Injunctive Relief in Patent Law under TRIPS

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Traditionally, intellectual property's right to exclude has implied that injunctive relief should always be available at the conclusion of a successful infringement action. However, in recent years that view has evolved. As discussed in Chapter 14, in the United States, the 2006 Supreme Court decision in *eBay Inc.* v. *MercExchange* imposed a four-part test requiring the plaintiff in a patent case seeking a permanent injunction to demonstrate "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." While this standard appears to impose quite a restrictive test, several members of the court emphasized that even under this discretionary standard, injunctive relief should remain available in the vast majority of cases.³

Furthermore, Justice Kennedy wrote a concurring opinion delineating specific areas where such relief might be appropriately withheld. First, he suggested that the availability of injunctive relief may furnish firms that use patents primarily to obtain licensing fees (so-called patent assertion entities or PAEs) too much bargaining power in licensing negotiations and that since they are only interested in fees, monetary relief is usually sufficient to compensate them.⁴ Second, he stated that when a patent is "but a small component" of a larger product, the opportunity for holdups creates undue leverage. As a result, injunctive relief in such cases could undermine the public interest.⁵ Third, he argued, giving the example of business

¹ Cf. Simpson 1936, 183.

² eBay (2006, p. 391).

³ Id. at 395 (Roberts, J., concurring, joined by Justices Scalia and Ginsburg); at 396 (Kennedy, J. concurring, joined by Justices Stevens, Souter, and Breyer).

⁴ Id. at 396.

⁵ Id. at 396–97.

method patents, that injunctions may be withheld when the asserted patents are vague and of "suspect validity." ⁶

As the other chapters in this volume attest, many countries have now adopted a similar discretionary approach to the award of injunctive relief. The question we address in this chapter is whether that position is consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS or the TRIPS Agreement).7 To be sure, the TRIPS Agreement is largely conceptual in character and the section addressing enforcement (Part III of TRIPS) is of a very general nature. However, the Agreement does require member states to give courts the authority to order parties to desist from infringement, 8 it requires remedies to deter future infringements,9 it imposes national treatment and most-favored-nation (MFN) obligations, 10 and it bars discrimination by field of technology. 11 In addition, it cautions member states that protection exceeding its standards is allowable, but only if such a measure "does not contravene the provisions of [the] Agreement."12 Thus, TRIPS also sets a ceiling on right-holder protection. Since empirical evidence on the effect of eBay in US patent litigation shows that its impact falls disproportionately on certain right holders (not surprisingly, PAEs in particular) and on specific industries, 13 all of these TRIPS obligations are implicated.

In this chapter, we first outline what we regard as the conceptual features of TRIPS. We then consider the individual provisions touching on enforcement and how they might be interpreted. Finally, we discuss specific applications of the discretionary approach and ask whether World Trade Organization (WTO) decision makers would find any of the outcomes incompatible with TRIPS obligations. Our analysis draws heavily on our book, A Neofederalist Vision of TRIPS.¹⁴

A. TRIPS AND ENFORCEMENT

Several features of the TRIPS Agreement (and indeed of international intellectual property law generally) would appear to limit its relevance to the question whether an *eBay*-like approach to injunctive relief is TRIPS-compliant. First, like most norm-setting international instruments in the field, the TRIPS Agreement largely imposes

⁶ Id

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, Vol. 31, 33 ILM 81 (1994) [hereinafter TRIPS Agreement].

⁸ Id. art. 41(1).

⁹ Id. art. 41(1).

¹⁰ Id. arts. 3 & 4.

¹¹ Id. art. 27(1).

¹² Id. art. 1(1).

¹³ See, e.g., Seaman 2016; Gupta & Kesan 2016; Lim & Craven 2009, 798.

¹⁴ Dinwoodie & Dreyfuss 2012.

only minimum standards. Thus, Article 1(1) of TRIPS provides that "Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement." Under a minimum standards regime, the possibility of noncompliance would arise directly only when a jurisdiction fails to make injunctive relief available, ¹⁵ fails to offer remediation that deters further infringement, ¹⁶ or interferes with the structural features of TRIPS, such as its various bars on discrimination. And to the extent TRIPS sets a ceiling, excessive enforcement could also raise compliance issues.

Second, TRIPS was one of the first multilateral forays into questions of patent (or indeed any intellectual property) enforcement other than at a very general level. As such, it is perhaps inevitable, if not desirable, that the text of the provisions on remedies has little detail, and that the plain language of the Agreement affords WTO members substantial flexibility. In other words, this part of the Agreement allows member states more latitude than one finds in areas where there has been a century or more of serial international convergence among nation states. Indeed, this cautious attitude has been emphasized by both a WTO dispute settlement panel and the WTO Appellate Body in the WTO TRIPS reports to date that have interpreted provisions in the enforcement section of the Agreement. (Reflective of this fact, post-TRIPS, developed countries have tried to ratchet up the level of

¹⁵ Art. 44(1).

¹⁶ Art. 41(1).

¹⁷ See Gervais 2012, 564; World Trade Organization 2012, 136; Roffe & Seuba 2015, 18–19. Some provisions on enforcement were contained in the trademark sections of the Paris Convention, see Paris Convention for the Protection of Industrial Property, Jul. 14, 1967, 21 UST 1583, 828 UNTS 305 [hereinafter Paris Convention], arts. 9–10, but these were focused primarily on border measures. Likewise, the adequacy of intellectual property enforcement options in the United States had been successfully challenged under the predecessor to the World Trade Organization, the General Agreement on Tariffs and Trade, but this had been on national treatment grounds. See Panel Report, United States – Section 337 of the Tariff Act of 1930, L/6439 (Nov. 7, 1989) [hereinafter US – Section 337].

See Taubman 2011, 110; Reichman 1997, 344 ("The enforcement provisions of the TRIPS Agreement have been drafted in terms of broad legal standards rather than as narrow rules. Their very ambiguity, allows ... dispute-settlement panels to take local circumstances and diverse legal philosophies into account when seeking to mediate actual or potential conflicts between states").

See Appellate Body Report, United States – Section 211 Omnibus Appropriations Act of 1998, WT/DS176/AB/R (Aug. 6, 2001) [hereinafter United States – Section 211] at para. 8.97 ("Prior to the TRIPS Agreement, provisions related to enforcement were limited to general obligations to provide legal remedies and seizure of infringing goods"); Panel Report, China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights, WT/DS362/R (Jan. 26, 2009) [hereinafter China – Enforcement] at para. 7.241 ("[Prior to TRIPS,] the pre-existing international intellectual property agreements contained comparatively few minimum standards on enforcement procedures beyond national treatment and certain optional provisions"). In contrast, Article 61, on criminal procedures, uses the formulation "Members shall provide for criminal procedures and penalties to be applied," a phrase the panel in the Saudi Arabia – IPR dispute interpreted as requiring states to do more than merely adopt a written law

international enforcement obligations through plurilateral and bilateral initiatives, such as the Anti-Counterfeiting Trade Agreement or ACTA.²⁰) Amplifying that point, this characterization of the enforcement provisions might also to a lesser extent be applied to the substantive patent provisions, which are arguably newer and less prescriptive than parallel sections of the Agreement on copyright or trademark.²¹

For example, although Article 41(1) mandates that specific enforcement procedures delineated in the subsequent provisions of the Agreement are available to courts, the general principles applicable to enforcement matters that are outlined in Article 41 appear more in the nature of standards than rules. This latitude is also reflected in the textual structure of the specific remedial provisions. Thus, many of the remedial articles (including Article 44 on injunctions, but also those addressing damages and other remedies) contain the formulation "the judicial authorities shall have the authority."²² As the WTO panel in China – Enforcement put it on reading the same language in Article 59, "the obligation is to 'have' authority, [it is] not an obligation to 'exercise' authority."23 Likewise, the Appellate Body in United States -Section 211 adopted a relatively narrow reading of Article 42, which generally requires that civil judicial procedures must be "made available" to enable right holders to protect against infringement.²⁴ Accordingly, while Article 44 requires that judicial authorities have "the authority to order a party to desist from an infringement" and Article 50 uses similar language regarding provisional remedies, neither mandates that injunctive relief (preliminary or mandatory) be awarded in all cases. Nor do they fully dictate the detail or form of that relief.

Third, Article 1(1) of the TRIPS Agreement explicitly endorses the longstanding principle of international intellectual property law that different WTO member states should be able to implement their international obligations in ways best suited to their jurisprudential tradition.²⁵ That position is reinforced in the enforcement section by Article 41(5), which states that this part "does not create any obligation to

- authorizing criminal penalties. See Panel Report, Saudi Arabia Measures Concerning the Protection of Intellectual Property Rights, WT/DS567/R (Jun. 16, 2020), at paras. 7.207–09.
- See Anti-Counterfeiting Trade Agreement, Mar. 31, 2011 Text, available at https://ustr.gov/acta [hereinafter ACTA]; see also Roffe & Seuba 2015, 18 (discussing Free Trade Agreements).
- Post-TRIPS efforts at reaching agreement on more detailed substantive patent law have stalled. See Reichman & Dreyfuss 2007.
- ²² See TRIPS, arts. 44-46.
- ²³ China Enforcement, at para. 7.236. Article 59 requires that "competent authorities shall have the authority to order the destruction or disposal of infringing goods." See TRIPS, art. 59.
- ²⁴ See *United States Section 211*, at para. 215 ("Making [civil judicial enforcement] available means making it 'obtainable', putting it 'within one's reach' and 'at one's disposal' in a way that has sufficient force or efficacy"); id. at para. 216 (noting that TRIPS reserved "a degree of discretion to Members on this, taking into account 'differences in national legal systems'," and commenting that "no Member's national system of civil judicial procedures will be identical to that of another Member").
- 25 See TRIPS Agreement, art. 1(1) ("Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice").

put in place a judicial system for the enforcement of intellectual property rights that is distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general."

Taken together, these features ensure that the TRIPS Agreement serves only to define in very general terms the substantial policy space in which WTO member states can themselves devise a variety of different approaches to the grant or structure of injunctive relief. Moreover, when the WTO's Dispute Settlement Body (DSB) interprets TRIPS, it sometimes looks beyond the text or the history of particular provisions and considers the national practices then in force. Accordingly, in disputes concerning TRIPS compliance with enforcement, the national practices revealed by the chapters in this volume, which address the situation in different countries, may contribute to the adjudicators' understanding of the meaning of TRIPS. Given the many differences in these practices, one might expect the DSB would allow different member states substantial room to implement their obligations in varying ways between the minimum and maximum.²⁷

That said, a relatively deferential approach to the detail of member states' choices on patent injunctions reveals a paradox. One of the principal motivations behind TRIPS was a sense among developed countries that many countries had enacted substantively compliant intellectual property regimes that were rendered nugatory by ineffective remedies.²⁸ Indeed, the principal WTO decisions to date addressing enforcement issues have highlighted this point.²⁹ But one must distinguish between the motivation for TRIPS and the content of what was finally agreed, especially when moving beyond the treatment of pirated or counterfeit goods (which nominally was the most urgent enforcement challenge justifying the developed world putting enforcement on the TRIPS agenda). However, as the next section discusses,

²⁶ See Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000) [hereinafter Canada – Pharmaceutical Patents], at para. 7.69. In Canada – Pharmaceutical Patents, given a lack of consensus on the question at issue, the panel took a deferential approach to the question of Canadian compliance. See id. at para. 7.82.

²⁷ See Dinwoodie & Dreyfuss 2012, 37 ("the provisions on remedies ... require legal systems to provide the 'authority' to order discovery, injunctions, damages, and other relief, but these provisions do not mandate particular forms of relief in individual cases, thus leaving it to local decision-makers to tailor remedies to local conditions"); see also Sarnoff 2010; Malbon et al. 2014, para. 41.13.

²⁸ See Taubman 2011, 109–10; Malbon et al. 2014, 615.

See, e.g., United States – Section 211, at para. 8.97 ("The inclusion of this Part on enforcement in the TRIPS Agreement was one of the major accomplishments of the Uruguay Round negotiations as it expanded the scope of enforcement ... of intellectual property rights"); China – Enforcement, at para. 7.241 ("One of the major reasons for the conclusion of the TRIPS Agreement was the desire to set out a minimum set of procedures and remedies that judicial, border and other competent authorities must have available to them. This represented a major advance in intellectual property protection"); see also TRIPS, recital 2(c) ("Recognizing ... the need for new rules and disciplines concerning ... the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems").

the standards are not toothless. Combined with substantive provisions that have received more scrutiny (such as the cornerstone guarantees of national treatment and MFN), there are specific obligations to which member states must adhere.

B. PROVISIONS IN TRIPS SPECIFICALLY RELEVANT TO PATENT INJUNCTIONS

The TRIPS Agreement includes several provisions relevant to the question of how much discretion courts (and member states) enjoy when remediating infringement. Article 41 sets out the general obligations on enforcement. Subsection (1) requires that remedial measures must be "effective," "expeditious" and "constitute a deterrent to further infringements." And they must "be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse." The procedural protections of Article 41(2)–(4) are similarly framed: procedures must be "fair and equitable," and "not . . . unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays." 32

Article 44 deals specifically with injunctions. Subsection (1) requires that "the judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods."³³ In some respects, this statement simply affirms that the measures required of member states under Article 41(1) should include the authority to offer injunctive relief. As noted, as per the *China – Enforcement* panel report, all that is required is that the authority to award such relief exists; it does not have to be exercised in any individual case. The power to deny injunctive relief is also evident in Article 44(2), which deals with the

^{3°} See TRIPS, art. 41(1).

³¹ See id.

³² See TRIPS, art. 41(2) ("Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays"); id. art. 41(3) ("Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard"); id. art. 41(4) ("4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case"). See also TRIPS art. 42 ("Members shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims").

³³ Article 44(1) also limits this obligation as regards innocent infringement, providing that "Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right."

specific issue of government use. It creates a general right for governments (and authorized third parties) to use an invention upon the payment of "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."³⁴ Although Article 50, on provisional relief, is somewhat more detailed, courts necessarily have more discretion over the decision to order such relief while the case is *pendente lite* – before the defendant is found to be an infringer – than after its liability is adjudicated.

Taken together, these provisions suggest that, other than possibly the question of the adequacy of monetary relief to deter infringement, the WTO might give scant scrutiny to challenges concerning the denial of injunctive relief. Indeed, Nuno Pires De Carvalho, a commonly cited commentator on the patent provisions of TRIPS, does not include in his introductory narrative a separate section on remedies or enforcement. He simply identifies enforcement as the source of a "cluster of flexibilities," representing "a very strong commitment by Members towards accommodation of different legal regimes." Even ACTA, which attempted to delineate signatory states' obligations on enforcement in far greater detail, nonetheless acknowledges that its enforcement requirements must take into account "differences in [states'] respective legal systems and practices."

Nonetheless, there is language in the Agreement that constrains member states at both ends. Thus, one might treat the juxtaposition of the requirements that measures must be "effective," "expeditious" and "constitute a deterrent to further infringements" with the caution found in Article 41(1) that remedies "be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse" as articulation of some standard of proportionality.³⁷ This would at least allow such considerations to be taken into account, and might even prohibit disproportionate injunctive relief.³⁸ De Carvalho takes this argument one step further. He notes that in contrast to the substantive "standards of protection – which are generally enunciated as minimum standards – many provisions in Part III of the TRIPS Agreement [on Enforcement] are phrased in a way that leaves WTO Members no alternative to the measures thereby established and thus do not provide for minimum standards but provide instead for mandatory standards. The reason for this, as enunciated in the first paragraph of the Preamble as well as in Article 44.1, is to avoid enforcement measures becoming abusive and constituting themselves as barriers to legitimate trade."39

³⁴ The provision specifically cites art. 31(h) for the standard of compensation government must pay.

³⁵ See De Carvalho 2010, 64.

³⁶ ACTA, supra note 20, recital 4.

³⁷ Cf. Taubman 2011, 110.

³⁸ See *infra* text accompanying notes 42–44.

³⁹ See De Carvalho 2010, 64 (emphasis in original).

While the distinction drawn by De Carvalho between "minimum" and "mandatory" is perhaps too stark, given the latitude that is incorporated via the broad language of the enforcement standards, ⁴⁰ there are provisions that support the view that there is something of a ceiling on enforcement – or at least that states can create one. Article 7, which articulates the objectives of the Agreement, stresses that TRIPS is intended to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." To accomplish that balance, Article 8(1) permits members "in formulating or amending their laws and regulations, [to] adopt measures necessary to protect public health and nutrition ... provided consistent with the Agreement." Article 8(2) notes that "appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology," and Article 40(2) authorizes WTO members to address anticompetitive licensing practices or conditions and adopt appropriate measures to prevent or control such practices.

It can even be argued that excessive enforcement might itself create a possible TRIPS violation.⁴¹ Notably, in 2010, India filed a WTO complaint against the European Union and the Netherlands regarding repeated seizures (based on alleged patent infringement) of generic drugs originating in India but transiting through ports in the Netherlands to third-country destinations. India alleged violation not only of the General Agreement on Tariffs and Trade (GATT) but also various provisions of TRIPS including Articles 41 and 42.⁴² The dispute has not been resolved. However, the complaint suggests that the provisions in Part III can be seen as imposing some maximum as well as minimum levels of protection for right

^{4°} See Reichman 1997, 348–49 ("the relevant enforcement provisions – unlike the substantive standards set out in the TRIPS Agreement – are truly minimum standards, as attested by the loose and open-ended language in which they are cast"). Professor Reichman is here using "minimum" to refer to the low level of harmonization that is required relative to the substantive standards.

⁴¹ Cf. *United States* – *Section* 211, at paras. 206–07 (noting that sections 1–2 of Part III "[introduce] an international minimum standard which Members are bound to implement in their domestic legislation").

Cf. Request for Consultations, European Union and a Member State – Seizure of Generic Drugs in Transit, WT/DS408/1 (May 11, 2010); EU, India Drop Generics Dispute to Focus on FTA Talks, FDAnews, Jan. 24, 2011, available at http://fdanews.com/newsletter/article?issueId=14404&articleId=133690; Request for Consultations, European Union and a Member State – Seizure of Generic Drugs in Transit, WT/DS409/1 (May 12, 2010) (complaint by Brazil); see generally Grosse Ruse-Khan 2011.

holders.⁴³ Article 1(1) does not preclude this argument because protection beyond that mandated must still be "consistent with the Agreement."

The analysis of the discretion member states enjoy over injunctive relief is additionally complicated by the possibility that the DSB might also consider other provisions of the TRIPS Agreement. These include the guarantees of national treatment and MFN in Articles 3 and 4, Article 27(1)'s bar on discrimination by field of technology, and the conditions attached to grants of compulsory licenses found in Article 31.

Because of the conceptual similarity between ordering monetary damages in lieu of injunctive relief and granting a compulsory license, Article 31 arguably imposes the most stringent and detailed limits on the exercise of discretion.⁴⁴ While that provision authorizes states to order compulsory licenses, it includes a long set of conditions.⁴⁵ Thus, member states must consider applications for licenses on their individual merits after efforts to obtain permission from the right holder; the decision must be appealable; the license must be limited to the authorized purpose; it must be nonexclusive and nonassignable; it must be terminable when the circumstance leading to the authorization ends; and it can extend only to supply of the domestic market of the authorizing state.⁴⁶ The provision also requires the payment of "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."⁴⁷ (This condition is referenced in Article 44(2) on government use.)

To some extent, a decision to deny injunctive relief complies with these conditions. The adjudication constitutes a consideration of the case on its individual merits and both the merits and the remedial award can be appealed. The denial of the injunction is limited in that it is framed by the claims in the complaint and, in some cases, it is also accompanied by specific conditions. Monetary damages are similar to court-ordered royalties and thus arguably serve as compensation (whether the compensation is adequate is taken up in Section C.1). However, except for cases where the infringer initially tried to license the patent, it is difficult to consider the institution of an infringement action a substitute for an effort to obtain authorization. And while this condition uses the term "may" rather than "shall," the subsection also appears to limit a waiver of this requirement to national emergencies or other urgent circumstances. Moreover, because decisions in infringement cases bind only the litigants, the use by the defendant is not, at least as a technical matter,

⁴³ See Taubman 2011, 110 ("TRIPS imposes positive obligations not unduly to hamper trade that does not infringe IP rights, even while recognizing that firms should expect credible and effective means of appropriately enforcing their IP rights"); Malbon et al. 2014, para. 41.25 (quoting Grosse Ruse-Kahn).

⁴⁴ See Dinwoodie & Dreyfuss, 2012, 76-78; Gervais 2012, para. 2.539 at 578.

⁴⁵ See Dinwoodie & Dreyfuss 2012, 77.

⁴⁶ See TRIPS, art. 31. The limit to use by the authorizing state was lifted by art. 31bis, but only as it pertains to protecting public health.

⁴⁷ TRIPS, art. 31(h).

"non-exclusive." Furthermore, the order likely runs to those in privity with the defendant, including assignees; as a final decision, it may not be terminable; and the award may not include specific geographic limitations.

To be sure, under Article 31(h), some of these conditions are not applicable to practices determined to be anticompetitive. Furthermore, the reference to anticompetitive behavior is supplemented by Article 8(2) on the right to prevent abuse and unreasonable restraints and by Article 40(2) on anticompetitive licensing practices. In addition, Article 31(l) permits compulsory licenses to deal with blocking patents. These present problems very similar to that posed by the owner of a patent on a small component of a large product trying to hold up development of the product, where Justice Kennedy suggested injunctions are inappropriate. However, it is an open question whether the DSB would read these provisions to include practices, such as PAE suits, which can have abusive aspects but do not rise to violations of a state's competition (antitrust) law. Nor is it clear whether it would consider hold-up problems sufficiently akin to the blocking situation to trigger the application of subsection (l).

Of course, the DSB might adopt a more formalistic approach, and confine assessment of a denial of injunctive relief to the mandates of Articles 41 and 44. It might also reason that since the enforcement part specifically references Article 31 (h), but not any of the other conditions set out in Article 31, the rest is not relevant. However, one cannot be entirely confident that this is how WTO adjudicators would approach the task. Experience to date suggests that panels tend to examine compliance under every conceivable provision. One notorious example is Canada – Pharmaceutical Patents. There, the panel first assessed the TRIPS compatibility of Canada's two challenged exceptions under Article 30, which creates a three-step assessment of the permissibility of domestic exceptions in patent law.⁴⁸ By its terms, such exceptions must be "limited" and one way in which Canada's exceptions were limited was that, as a practical matter, they applied only to pharmaceuticals (see Chapter 5 on Canada). However, the panel also subjected the exceptions to the rigors of Article 27(1), which prohibits discrimination against a particular field of technology, but which was arguably intended only to guarantee protection for a variety of subject matter previously unprotected by patent in a number of countries. 49 Elsewhere, we have heavily criticized the approach of the Canada -Pharmaceutical Patents panel,50 and this discussion, showing how Article 31 could undermine the latitude built into the enforcement part, supports the notion that WTO adjudicators should be cautious when applying provisions cumulatively. Not

⁴⁸ See TRIPS, art. 30 ("Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties").

⁴⁹ Canada – Pharmaceutical Patents, at para. 7.91; see also id. at para. 4.6 n. 27.

⁵⁰ See Dinwoodie & Dreyfuss 2012, 66–67 & 71.

all provisions are like the Basic Principles in Part I, which are meant to apply to the Agreement as a whole. Nonetheless, the prospect that a panel or the Appellate Body might apply Article 31 cannot be dismissed, in which case some denials of injunctive relief are suspect.⁵¹

The applicability of other guarantees that arguably constrain judicial discretion is highly dependent on the impact of denials of injunctive relief. We now consider them, along with the question of the adequacy of relief.

C. APPLICATION OF A DISCRETIONARY APPROACH ${\tt TO\ INJUNCTIVE\ RELIEF}$

Putting the application of Article 31 to one side, it can readily be argued that the approach the US Supreme Court articulated in *eBay* would satisfy TRIPS standards. Indeed, several scholars have explored the issue and concluded that *eBay* is likely consistent with TRIPS.⁵² Although, as illustrated in the other chapters of this volume, the approach to the issue of injunctive relief varies quite widely among member states, sometimes for reasons related to the character or organizations of particular legal systems, we reach similar conclusions as to the variations described in this volume. The structural features of TRIPS noted earlier, as well as experience with WTO adjudicators hesitating to go far beyond the text and resolving contested policy choices, suggests that future decisions are likely to allow continued room for such choices unless they violate a clear textual dictate.

Yet, as noted, there are a few clear textual requirements. Injunctions must be available in at least some instances; that is evident from Article 44. And Article 41(1) sets out general requirements according to which decisions to grant, deny or condition relief must be assessed: the relief must be effective and expeditious, and remedies must be sufficient to deter future infringement. These are the TRIPS standards that are most likely to be engaged by any approach to injunctive relief, but discretionary decisions can have differential impacts that might raise issues under other provisions in the Agreement. Thus, our conclusion comes with several caveats.

1. The Adequacy of Monetary Damages

Article 41(1) requires that the relief granted – under *eBay* this would be something short of an injunction – must be effective and sufficient to deter future

Not everyone agrees. See Knowledge Ecology International, General Statement to the 15th Standing Committee on the Law of Patents (SCP) (Oct. 12, 2010), available at www.keionline.org/21393 ("Finally, KEI notes that the experts failed to distinguish between compulsory licenses that are granted under the procedures of Part II of the TRIPS, concerning patent rights, and those granted under Part III of the TRIPS, concerning the remedies for infringement of those rights"); Sarnoff 2010, 58 & 59.

⁵² See, e.g., De Carvalho 2010, 64; Sarnoff 2010, 48; Malbon et al 2014, paras. 44.04–44.05.

infringement. So, will offering the patentee damages in lieu of an injunction meet this standard? To be sure, the four-factor test set out in *eBay* requires the court to consider whether the right holder could be adequately compensated with money damages and presumably other countries do the same. Yet adequate compensation may not always be enough to deter infringement. A rational actor may believe that there is a strong probability that its infringement will not be discovered and that if it is, the award of damages will be no less burdensome than royalties. Indeed, awards in the future may be considerably lower than royalties. After all, courts tend to make their calculations by reference to comparable licensing arrangements,⁵³ but comparable rates may fall over time as potential licensees come to understand the circumstances in which they will not be enjoined and, in those circumstances, refuse to pay what the patent holder demands. As a result, these judicially established royalty rates may come to set a ceiling on the price patent holders can negotiate from licensees.⁵⁴

Whether that violates TRIPS may depend on the rationale cited to withhold relief. One concerns PAEs. Christopher Seaman's work shows that the impact of *eBay* on them is considerable.⁵⁵ Since one of the justifications for denying an injunction in these cases is that the PAE industry was developed "primarily to obtain licensing fees"⁵⁶ and that the fees demanded with threats of injunctive relief were "exorbitant,"⁵⁷ awarding them damages at a low rate may not raise difficult questions. Normatively, their return on investment should be lower than their exorbitant demands. But since Justice Kennedy was likely thinking about patent trolls – right holders who send demand letters to naïve defendants in the hope they will quickly capitulate and pay up⁵⁸ – denying injunctive relief could be thought of as a safeguard against abuse, which, as we saw, is specifically mentioned in Article 41 (1), as well as in Articles 8(2) and 40(2).

However, it is not clear that all entities that earn their revenue through assertions are the bad actors the Supreme Court had in mind. For one thing, there are organizations that specialize in inventing. For example, universities and government laboratories are largely engaged in fundamental research; they do not commercialize their work themselves. In some cases, they may assign their patents and turn over enforcement to assignees. Since they are strongly encouraged to license on a nonexclusive basis, enforcement will largely be up to them. ⁵⁹ To courts, they may

⁵³ See, e.g., Cotter 2018, 164.

⁵⁴ Venkatesan 2009; Lim & Craven 2009, 817.

⁵⁵ See Seaman 2016, 1988 (noting that PAEs prevailing on liability were awarded injunctions in 16% of the cases as compared to other patentees, who were successful in 80% of their cases).

⁵⁶ *eBay* (2006, p. 396) (Kennedy, J., concurring).

⁵⁷ Id

⁵⁸ See, e.g., Lemley & Melamed 2013, 2163 (describing "bottom-feeder trolls"); Johnson 2014, 2033 (describing the problem in Vermont and its response in Act of Jul. 1, 2013, No. 44, § 6, 2013 Vt. Legis. Serv. 44 (West) (codified at Vt. Stat. Ann. tit. 9, § § 4195–99 (2013))).

⁵⁹ See AUTM 2007, Points 1 & 2. See, e.g., Textile Productions (Fed. Cir. 1998).

then appear to be PAEs. Yet it is hard to argue that the fees demanded for using fundamental discoveries are exorbitant or that they are abusing the system. ⁶⁰

In addition, Seaman's study shows that to a significant extent, *eBay* is applied to deny relief to patent holders who are working their invention, but are not in direct competition with the infringer (for example, a party who holds rights on a patent to manufacture lenses and makes lenses for cameras but not for eyeglasses is not in direct competition with infringing eyeglass manufacturers). These patentees are also not abusing the system. It may be true that, like PAEs, they rely only on monetary returns and that in the markets that they are not exploiting there are no subsidiary nonmonetizable benefits, such as developing a loyal customer base or selling ancillary products. Still, a system that depresses royalties can deny inventors fair compensation in markets to which their inventions contributed. Furthermore, such a system will fail to deter infringement.

But these considerations may be better directed to national lawmakers than to WTO adjudicators. The effect of withholding injunctive relief depends on how damages are calculated and it may be difficult to challenge such calculations under TRIPS. Article 45 provides little guidance on how to determine appropriate relief and we doubt that WTO adjudicators would consider relief on a case-by-case basis: a systemic analysis that looks at cases and licensing practices over a period of time, appears more consistent with the purpose of TRIPS and the WTO. Furthermore, as long as licensing negotiations occur, it is unlikely that the DSB would find deterrence inadequate.

A second rationale concerns holdups. Justice Kennedy was concerned that when a product was made up of many components, the holder of a patent on any one of them could demand high royalties and the leverage of an injunction would allow it to extract a disproportionate share of the value (or, of course, the product might simply not come to market). The adequacy of compensation is a problem here as well, in part because experience shows that determining the appropriate royalty rate for a small component in a large product is notoriously difficult. In the United States, it has been the subject of multiple cases and considerable uncertainty. Which way this difficulty cuts is, however, another question. It suggests that the compensation awarded could easily be inadequate and fail to deter infringement. But since there is no generally accepted way to calculate royalties in these situations, the WTO is unlikely to step in and declare any particular method incompatible with TRIPS.

⁶⁰ In many cases, research institutions transfer their patents to aggregators who specialize in licensing and enforcement, at prices that are a function of the rewards the aggregator can extract. Treating these aggregators as PAEs will depress what they are willing to pay and reduce the return on fundamental research. See, e.g., Chien 2014.

⁶¹ Seaman 2016 (21% of prevailing noncompetitive patentees vs 84% of patentees who were in competition with the infringer).

⁶² See Clemons 2014; Kappos & Michel 2017, 1433.

Justice Kennedy also suggested a third justification for withholding injunctive relief: patents are sometimes vague and of suspect validity. ⁶³ In the United States, courts appear to be applying this criterion. Thus, holders of software patents – which raise significant validity questions – suffered the lowest grant rate of injunctive relief in Seaman's study. 64 But denying injunctive relief to take account of "suspect validity" is a cheap way to solve the problem of low-quality patents. Article 28 requires member states to grant the same set of rights to all patentees. Thus, it would seem that a court must either invalidate such a patent or treat it, for purposes of awarding final relief, the same as every other patent. While it thus strikes us that denying an injunction on this ground is a clear violation of TRIPS, we do not believe that problem will arise often. Under Article 52 of the European Patent Convention, programs for computers claimed as such are not patentable. Significantly, within a few years after eBay, US Supreme Court decisions in a group of cases relating to patent-eligible subject matter also made it extremely difficult to patent not only the business methods specifically mentioned by Justice Kennedy, but also computer software inventions. 65

Although not among Justice Kennedy's justifications for denying permanent injunctive relief, the public's interest in health, safety and employment may provide other rationales for allowing infringers to continue their operations. Justice Kennedy's failure to mention health and safety may have stemmed from the fact that these considerations were well recognized as rationales for denying injunctions even before eBay. 66 However, in the United States, these cases are rare and depend on a demonstration of necessity. Seaman, for example, found that post-eBay, injunctions were awarded in 100 percent of the biotechnology cases and 92 percent of the pharmaceutical cases, likely on the theory that the public interest favors maximizing incentives to invent in these sectors, and thus supports granting injunctions. ⁶⁷ But in some countries, courts may deny injunctions on such grounds. Whether a denial based on public interests is compatible with TRIPS may depend on the specifics of the situation. It is noteworthy that the Canada-Pharmaceutical Products panel never considered the public interest once it found that Canada's stockpiling exception was not "limited" and therefore violated the first part of Article 30 three-step exception test.⁶⁸ Moreover, Article 31 specifically contemplates the public interest in subsection (b), where it singles out only "national emergencies or other circumstances of extreme urgency" for special consideration. While the WTO's Doha Declaration emphasized the interest in health and stressed the right

⁶³ eBay (2006, p. 397).

⁶⁴ Seaman 2016, 1985 (grant rate of 53%, compared to 100% in biotechnology).

⁶⁵ Alice Corp. (2014); Bilski (2010).

Examples include Vitamin Technologists (9th Cir. 1945); City of Milwaukee v. Activated Sludge (7th Cir. 1934).

⁶⁷ Seaman 2016, 1985 & 2004.

⁶⁸ Canada-Pharmaceutical Products, para. 7.38.

of every country to determine for itself what constitutes an emergency,⁶⁹ it remains likely that very close scrutiny will be given to a practice of denying injunctions on public interest grounds. First, the determination of an emergency may not be entirely self-judging.⁷⁰ Second, the size of the monetary relief awarded in lieu of an injunction may loom large in the determination. For example, awards of the sort contemplated as remuneration by the World Health Organization may not be considered sufficient.⁷¹

2. National Treatment and MFN

As noted above, patentees not in competition with infringers are not awarded injunctions at the same rate as those that exploit the patent in the infringer's field. To the extent that patent holders are more likely to license (rather than practice) in remote jurisdictions, they may find themselves treated differently from local right holders. Such cases arguably raise challenges under the national treatment or MFN obligations in TRIPS.⁷² For example, it may be more convenient for US and Canadian holders of US patents to exploit their patents in the United States than it is for a Japanese holder of a US patent, who will have to expend resources to develop support materials in English and acquaint itself with North American preferences. If the Japanese right holder is considered a PAE, it could be treated differently from the American (a national treatment violation) and the Canadian (an MFN problem).

Admittedly, there is no *de jure* discrimination in this scenario: all patent holders that sue noncompetitors are subject to the same discretionary rule, based on the notion that monetary damages are sufficient to compensate. However, in the *EC-GI* case,⁷³ a panel held that *de facto* discrimination may also constitute a violation of TRIPS. The regulation at issue made it easier for those producing foodstuffs in the EU to obtain EU geographical indications (GIs) than those producing foodstuffs elsewhere.⁷⁴ Although the discrimination was not based on the nationality of the producer, the panel reasoned that "the vast majority of natural and legal persons who produce, process and/or prepare products according to a GI specification within the

⁶⁹ WTO Ministerial Conference, Declaration on the TRIPs Agreement and Public Health, WT/ MIN(01)/DEC/2, paras. 4 and 5(c) (Nov. 20, 2001) [hereinafter Doha Declaration].

^{7°} See Saudi Arabia – IPRs, para. 7.230 (requiring interpretation of the security exception of TRIPS Article 73 to meet a standard of plausibility).

Vorld Health Organization 2005, 6 ("When countries are facing difficult resource constraints, and cannot provide access to medicines for all, royalty payments should normally not exceed a modest fraction of the generic price").

⁷² See TRIPS, arts. 3-4.

⁷³ Panel Report, European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, WT/DS174/R (Mar. 15, 2005) [hereinafter EC-GI].

⁷⁴ EC Council Regulation (EEC) No. 2081/92 of Jul. 14, 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, as amended.

territory of a WTO Member party to this dispute will be nationals of that Member," and that accordingly, "the Regulation . . . will operate in practice to discriminate between the group of nationals of other Members who wish to obtain GI protection, and the group of the European Communities' own nationals who wish to obtain GI protection, to the detriment of the nationals of other Members." Arguably, the same would be true of a rule that awards injunctive relief based on whether the plaintiff exploited the patent or licensed it. If it could be demonstrated that the vast majority of those exploiting the patent in the relevant field were locals, the denial of relief on the basis of whether the patent holder was in competition with the infringer could be considered *de facto* discrimination.

But such a finding is far from certain. The *EC–GI* panel found that discrimination was "a feature of the design and structure of the system." It was also impressed by the link between "persons, the territory of a particular member, and the availability of protection." Here, the reasoning is that if monetary damages are sufficient to compensate for the injury (as discussed in Section C.2), injunctive relief is not required to make any patent holder whole. Since injunctions can promote abusive practices, courts should have the discretion to deny a form of relief that could injure the public and which the plaintiff does not need. Protectionism is not a feature of such a system. Moreover, GIs are meant to signify a connection between product and territory; patents lack that symbolic connection.⁷⁸

3. Discrimination by Field of Technology

Justice Kennedy argued that patents should also be denied when the "patented invention is but a small component of the product" produced.⁷⁹ As suggested earlier, his concern was holdup: that the patent holder could use the threat of an injunction for "undue leverage."⁸⁰ Because not all products are made up of components, the impact of this provision is highly field-dependent. Thus, Seaman found that posteBay, the rate at which injunctions were granted was lower for medical devices, electronics and software, where products often have multiple patented components, than is the rate in fields like biotechnology and pharmaceuticals, where the

⁷⁵ EC-GI, at para. 7.194.

⁷⁶ Id.

⁷⁷ Id. at para. 7.189.

A country might also allow a firm that is employing locals to work the patent to continue its operations when a foreign patent holder relies on importation rather than domestic production. This would similarly raise national treatment problems. It would also raise concerns about compatibility with the local working provision in art. 5 of the Paris Convention, which are beyond the scope of this chapter. See Dinwoodie & Dreyfuss 2012, 43–45.

⁷⁹ eBay (2006, p. 397).

⁸⁰ Id.

patent-to-product ratio is much lower. ⁸¹ The holders of patents on medical devices are particularly hard hit because the demand for an injunction can also fail under the fourth factor in *eBay*: given the number of people dependent on medical devices such as hip and heart valve replacements, an injunction could have severe public interest consequences. Of course, biotech and pharmaceutical inventions raise similar public interest concerns. However, as Seaman notes, in both fields, the risks and costs associated with bringing products to market are high, courts see strong patent rights as so necessary to encourage innovation that interest dominates over the interest of the public. ⁸²

Does this difference in treatment violate Article 27(1), which prohibits "discrimination as to ... the field of technology"? As we saw, the Canada-Pharmaceutical *Products* panel was highly sensitive to the issue of field discrimination and applied the provision in a manner similar to the way the cornerstone obligations of national treatment and MFN are handled – as an overarching consideration. At the same time, however, the panel also recognized that fields can raise unique problems. As long as the principle at issue is "also applied to other areas where the same problem occurs," the differential treatment does not violate TRIPS. 83 Indeed, the panel saw this approach to developing the law as "a common desideratum in many legal systems."84 Here, holdup concerns and holdup-like concerns would presumably be treated the same way in any field - indeed, Seaman's study found three fields affected by this approach. Furthermore, the same rule is sometimes applied to holdout and holdout-like situations, where the user refuses to accept a license. Consider, for example, FRAND licenses, which are common in fields, such as communication technologies, where interoperability is a concern. In these fields, standard-setting organizations choose the inventions that will constitute the standard, and often require the holders of rights over these inventions to license their socalled standard essential patents on fair, reasonable and non-discriminatory (FRAND) terms. Disputes often arise as to what constitutes FRAND terms and some jurisdictions argue that a patentee bound by a FRAND promise cannot be awarded injunctive relief when the implementer rejects the license on the ground that the patentee is asking too much – that its offer of a license is not FRAND.⁸⁵

Other arguments also support the failure to award injunctive relief in such cases. Refusing a FRAND license is essentially an attempt to extract disproportionate royalties; as such, it is a form of abuse in that it either diverts rewards from other

⁸¹ Seaman 2016, 1985 (comparing the injunction rate for biotech patents (100%) and pharmaceuticals (92%) with the rates for electronics (67%), medical devices (65%) and software (53%).

⁸² Id. at 2005.

⁸³ Canada-Pharmaceuticals, para. 7.104.

⁸⁴ Id

⁸⁵ See, e.g., Apple, Inc. (ND Ill. 2012)(Posner, J.,), aff'd in part, rev'd in part and remanded, 757 F.3d 1286 (Fed. Cir. 2014); Microsoft Corp. (9th Cir. 2012); Huawei Techs. Co. Ltd. (CJEU 2015); Unwired Planet Int. Ltd. (EWHC 1304 (Pat.) 2017). See also Brankin et al. 2015; Epstein & Noroozi 2017, 1381.

worthy inventions or stymies the development of products consumers might enjoy. Similarly, holdouts abuse the patent holder's promise and divert revenue from the inventor to the implementer. The denial of injunctive relief in these situations can also be analogized to an effort to deal with blocking patents, which is permissible under Article 31(l). Finally, denials here may be justified under the Objectives and Principles of the Agreement. Because these behaviors can prevent manufacturers from bringing product improvements to market, they implicate Article 7 and its objective of promoting technological innovation and seeking the "mutual advantage of producers and users." Furthermore, Article 8 allows states to protect public health, which is a concern for medical devices.

Admittedly, the weight to be afforded to Articles 7 and 8 was cast into some doubt by the report of the WTO panel in *Canada–Pharmaceutical Patents*. However, the Doha Ministerial Declaration buttresses their invocation. Admittedly, the precise status of the Ministerial Declaration is uncertain. ⁸⁶ However, the Appellate Body in the *Australia–Plain Packaging* dispute supported the panel decision's emphasis on Articles 7 and 8, if not its reliance on the Ministerial Declaration itself. ⁸⁷ Thus, as Daniel Gervais has suggested, post-Doha panels may give these provisions a "somewhat higher normative profile," and be more receptive to flexibilities when cast in terms of public health. ⁸⁸ In addition, the Doha Declaration, like Article 8, is directed at heath and "promoting both access to existing medicines and research and development into new medicines." ⁸⁹ Thus, while it may support the denial of injunctions in medical device cases, the nature of the interaction between TRIPS and fundamental (human) rights outside the sphere of healthcare is more contested. ⁹⁰

D. CONCLUSION

Over time a country may be able to show systematic denials of rights, or inadequate compensation in lieu of injunctions, based upon patterns of decisions granting or denying injunctive relief. But the mere fact that courts have the discretion to deny injunctive relief that might result in the failure to meet the standards will not of itself constitute a TRIPS violation. The Appellate Body has made clear that panels should not assume that member states will exercise discretion inconsistently with their

In Appellate Body Reports, Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, WT/DS435/AB/R and WT/DS441/AB/R (Jun. 9, 2020), the Appellate Body refused to opine on the panel's view that the Declaration is a subsequent agreement between the parties and binding under the Vienna Convention on the Law of Treaties, para. 6.626.

⁸⁷ Id.

⁸⁸ Gervais 2008, para. 2.87; Gervais 2012, paras. 1.66–1.67 at 62–63; Gervais 2007, 19.

⁸⁹ Ministerial Declaration, para. 17, WT/MIN(01)/DEC/1, Nov. 20, 2001.

^{9°} See generally Helfer & Austin 2011.

TRIPS obligations.⁹¹ Thus, compliance will only become an issue when a pattern or practice emerges that reveals that a rule has evolved out of the nominal discretion.⁹² And the *China–Enforcement* panel put a heavy burden of proof on the United States in this regard.⁹³

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⁹¹ See United States – Section 211, at para. 259 (citing Chile–Taxes on Alcoholic Beverages, para. 74, WT/DS87/AB/R, WT/DS110/AB/R (WTO Appellate Body, 2000)).

⁹² See Dinwoodie & Dreyfuss, 2012, 74; see also Reichman 1997, 346–48 (arguing for a ripeness doctrine).

⁹³ See China – Enforcement, paras. 7.289–7.291 & 7.297.

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