Bali, Brazil proposed to work on a Declaration on IP and climate change that would have

[250] Hestermeyer (2007), 251.
[251] Abbe Brown (2020), 822 ff.
[252] For such an argument, Nanda (2009), 245; Abbott (2009), 27 ff; Correa (2016b), 89; Abbe Brown (2017), 972; Rimmer (2019), 9.

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taken a similar structure as the Doha Declaration.[253] In Copenhagen at the COP-15 in 2010, the interface between IP and climate change was highly contentious and China and India (as representatives of the group of the '77') pushed for commitments on compulsory licences on climate technologies.[254] In 2013, Ecuador proposed a Communication in the Council for TRIPS with two main objectives: (1) 'reaffirmation of the existing flexibilities in the TRIPS Agreement so that Members use them in connection with ESTs, for example through a declaration addressing flexibilities in the TRIPS Agreement, climate change and access to ESTs' and (2) 'initiation of a review of Article 31 of the TRIPS Agreement to determine which of its provisions may excessively restrict access to and dissemination of ESTs, and particularly its paragraph (f) and the need to include provisions on, as the case may be, the transfer of expertise or know-how to implement compulsory licences'.[255]

However, several authors have argued that such a Declaration would not fundamentally change the political power relations at stake[256] because the use of compulsory licences would remain a risky decision for the involved actors. The interface between IP and climate change has been highly disputed, not least with respect to the chosen forum in which to hold this debate.[257] As mentioned, the UNFCCC has been the main forum chosen by developing States pushing for a Doha-style Declaration on IP and climate change. They have based their action on Article 4 of the UNFCCC, especially Article 4(5). The Kyoto Protocol also mentions technology transfer in its Article 10, calling for 'cooperating in the promotion of effective modalities for the development, application, and diffusion of, and taking all practicable steps to promote, facilitate and finance, as appropriate, the transfer of, or access to, environmentally

[253] Ni (2015), 708; Abbe Brown (2017), 93 ff. Finally, the Bali Action Plan decided in 2007 only contains one occurrence of 'intellectual property' in its Annex. Article 12(b) of the Annex calls: 'To encourage Parties to avoid trade and intellectual property rights policies, or lack thereof, restricting transfer of technology.' UNFCCC, Report of the Conference of the Parties held in Bali from 3 to 15 December 2007, 14 March 2008, FCCC/CP/2007/6/Add.1.

[254] Cheng (2022), 388.

[255] Communication from Ecuador: Contribution of Intellectual Property to Facilitating the Transfer of Environmentally Sound Technology, 27 February 2013, Council for TRIPS, WTO Doc. IP/C/W/585, § 17.

[256] For references, Cheng (2022), 393 ff.

[257] On the strategy of forum shopping as a lesson learnt from the public health debate, Abbott (2009), 19 ff.

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sound technologies (...) in particular to developing countries'.[258] The fate of this specific interface between IP and climate change is particularly exemplified by the Paris Agreement negotiations. Fiercely debated during rounds of preparation, the interface does not appear in the final Agreement, which only refers to technology transfer in general (Article 10 Paris Agreement).[259] Intellectual property is not mentioned in the final text. In the context of IP-related fora, WIPO has also played an important role with its '*Green initiative*'.[260]

If the connection between IPRs and technologies that could help prevent and mitigate climate change is strongly advocated by developing economies, developed economies and patent holders have pushed the argument that strong IPRs are a precondition for technology transfer. Contrary to this line of argument, my reconstruction of the normative foundations of the TRIPS has shown that IPRs depend upon the fulfilment of broader societal objectives, among which climate change prevention and mitigation appear crucial. In that sense, authors have also addressed further IP-strategies potentially useful in improving the supply of ESTs. These strategies draw upon patent flexibilities[261] but also further IPRs.[262]

Overall, compulsory licences, or even further flexibilities of the TRIPS, cannot alone address the multiple dimensions of climate change as a policy challenge. However, the fact that compulsory licences are not the solution to all problems does not logically mean that they cannot contribute to the solutions.[263] As I will discuss later, there is an important connection to be made with the obligations of Article 66 of TRIPS to promote technology transfer. Moreover, a Doha-type declaration appears as a strategic move that allows for the promotion of several important messages: (1) the common global concern that climate change represents, (2) the uneven distribution of technological means to prevent, mitigate,

[258] Kyoto Protocol to the UNFCCC, entered into force on 16 February 2005 (cited as Kyoto Protocol).

[259] Rimmer (2018). The struggle to put IP and climate change on a common agenda has numerous examples. See Machnicka (2016), 424–425.

[260] WIPO Green The Sustainable Technology Marketplace, Charter, February 2013. Brown mentions the example of 'eco-patent commons' as a scheme that was put in place as part of this WIPO Green Initiative. Abbe Brown (2017), 981 ff.

[261] Machnicka discusses the improvements to be made in the functioning of the patent system (incl. national patent offices). Machnicka (2016), 428–429.

[262] These include trade secrets, industrial design, and copyright. For a discussion, Abbott (2009), 4 ff.

[263] Machnicka (2016), 418–419.

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or adapt to climate change and its consequences, (3) the requirement to think about these challenges as issues of justice, and (4) the reference to human rights duties and responsibilities for States and private companies, both in an access modality but also in an infrastructural modality. As shown by the public health debate, these messages represent the core of an efficient public communication and advocacy movement that fully acknowledges that the TRIPS is not only a legal reality, but also a political framing of extreme importance for the international IP regime.[264]

5.3.4.4 Addressing Structural Technological Domination

Beyond climate change and ESTs, one should push the argument further and address hypothetical structural risks of technological domination. As my reading of Article 7 of TRIPS argues, technological domination could be especially challenging because it imposes structural weaknesses that question the capacity of developing and least-developed economies to compete on fair terms in several sectors. This not only represents an occasional weakness, but also a substantial structural downgrading.

Assuming a situation of technological domination, the question hence arises about the use of compulsory licences. These licences would not be used to address a specific, immediate threat to the public, but rather to prevent or mitigate a situation of structural domination. Compulsory licences would then be used to empower a State to compete globally. Of course, the use of compulsory licences is not an exclusive solution and should be part of an ambitious technology transfer agenda.

Interestingly, the idea of anti-competitive practices could here be drawn upon, albeit at a different level. It is the overall economic, industrial, and innovative capacity of a State that is threatened by anti-competitive practices preventing this State from competing on fair terms with other States. With the objective to restore fair international competition, the use of compulsory licences would hence level the playing field.

This approach proves politically difficult to defend. Indeed, as the Chairman's Statement read before the 2003 Waiver decision recalls, 'Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.'[265] The last part of

[264] Abbott (2009), 19 ff; Thambisetty, McMahon, McDonagh, Kang and Dutfield (2021), 37.
[265] Minutes of the Meeting, WTO General Council, 13 November 2003, WT/GC/M/82, para. 29.

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this sentence has been considered crucial in obtaining the support of developed economies, especially the United States. Compulsory licences used in the context of the Article 31*bis* mechanism should not be used for the sake of industrial or commercial policy objectives.

Indeed, the idea of structural technological domination goes further than that. To clearly see the difference necessitates imagining a hypothetical case in which fair competition among States is made impossible (e.g., in key industrial sectors) because of several patented inventions.[266] Assuming this scenario, a republican-sufficientarian reading of the TRIPS would provide a justification for the use of compulsory licences, combining Article 8 and Article 31 of TRIPS. The republican dimension (preventing arbitrary interferences and securing fair competition) and the sufficientarian dimension (allowing individuals to reach a determined threshold in terms of capabilities) converge to empower Member States to break out of this structural domination.

5.4 Technology Transfer and Technical Assistance

Article 66 of TRIPS is titled 'Least-developed country members' and Article 66(1) of TRIPS in particular deals with the general principle of differentiated responsibility for LDCs. To recall, the Committee for Development Policy (a body of the Economic and Social Council) is responsible for the status of LDCs. Currently, forty-six countries have this status, encompassing 12 per cent of the world population.[267] As part of Title VI regarding 'transitional arrangements', Article 66(1) is the legal basis for the transition period for LDCs in preparing their domestic legislation to respect TRIPS obligations. In brief, the transition period allows LDCs to apply only the provisions of Articles 3, 4, and 5 of TRIPS. In June 2021, this transition period was extended for an additional time up to 1 July 2034.[268]

Article 66(2) of TRIPS deals with specific obligations for developed States on technology transfers for LDCs. Article 66(2) is taken together with Article 67 of TRIPS about technical cooperation. The subject matter

[266] I have proposed such a hypothetical scenario based on a super, brain capacity-enhancing drug. See Rochel (2019a).

[267] For the current list, www.un.org/en/conferences/least-developed-countries (consulted 15 June 2025).

[268] Extension of the Transition Period Under Article 66.1 for Least Developed Country Members, Decision of the Council for TRIPS of 29 June 2021, WTO Doc IP/C/88.

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of the two provisions is different (though arguably related), but both prescribe obligations for developed States. Several authors have considered these provisions as part of a package characterised by the fact that they both describe obligations for developed States in their relations towards LDCs.[269]

The issue of technology transfer has been especially challenging. Stakeholders have not been able to find common ground on the definition of the concept, how to measure it, and how to best realise it.[270] The attempt under the auspices of the UNCTAD to negotiate an international agreement on technology transfer (Draft International Code of Conduct on the Transfer of Technology) bears evidence of these difficulties. This Code of Conduct has never been adopted as an international instrument.[271]

This section is organised into four parts: a clarification of the key terms of Article 66(2) of TRIPS, a proposal on how to allocate technology transfer obligations among developed economies and their enterprises, a discussion of Article 67 of TRIPS, and a presentation of the lessons learnt. Considering the general objective of this work, this section aims at a mainly conceptual and normative contribution. It does not focus on the rich empirical literature dealing with economic considerations, innovation patterns, and numerous national case studies on best practices.[272] Rather, it focuses on a general sufficientarian-republican interpretation of Articles 66(2) and 67 of TRIPS. It will *inter alia* address how to define what developed States owe to LDCs as a result of Article 66(2) of TRIPS. In the continuation of the reflections on the right to science in Chapter 4, this question requires designing a responsibility allocation mechanism.

5.4.1 Technology Transfer for LDCs

Article 66(2) of TRIPS prescribes that 'developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base'. This subsection provides key definitions, focusing on technology transfer and LDCs as beneficiaries.

[269] UNCTAD (2005), 731; Michaels (2009).
[270] Fernández (2025), 66.
[271] Roffe (1985).
[272] Bozeman, Rimes and Youtie (2015); Link and Oliver (2020), 1–13.

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5.4.1.1 Definition of Technology Transfer

Article 66(2) of TRIPS remains unspecific about its key object: technology transfer. This missing definition has been considered one of the main implementation challenges.[273] In the practice by technologically powerful States, the definition of 'technology transfer' provided by New Zealand is considered the most comprehensive[274] by including training, education, and 'know-how' alongside capital components and mentions four key modes of technology transfer: (1) physical objects or equipment, (2) skills and human aspects of technology management and learning, (3) designs and blueprints which constitute the document-embodied knowledge on information and technology, and (4) production arrangement linkages within which technology is operated. The definition used by WIPO also encompasses objects being transferred (skills, knowledge, ideas, know-how, and technology) and actors (universities and research institutions, international organisations, IGOs, NGOs, private sector entities, and individuals), all of which could be implicated in these processes.[275]

In the literature, the definition proposed by Maskus and mentioned in Chapter 4 remains influential. His definition of technology includes 'the information necessary to achieve a certain production outcome from a particular means of combining or processing selected inputs'.[276] Accordingly, a technology can be codified (formulas, blueprints, or drawings) or not (informal know-how of individuals). On this basis, a technology transfer refers to 'any process by which one party gains access to a second party's information and successfully learns and absorbs it into its production function'.[277] He further distinguishes between market-mediated technology transfer (with a formal transaction) and non-market mechanisms. Examples of market transactions include trade in technological goods and services, foreign direct investment (FDI) through multinational companies, technology licensing, or the cross-borders movements of engineers and technicians.[278] Non-market mechanisms include imitation (e.g., reverse engineering), reading of patent

[273] For a general conceptual embedding of technology transfer into innovation theories, Gehl Sampath and Roffe (2012); Gries, Grundmann, Palnau and Redlin (2017).
[274] Moon (2011), 4.
[275] See WIPO, Committee on Development and Intellectual Property, 'Project paper for the Project on Intellectual Property and Technology Transfer: Common Challenges-Building Solutions (Recommendations 19, 25, 26, and 28)', 26 October 2011, CDIP/8/7.
[276] Maskus (2004), 9.
[277] Maskus (2004), 9.
[278] Maskus (2019), 5–6.

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information, or HR rotations through which engineers share their knowledge in a different setting.

Article 66(2) of TRIPS is not focused on market-based technology transfer but is rather about what should be put in place when market-based transfer does not work, as is shown to be the case for LDCs that do not have the capacity to generate and/or absorb market mechanisms.[279] Technology transfer as prescribed by Article 66(2) of TRIPS is a crucial dimension of the bargain that developing economies (here LDCs) have accepted.

With respect to Article 66(2) of TRIPS, technology transfer is considered to affect IP protected and non-protected content. As Watal and Caminero recall, the article does not specify anything on this question.[280] For many commentators, the presence of this provision in the TRIPS, as a crucial part of the diplomatic negotiations that led to the acceptance of the text, clearly indicates that IP-protected content must be included in technology transfer.[281] The obligation to incentivise transfer not only bears upon technology in the public domain, though this category might, of course, be relevant. Furthermore, as Forey explains, knowledge and know-how, which help adapt innovations to a local context, are essential for successful technology transfer.[282]

The obligation of technology transfer is not limited to the TRIPS. Importantly, the international framework on climate change includes important provisions on technology transfer,[283] including general provisions to promote technology transfer to developing countries, especially with respect to ESTs (mainly Article 4(3) UNFCCC, Article 16 CBD, Article 3(14) Kyoto Protocol, and Article 10 Paris Agreement). These distinct normative contexts have been the object of important scholarship.[284] Such climate-related frameworks could themselves be integrated into a broader development agenda, such as the Agenda 2030.[285]

5.4.1.2 Beneficiaries

Least developed countries are the beneficiaries of the technology transfer that developed economies are supposed to incentivise. The wording of

[279] Maskus (2019), 9–10.
[280] Watal and Caminero (2017), 5–6.
[281] UNCTAD (2005), 731; Correa (2020b), 474.
[282] Foray (2009), 4. See further Gehl Sampath and Roffe (2012), 6; Fox (2019), 4.
[283] Hutchison (2006), 521–523.
[284] Machnicka (2016), 435; Abbe Brown (2017); Rimmer (2019).
[285] UN General Assembly (2015), Transforming our World: the 2030 Agenda for Sustainable Development, A/RES/70/1. Gehl Sampath (2019), 60 ff.

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Article 66(2) of TRIPS clearly targets LDCs and not all developing economies, which are instead mentioned in Article 67 of TRIPS.

Article 66(2) of TRIPS formulates a clear obligation and not a gift chosen by developed economies. Rather than passive recipients of a benevolent action, LDCs must be active in this setting. The text of Article 66(2) of TRIPS clearly specifies that the technology transfer should be set up 'in order to *enable them* to create a sound and viable technological base' (emphasis added).[286] The transfer should have an enabling function for LDCs but, in the end, they must create the sound and viable base from which they will be able to address their specific needs.[287] Article 66(2) of TRIPS should be considered an important expression of the right to self-determination. The specific mention of 'technological development' in Article 8(1) of TRIPS is also a component of the competence that LDCs have the right to claim. The active formulation of Article 66(2) of TRIPS is also an important protection against risks of domination by developed States and private actors. For the sake of supporting LDCs, they could impose their own technological, industrial, or trade-related agenda. This dimension is also very relevant for Article 67 of TRIPS.

The active dimension of Article 66(2) of TRIPS has a corollary for LDCs: they have a duty to identify and communicate their needs.[288] The final objective of the creation of a sound and viable technological base implies that LDCs should be able to define their needs and inform developed economies who cannot fulfil their obligations without knowing the type of technology transfer they should incentivise.

The phases of identification and prioritisation should themselves be conducted without risks of internal domination (e.g., a subgroup of the population not considered). These phases should be as inclusive and participatory as possible and should consider the importance of scientific research as a means through which to address the most pressing

[286] Watal and Caminero (2017), 23 ff.

[287] As the Preamble of the Istanbul declaration recalled in 2011: 'Recognizing that least developed countries deserve particular attention and special and well-targeted support in line with their development strategies to address their development needs and specific challenges in a coherent manner in trade, investment, finance, including official development assistance (ODA), technology and capacity-building.' Istanbul Declaration, Fourth UN Conference on the Least Developed Countries held in Istanbul, Turkey, on 9-13 May 2011, A/CONF.219/L.1.

[288] Moon (2008), 7; Watal and Caminero (2017), 25.

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challenges for the State.[289] The goal is to draw upon and proactively include in the policy-making conversation domestic stakeholders such as civil society representatives.[290] The specific situation of vulnerable groups such as indigenous peoples should be duly considered during these identification and prioritisation phases.[291]

5.4.2 *Proposal for an Allocation Mechanism*

This section presents an argument about what should be expected from developed economies following Article 66(2) of TRIPS.[292]

For now, due to diplomatic blockages, implementation of Article 66(2) of TRIPS mainly consists of procedural requirements, such as regular reporting. Many scholars have detailed the story of the diplomatic pressure exercised by developing economies towards better reporting mechanisms.[293] Meanwhile, the Working Group on Trade and Technology Transfer created by the Doha Ministerial Declaration in 2001 continues its reflections.[294] According to many commentators, the regular reporting of developed economies is insufficient from an output perspective.[295] Furthermore, the reporting is difficult because definitions and, most importantly, standards evaluating what is 'enough' in terms of incentives to be provided by developed economies are missing.[296]

The present subsection presents the main dimensions of a standard to answer that question. The standard is composed of a common metric, an

[289] This is one of the core obligations identified by the General Comment: 'develop a participatory national framework law on this right that includes legal remedies in case of violations, and adopt and implement a participatory national strategy or action plan for the realization of this right that includes a strategy for the conservation, the development and the diffusion of science'. General Comment 25, § 51.

[290] For this effect in the framework created by the Marrakesh Treaty, see Land (2018), 551–552.

[291] Shabalala (2018), 68 ff.

[292] For a similar objective, Michaels (2009).

[293] UNCTAD (2005), 731; Watal/Caminero distinguish four phases of implementation. Watal and Caminero (2017). See, for instance, the qualification of the mechanism of Article 66(2) of TRIPS as a 'pipe dream' by India. Intervention of India on 10th Annual Review of Article 66.2 TRIPS Agreement, Council for TRIPS, November 2012 (available at www.keionline.org/22036).

[294] § 37 Doha Declaration. Pires de Carvalho (2014), 187–188. For information, www.wto.org/english/tratop_e/devel_e/dev_wkgp_trade_transfer_technology_e.htm (consulted 15 June 2025).

[295] Moon (2008), 6 ff; Abbott (2009), 18; Correa (2020b), 474.

[296] Fox (2019), 24. See further Moon (2008), 3 ff; Watal and Caminero (2017), 23.

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objective, the means to achieve this objective, a clarification of the obligations of developed economies, and a discussion of the responsibilities of enterprises and institutions.

5.4.2.1 Common Metric, Objective, and Means

The first element of a standard is the definition of a metric. This metric is about having a common language to assess a situation (both to capture a baseline and a new situation after specific measures have been carried out).[297] As proposed in this work, the most relevant general metrics are human rights. The capacity of LDCs to fulfil their human rights duties, then, is the most relevant way of measuring whether obligations are fulfilled. As I explore later, this does not mean that the obligations are open-ended, however. The question of the demandingness of the obligations is different from the determination of the metric. Indeed, the human rights metric can be further specified using a related metric, such as the SDGs.[298]

Secondly, one needs to define an objective as the core of the standard. This objective is already formulated by Article 66(2) of TRIPS, namely the enablement of LDCs to create a 'sound and viable technological base'.[299] What constitutes 'sound' in the context of this technological base is what an LDC needs. LDCs are clearly recognised as active agents, and not as passive beneficiaries of foreign support. Specifying this general objective requires a priority-setting effort from LDCs.

The base should furthermore be 'viable'. This excludes short-term understanding (which is hardly compatible with the concept of 'base' anyway) and reinforces the previous point about the necessity to think in terms of the sustainability of LDCs to develop their own capacity to use, transform, and ultimately develop technologies.[300] Article 66(2) of TRIPS is not only about the usage of technological devices and tools, but also about the development of an infrastructural capacity.

This interpretation is based on the function that Article 66(2) of TRIPS plays in the overall balance of the Agreement. Developing economies and

[297] This is an important element of the WIPO Development Agenda. See Cluster D, recommendation 33 (establishing specific indicators and benchmarks).

[298] As Cottier argues, 'SDGs will be of the utmost importance in developing new and effective disciplines on transfer of knowledge and technology on the basis of Articles 7 and 66(2) of the TRIPS Agreement in support of attaining the benchmarks defined by SDGs.' Cottier (2017), 33; Gehl Sampath (2019), 60.

[299] Correa (2005), 253.

[300] Seuba and Genovesi (2019), 87.

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LDCs in particular have agreed to the TRIPS under the conditions – as expressed in the Preamble, Articles 7 and 8 of TRIPS – that they will be supported in their capacity to build up viable technological capacities. For LDCs, Article 66(2) of TRIPS is the key provision for this specific part of the bargain.[301] Indeed, this provision is part of a transversal effort towards LDCs as part of WTO law.[302]

Thirdly, we need to identify the means prescribed by Article 66(2) of TRIPS. Among many possibilities to support the creation of a technological base for LDCs, Article 66(2) of TRIPS focuses on technology transfer. To do so, developed economies should provide 'incentives for enterprises and institutions'. Developed economies should actively and specifically enact measures to increase the chances that enterprises and institutions will contribute to technology transfer. It is worth briefly pausing to clarify three implications.

First, Article 66(2) of TRIPS is not a provision about the direct responsibility of the States for technology transfer, but rather about the incentivisation of further actors.[303] Absent this demarcation, the structure of Article 66(2) of TRIPS would be changed. Second, a merely passive or 'business-as-usual' attitude will not fulfil a general definition of 'incentives' in the context of Article 66 of TRIPS.[304] The State must actively do something. Indeed, when looking at the reports submitted by developed economies as part of the implementation measures put in place, they mention active measures meant to support LDCs.[305] And third, the term 'provide incentives' implies that the State is not obliged to force enterprises to engage in technology transfer. 'Incentives' means an action that remains non-mandatory, though it might be supported by the State. However, the definition of 'incentives' can only do part of the necessary job. The key question is not the qualification as incentives, which is mostly unproblematic, but rather the applicable standard for assessing whether a specific State has done something relevant in the context of the specific obligation of Article 66(2) of TRIPS and whether this something is 'enough'.

[301] Moon (2011), 6; Gehl Sampath (2019), 41–42; Fox (2019), 26.
[302] UNCTAD (2005), 737.
[303] Fox (2019), 30.
[304] Moon (2011), 6.
[305] See, for instance, the latest report by the EU (October 2023), https://e-trips.wto.org/En/ImplementationOfArticle662Notifications/View/1001819 (consulted 15 June 2025). In order to browse all the reports, https://e-trips.wto.org/En/Reports/TRIPSRelatedReportsSubmission.

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Overall, to make sense as an important pillar of the overall balance of the TRIPS, Article 66(2) of TRIPS cannot be considered fulfilled under the condition that a developed economy does something without any consideration for the objective identified and expressed with the specified metric. It hence cannot list official development aid that is not related to the creation of a technological base. As Fox argues based in his analysis of the reports submitted in 2017 by developed economies, 'more than half of the Australia, Japan, and the U.S. programs were government-led initiatives. (. . .) The Japan report is especially troubling with respect to its reliance on government-led transfers of technology. Nearly 70% of the Japanese programs were facilitated directly via the Japanese national government.'[306]

Furthermore, it cannot list measures that are related to but do not produce any relevant effect for LDCs with respect to the objective identified above (the creation of the technological base). The technology transfer must have a connection to the capacity of the LDCs to create a sound and viable technological base. This implies a contribution to the creation of the technological infrastructure of the LDCs (understood in general terms, not only materially, but also regarding know-how), and not only as a symptom-fighting dimension or a general contribution to society.[307]

The Doha Implementation Decision has underlined this point. The Decision requires the submission of reports presenting evidence about 'the functioning in practice' of the incentives set by developed economies.[308] This focus on the functioning in practice makes clear that what eventually counts is the effectiveness from the perspective of LDCs.[309]

5.4.2.2 Obligations of Developed Economies

Article 66(2) of TRIPS does not specify how to determine the fulfilment of the prescribed obligation.[310] The general strategy adopted here is to

[306] Fox (2019), 30–31.

[307] As Thambisetty et al. argue in the context of COVID-19, 'the reluctance to share not just in the end products (including drugs or vaccines) but the underlying technology transfer has been a consistent failure of the TRIPS settlement and has arguably prolonged the capacity of a small number of large companies to manipulate artificial scarcity globally'. Thambisetty, McMahon, McDonagh, Kang and Dutfield (2021), 40.

[308] Implementation-Related Issues and Concerns, Decision of 14 November 2001, WTO Doc WT/MIN(01)/17, § 11.2.

[309] Correa (2005), 253.

[310] This requirement to interpret Article 66(2) is compatible with a position giving considerable discretion to the developed States on how to discharge this duty. UNCTAD (2005), 730.

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combine the primary identification of the most pressing technology-related needs by LDCs and the definition of an allocation principle to assess what developed economies should do to address these needs.

The first stage of the argument is the required coordination between the LDC's needs, and the incentives provided by developed economies. What LDCs need for their population to reach the threshold should be defined by LDCs themselves, in light of their human rights duties.[311] Taken in *globo*, these needs represent the priority set of requirements that developed economies must address. The first stage of the argument leads to an overview of the technology-related needs of LDCs.

The specificities of Article 66(2) of TRIPS relate to its structural role in the Agreement, but also to the chosen focus on technology.[312] The claim to incentivise something considered part of a technology transfer cannot encompass anything beneficial for society (as an objective) or unrelated to technology (as a means of achieving this objective).[313] In this respect, the support of school systems (e.g., those aimed at primary school curriculum) does, in some way, contribute to the technological base of a country, but arguably not specifically enough. This is to be compared with support of higher education (high schools or universities) with the objective to create capacity in LDCs to teach local students and give them opportunities to be trained in specific technological matters. To find that an action taken by a developed economy is not Article 66(2)-relevant does not mean that the State should abandon it, or, going further, that it has no responsibility to implement it. As discussed with the right to science, there is a set of responsibilities all States carry as a matter of human rights responsibilities, independently from Article 66(2) of TRIPS.

The second stage of the argument is the definition of an allocation principle(s) to fairly distribute the burden among the developed economies. The main function of such a principle(s) is to locate individual effort by each developed economy as part of a collective obligation held by the developed economies together. The difficult articulation between

[311] As Foray argues, 'the locus of decision-making regarding modes of learning and areas for focus must shift away from foreign bodies to local agents and authorities'. Foray (2009), IX.

[312] UNCTAD (2005), 737.

[313] Moon (2011). Watal and Caminero have clustered the technology transfer programmes of developed States into sixteen categories. The category of environment/water is the most important. Watal and Caminero (2017), 17 ff.

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the State's obligations and the private entities' responsibilities will be addressed below.

Two broad principles can be drawn upon for that allocation: the general capacity of a State to contribute to improving the situation of LDCs and the benefits this State receives from the protection of IPRs offered by the TRIPS. The first principle is built upon the moral ground that the more powerful States (e.g., in terms of economic capacity) should contribute more to the creation of a technological base for LDCs. There are several proxies to measure the 'capacity' of a State. The most intuitive one is the economic capacity, measured with proxies such as GDP. However, it would also be possible to use the UN human development index as a proxy for the level of capacity reached by a State.

The second principle relates to another moral ground, namely the benefits associated with the TRIPS, which can but need not be combined with the first principle. The argument runs as follows: if Article 66(2) of TRIPS is a crucial part of the bargain sustaining the TRIPS, it makes sense to look for the States that derive the most advantage from the existence and enforcement of IPRs as prescribed by the TRIPS. The ones that make the most out of the TRIPS' obligation (one end of the bargain) are the ones that should contribute most to the improvement of LDCs' technological capacity (the other end of the bargain). This argument is based upon the previous reading of the conditionalities of Article 7 of TRIPS: the legitimacy of TRIPS relies upon societal objectives. Article 66 (2) of TRIPS can be understood, then, as a specification of these conditionalities in the form of specific obligations for developed economies.

There is indeed a challenge to provide a reliable proxy to measure how much advantage the TRIPS offers to a State. An illustrative example is the WIPO Innovation Report, which ranks countries according to their capacity to innovate.[314] Part of the eighty-one parameters used for this report could be used as a proxy to measure the principle outlined here. It would be assumed that countries performing well as innovation hubs (e.g., Switzerland) are the ones profiting most from the existence of common minimal standards for enforceable IPRs.

Further principles should arguably be considered. For instance, building upon the work by Pogge, countries that benefit most from the existence of the WTO should arguably be the ones to contribute most to global justice obligations.[315] This proposal could be included in the

[314] WIPO Global Innovation Index 2021, 20 September 2021, PR/2021/880.
[315] Pogge (2008).

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determination of the capacity (first principle) or could be considered an extension of the benefit taken from TRIPS (second principle). However, the two principles mentioned are the ones which can be directly deduced from our TRIPS' framing. They are built into the function of Articles 7 and 8 of TRIPS and the structural role of Article 66 of TRIPS. Further principles might indeed be formulated, but they will be more difficult to account for from the internal perspective of the TRIPS.

This general argument, combining a definition of the needs by LDCs and an allocation principle to distribute the burden among developed economies, has a collective dimension. Developed economies need to accept a common allocation principle (and corresponding measurement methods), and LDCs must individually and collectively be able to identify and communicate their needs.

With respect to current practices in the context of the implementation reporting on Article 66(2) of TRIPS, the underlying rationale is turned upside down. Developed economies should not report everything they do (providing a very broadly understood link to a technological base) but should report with respect to the needs identified by LDCs. The key criterion is the capacity to assess which needs identified by LDCs are impacted by the incentivisation and the associated measures taken by enterprises and institutions. This new approach requires redesigning the implementation mechanism to ensure transparency both for developed economies with respect to measures put in place (from a burden-sharing perspective), and for LDCs regarding the concrete measures enacted and their impact on the identified needs.

Following this argument, Article 66(2) of TRIPS ceases to require measures by developed States when LDCs have reached the threshold in terms of technological capacities. Article 66(2) of TRIPS does not prescribe a continuing obligation aimed at addressing inequalities between developed and developing economies. It specifically focuses on LDCs and should hence be understood as a sufficientarian obligation that ceases when an LDC reaches a defined threshold.

These specific obligations would cease in two scenarios. On the one hand, LDCs have become developing economies and are therefore no longer the beneficiaries of Article 66 of TRIPS. This is the case if an LDC gets out of LDC status. On the other hand, there is no contribution that can be made with respect to the technological base. However, this second scenario appears implausible as it seems that if a State is still an LDC a technological base would contribute to addressing its needs. However, if obligations prescribed by Article 66 of TRIPS only apply to LDCs,

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Articles 7 and 8 of TRIPS continue to be relevant for all TRIPS' norms. They do not cease to be applicable when a State changes its status.

5.4.2.3 The Responsibility of Enterprises and Institutions

The constellation created by Article 66(2) of TRIPS suffers a major weakness that might result in a responsibility gap or in blackmailing danger for the State.[316] This danger reflects that Article 66(2) of TRIPS is an international law obligation (bearing on States) but can only be fulfilled with the support of private entities not directly bound by the obligations. On the one hand, concrete answers given to LDCs' needs come from the measures taken by enterprises and institutions. Incentives alone do not tell us something about the improvement of the situation for LDCs, which is the objective.[317] On the other hand, enterprises and institutions might require high(er) incentives to do technology transfer from the State. Because the State is dependent upon these private entities to fulfil its TRIPS obligations, this potentially results in *de facto* blackmail.[318] In order for Article 66(2) of TRIPS to be effective, there is a requirement to hold private entities accountable with respect to their responsibilities for human rights.

To recall, two types of responsibilities for private companies are mainly relevant here.[319] Firstly, private companies and institutions must respect human rights (baseline approach of the 2nd pillar of the UN Guiding Principles). This is relevant if some of their business practices impede technology transfer. Clear human rights policy and the documentation of one's impact on specific situations can help avoid this impediment. Secondly, companies have a responsibility to achieve societally desirable goals. As mentioned, this responsibility includes measures such as differential pricing, free licences, or technology transfer support.

[316] See, for instance, the declaration by the EU as part of its implementation report in 2018: 'In their efforts to encourage and promote technology transfer, developed country governments are usually limited by two factors: (1) they do not own the vast majority of such technologies; (2) they cannot force the private sector to transfer its technologies. Incentives can therefore only take the form of encouragement, promotion and facilitation of projects which are part of a global and comprehensive approach to development.' Report on the Implementation of Article 66.2 of the TRIPS Agreement (European Union), 16 February 2018, IP/C/W/631/Add.7.

[317] Correa (2005), 252.

[318] A situation which is, according to Maskus, going to provoke strong domestic opposition. Maskus (2004), 3. This is reinforced by the fact that the technological enterprises often have considerable market power. Maskus (2019), 12.

[319] *Infra* (Ch. 4.1.2.1.).

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However, even if we assume that the worst-case scenario of a complete dilution of responsibilities can be avoided (because companies acknowledge they have responsibilities), the question of 'how much' is considered enough remains crucial. The 'how much' question for private entities is similar to the question about how much for States and can be addressed using similar categories. Assuming that we know how much each developed economy should do (based on the previous argument), we can replicate the argument with respect to domestic enterprises and institutions. Considering the principles of capacity and/or benefits taken from the TRIPS, we could assess how much is expected from each private entity. This coordinated approach requires burden-sharing mechanisms at the national level where all stakeholders gather to discuss the allocation principles and the methods of measurement. This kind of approach is necessary to avoid inaction, due, for instance, to the difficulty for a company to define its 'fair' share on its own and to act accordingly. As prescribed by Article 66(2) of TRIPS, the State is the relevant territorial unit to conduct this process.

There are several methods that States could use to improve their capacity for action. First, as Forey argues, we need to understand that the incentives provided by States should focus on projects in which technology transfer is the primary product.[320] It should not be linked with other economic policies as a kind of 'side-project'. Technology transfer projects should be perceived as operations with little to no commercial return ambition.

Second, States should focus their attention on projects with relevant partners on both the supply and demand sides, mainly with respect to local partners able to address a local need identified by the LDC. Part of this attention should be focused on the consolidation of the transfer, the resources required for absorption and adaptation, and subsequent operations. Local dynamics are a key part of the capacity of people and companies to use the technologies.[321]

Third, an important scholarship looks at public–private partnerships (PPPs) as an efficient organisational approach.[322] However, it is important to approach this concept with some caution. In its structure, Article 66(2) of TRIPS could be seen as forcing the 'creation' of PPPs. But, as Gehl Sampath argues, PPPs should be reserved for projects in which the partners are considered equal in a relatively long-term process, with a

[320] Foray (2009), IX.
[321] Gehl Sampath and Roffe (2012), 11 ff.
[322] See the collection of contributions in Abdel-Latif, Chon and Roffe (2018).

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Table 5.2 *Article 66(2) of TRIPS*

Schematic overview of the argument related to Article 66(2) of TRIPS based on the republican-sufficientarian framework
1st step:
Definition of the technology-related needs of LDCs:
(a) Participatory and inclusive definition of the needs in light of human rights duties
(b) Communication of needs in the TRIPS council
2nd step:
Definition by the developed economy of the allocation principle(s) to be used:
(a) Ad hoc procedure to define the principles and the methods of measurement to be used (e.g., 'Economic capacity' and 'Advantages created by the TRIPS')
(b) Application of the principles to the needs identified by LDCs
(c) Every developed economy has a 'fair' share to do by providing incentives to its home-based enterprises and institutions
3rd step:
Definition in each developed economy of the allocation principle(s) to be used with respect to its enterprises and institutions:
(a) Ad hoc procedure to define the principles and the measurement methods to be used
(b) Application of the principles to the domestic share to be done
(c) Negotiations about the type of incentives required for the envisioned technology transfer

common understanding about the goals to be achieved.[323] In this case, PPPs can be characterised as processes of technology sharing, more than transfer, with clear senders and recipients.

Table 5.2 presents an overview of the arguments made.

5.4.3 *Technical Assistance of Article 67 of TRIPS*

Article 67 of TRIPS offers the possibility for developing economies and LDCs to request technical assistance in order to 'facilitate the

[323] Gehl Sampath (2018), 334.

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implementation' of the TRIPS. This subsection briefly addresses the structure of this provision and outlines a republican-sufficientarian interpretation.

5.4.3.1 Structure of Article 67 of TRIPS

The general objective of Article 67 of TRIPS is to facilitate the implementation of the TRIPS.[324] Article 67 of TRIPS entails a specific obligation of developed economies to provide technical and financial assistance to help developing States implement TRIPS in their domestic legislation. In that sense, this provision should be seen as part of the ambition to ensure that every WTO Member State has the concrete means to fulfil its TRIPS obligations.

This general goal is clarified by the explicit mention of three distinct forms of assistance: the preparation of laws and regulations on the protection and enforcement of intellectual property rights, the preparation of laws and regulations on the prevention of IPR abuse and support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters and the training of staff. This list is not exhaustive and further types of assistance might be considered relevant.[325]

This assistance must be given on two conditions: upon request and upon mutually agreed terms and conditions. The first condition recalls that developing economies and LDCs shall take the initiative to ask for assistance in implementing TRIPS. They can activate the obligation to support other States.[326] This first condition is meant to protect requesting States from unwelcomed assistance. States willing to help have, or at least are often perceived as having, pursued a different agenda.[327] The second condition requires 'mutually agreed terms and conditions'. It provides a similar protective function that gives States requesting assistance the guarantee that they could co-decide on the way and conditions in which assistance is provided.[328] 'Mutually agreed' prescribes negotiations among

[324] For a critical reconstruction of technical assistance in IP policies in African countries, Acquah (2022).
[325] For an overview, Deere and Roca (2011).
[326] UNCTAD (2005), 730.
[327] For interviews of involved stakeholders, Kostecki (2006).
[328] Article 11(5) of the WHO Pandemic Agreement uses this formulation and defines it in the following way: 'For the purposes of the WHO Pandemic Agreement, "as mutually agreed" means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements.'

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the involved stakeholders with the objective to find an agreement on how assistance should be provided. It does not guarantee that developing economies and LDCs will obtain their desired type of assistance.

5.4.3.2 Republican-Sufficientarian Interpretation

The objective of Article 67 of TRIPS and the two conditions prescribed for the assistance should be interpreted in a republican-sufficientarian way.

Firstly, the objective of Article 67 of TRIPS must be aligned with the general framing of the TRIPS proposed in this work. The TRIPS is not only a set of obligations to protect IPRs that have to be implemented in national legislation. It must also be understood as a balanced set of norms which, taken together considering Articles 7 and 8 of TRIPS, enable WTO Member States to face their domestic challenges at their own state of economic development.

The two conditions prescribed by Article 67 of TRIPS should also be interpreted as protection against domination by developed economies or by specialised agencies such as WIPO. On the one hand, it means that flexibilities are an integral part of the TRIPS and should hence be integrated as such in technical and financial assistance. Developed States should provide balanced assistance, covering all relevant norms of the TRIPS, and not only norms that correspond to the economic interests of IPR holders.

On the other hand, the specific needs of the State requesting assistance are key.[329] This State should have the right and the concrete capacity to identify its priority needs and to act accordingly. Assistance designed according to Article 7 of TRIPS must give priority to domestic legislation that enables the State to fulfil its human rights duties, thereby focusing on specific flexibilities of the TRIPS.

The methods of assistance are the subject of a co-decision process that should ensure 'mutually agreed upon' solutions. These safeguards are meant to protect the Member State's capacity for self-determination. In this context, an important challenge is the apparent neutrality of technical and financial assistance. The assistance is promoted as neutral support that Member States are free to use or not.[330] But the assistance

[329] Correa (2020b), 476.

[330] As Acquah argues, technical assistance 'seeks to establish and sustain an understanding of the rule of law largely by those it governs as uncontroversial and non-problematic: a self-evident foundation for the organisation and understanding of their everyday lives and more broadly for global politics'. Acquah (2021), 201.

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provided is never void of political positions which, in brief, crystallise the TRIPS-related debates addressed in this work. To provide assistance for the sake of implementing the TRIPS necessarily means taking a position on the foundations of the TRIPS and on the interface between development policy and IP protection.[331] Kostecki identifies several types of bias found in this process of assistance: assistance providers' bias, expert bias, ideological bias, and FDI bias.[332] The interpretative approach defended in this work does not aim at a conceptually impossible, non-biased assistance. It rather aims at 'biased' assistance (if one wants to use that word) as aligned with Articles 7 and 8 of TRIPS and the interpretation based on human rights duties of the Member States.[333]

Of course, it might seem counterintuitive to require developed economies (and specialised agencies) to support weaker States in becoming stronger at facing pressure to reinforce IPR protection in their domestic legislation. However, this obligation reflects the general setting of Article 67 of TRIPS (and the obligations' package of Articles 66 and 67 of TRIPS): developed economies are the stronger parties and should empower weaker States to fulfil their domestic duties (most importantly human rights duties) and to become truly participating members in globalised trade competition.[334]

5.4.4 *Republican Obligations for Developed Economies*

As proposed earlier, Articles 66(2) and 67 of TRIPS should be considered together as a set of obligations relevant to developed economies. The objective of this subsection has been to address these obligations conceptually and normatively as part of a republican-sufficientarian reading of the TRIPS.

Firstly, Articles 66 and 67 of TRIPS were shown to be crucial pieces of the overall bargain that the TRIPS represents. While most of the TRIPS' provisions describe in detail how IPRs shall be protected, these two provisions explicitly mention what developed States and private entities

[331] Interestingly, the WIPO Development Agenda recommends seeing these missions in light of Article 7 of TRIPS (enforcement can be improved considering broader societal interests and development-oriented concerns). See Recommendation 45.

[332] Kostecki (2006), 29.

[333] As shown by Acquah with respect to technical assistance provided by WIPO and UPOV in African countries, this has not always been respected. Acquah (2022), 370 ff.

[334] Acquah (2021), 217–218.

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are expected to do. In that structural sense, Articles 66 and 67 of TRIPS draw upon and specify the foundations laid down in Article 7 of TRIPS.

Secondly, these obligations are an answer to the sufficientarian duties that all WTO Member States must be able to fulfil. For developing economies, and mostly for LDCs, the issue of technological capacities has been shown to be crucial in securing the capacity of States to fulfil their duties with respect to their population. For developed economies, it is about the mirror responsibility to support these States in their efforts towards this goal. Articles 66(2) and 67 of TRIPS are the provisions where this responsibility is most explicitly formulated. The human rights-based approach to the TRIPS' flexibilities should here be used to more specifically define the objective, metric, and allocation mechanism required by Article 66(2) of TRIPS.

Thirdly, these obligations are a set of anti-domination measures on distinct levels. Their existence aims at improving the capacity of developing economies to take part in global trade relations. By providing support and assistance on different levels, developed economies empower weaker States to resist domination. The obligations discussed earlier can hence be read as obligations to reinforce the capacity of States to prevent arbitrary interferences. If freedom as non-domination is part of the general objective, it is also an important feature of the methods which should be used to provide support and assistance. The positive objective (support) does not make every method legitimate. For Article 67 of TRIPS, the requirement to secure 'mutually agreed upon' terms and conditions of technical assistance arises as an example of this protection.

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