ISDS and Intellectual Property in 2020—Protecting Public Health in the Age of Pandemics

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A. Introduction

11.01 Much as in 2019, intellectual property (IP) was not a major feature of the investor-state dispute settlement (ISDS) landscape in 2020. Some of the cases instituted earlier remained pending and new cases were filed, but there were no final awards directly related to IP. Unlike last year, however, the events of 2020 laid fertile ground for future investment disputes. Should these materialize, they will raise crucial questions regarding a state’s authority to protect public health in ways that have a deleterious impact on IP assets. That issue was at the heart of the cases that first drew attention to the consequences of considering IP an investment entitled to protection under international investment agreements (IIAs). In the two disputes decided on the merits, Philip Morris v Uruguay and Eli Lilly v Canada, the states won. However, the awards left many open issues on the scope of regulatory autonomy over IP rights. As I posited in last year’s Yearbook, the dearth of follow-on challenges suggested that both states and investors were reassessing their approach to exclusive rights in knowledge-based assets, at least when they affect public health. Right holders may have become reluctant to engage in disputes that would prompt states to negotiate new IIAs to better safeguard their regulatory authority. Moreover, states may have become wary of taking on the risks and costs associated with investor-state challenges to measures that impinge on IP rights.

11.02 However, the pandemic that began in 2019 left many states with little choice but to step in. Information exchange was critical to contain the raging coronavirus and speed the development of diagnostics, treatments, and vaccines. Scientists needed access to data on SARS-CoV-2, including all its variants, existing pharmaceuticals (to see whether they could be repositioned), diagnostics, vaccines, and manufacturing platforms (to determine whether they could be adapted), and research results of others working in the field. Because technologists predicted that multiple production facilities would be needed to satisfy global demand for medicines, diagnostic kits, and vaccines, as well as personal protective equipment, testing gear, ventilators, refrigeration units, vials, syringes, and the like, widespread dissemination of specifications, safety, and efficacy data, and manufacturing details was contemplated. To ensure safety and treat patients with ‘long COVID’ (symptoms that extend beyond the point of nominal recovery), it was also anticipated that there would be a continuing need to share data on variants, new treatments, and patients and their welfare.

11.03 Much of this information was patented, claimed in patent applications, copyrighted, subject to data exclusivity regimes, or kept as trade secrets. To release the information, governments and scientific, international, and non-governmental organizations encouraged data sharing, private-public partnerships, patent pools, IP pledges, and voluntary transfers of technological information and finished products at low (or no) cost. However, not everyone was on board with this approach. Many pharmaceutical firms branded voluntary schemes ‘nonsense’: they had invested billions in coronavirus-related research and argued that it would be ‘dangerous’ to be stripped of exclusive rights in what they discovered. Moreover, some countries succumbed to vaccine nationalism and engaged in advance purchase and other financing schemes that deprived the rest of the world of a proportionate share in early supplies. The result was that many states enacted measures to limit IP
rights as a way to ensure local access. Others expanded existing exceptions and limitations. Several members of the World Trade Organization (WTO) asked for a waiver of their obligations under the TRIPS Agreement for the duration of the pandemic—a move eventually endorsed by the US but opposed by many of the countries where research on COVID-19 was conducted.

11.04 As of the date of this chapter (May 2021), the waiver question has not been resolved. But even if the WTO were to agree to waive TRIPS obligations, the decision would bind only the member states; it would not directly affect the private parties who own the relevant IP rights. Thus, the events of 2020 could raise difficult questions as to whether right holders can successfully challenge COVID-related state action under investment law. The pandemic will, in short, constitute a stress test. In this chapter, I conduct a thought experiment on how such suits might unfold. The first part describes how states sought or may seek to exercise control over the knowledge and products needed to protect public health during the global pandemic. The second considers the challenges that investors might lodge and identifies the places where safeguards protecting sovereign authority over healthcare may fall short.

B. Limiting IP Rights

11.05 The pandemic of 2019−20 spurred many voluntary initiatives to facilitate coronavirus research and disseminate the materials needed to combat the pandemic. The World Health Organization (WHO), with the aid of the Bill and Melinda Gates Foundation, CEPI, GAVI, UNITAID, the Wellcome Trust, and others, launched a time-limited collaboration to develop, produce, and distribute health technologies relevant to the pandemic. Although participation in that effort was not universal, a variety of platforms and agreements emerged or were expanded. Examples included COVAX, launched by the WHO, the European Commission, and France to provide equitable access to innovations to treat COVID-19; the US Patent and Trademark Office’s Patents 4 Partnerships, which created a list of relevant US patents that were available for licensing; UNITAID’s Medicines Patent Pool, which expanded on previous efforts to promote the licensing of drugs treating other infectious diseases; the Open COVID Pledge, which focused on IT and engineering information; private-public partnerships, such as the one between Oxford University and AstraZeneca to develop a vaccine; and agreements between firms in developed and developing countries, such as the agreement between Novavax and the Serum Institute of India on manufacturing. In addition, organizations such as the World Bank made financial resources available to ensure that needed medicines and vaccines would be distributed in developing countries.

11.06 Important though these initiatives were, they had critical shortcomings. Financial commitments were inadequate to protect the entire population of the globe. For example, as of the beginning of December 2020, COVAX had reserved only 700,000 doses of vaccine, yet over 2 billion doses were needed to vaccinate the population it wished to serve. Some states slipped between the cracks: although they lacked resources to meet their own needs, they were too rich to attract financial support. While patent pledges could lead to more research and production, they too had potential limitations. Some may have allowed the use of the claimed inventions for development purposes but did not include the right to distribute the fruits of the research; some may not have covered the safety and efficacy data critical for acquiring marketing approval or the trade secrets needed for manufacturing. Some initiatives were essentially clearinghouses. Complex licensing negotiations were required to make use of the protected knowledge. In most cases, the commitments were also time-limited: the information and products they covered could be used during the pandemic and perhaps for a short time afterwards. But it was not clear the period envisioned would extend to treating patients suffering from long COVID; inoculating future
generations; or dealing with the possibility that continued immunity would require boosters, with mutations requiring new treatments and different vaccines, or with other sources of pandemic.

11.07 It is therefore not surprising that states supplemented these voluntary efforts. Legislatively, compulsory licences dominated. Typically, these measures give governments the authority to permit a party to practice a patented invention without the patentee’s permission. Still, these licences are usually granted only after efforts have been made to acquire permission from the right holder and only upon a court order. However, in the early days of the pandemic, several countries enacted new provisions to allow government authorities to issue such licences more expeditiously. For example, France’s Emergency Law No 2020-290 to combat the COVID-19 pandemic added a provision giving the French prime minister authority to requisition goods and services necessary to fight health disasters, provided the measures were proportionate to the health risk and terminated when no longer needed. Although not mentioned in the emergency law, implementation of the provision would presumably also allow the prime minister to override relevant data exclusivities (and, presumably, trade secrecy rights) so that the goods and services could actually be provided.

11.08 In addition, some countries expanded government (crown) use. Although these provisions are common in the legislation of many countries, historically, they were rarely invoked. However, the pandemic led to renewed interest in them. For example, while Canadian patent law previously permitted the national or a provincial government to authorize government use of a patented invention, its COVID-19 Emergency Response Act added a compulsory licence provision—good through 20 September 2020—requiring the minister of health to allow a party other than the patentee ‘to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency.’ The provision also required the minister to declare a health emergency formally. However, it did not, as per its predecessor provision, mandate efforts to obtain authorization on reasonable terms (although it did require payment of an amount that ‘the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization and the extent to which they make, construct, use and sell the patented invention’). As with France’s emergency law, the measure would presumably lead Canada to override related rights as well.

11.09 There were also suggestions that countries alter their approach to trade. One idea was that countries replace regional or national exhaustion policies with international exhaustion rules so that needed materials could be imported from places where they were plentiful and available at a reasonable price. Another recommendation was addressed to countries that had opted out of a TRIPS amendment which permits one WTO member state to authorize production on behalf of another. The view was that if these countries opted back in, they could optimize their ability to secure adequate supplies of needed materials. Furthermore, several countries imposed export restrictions. For instance, Australia prohibited the export of goods essential for preventing COVID-19.

11.10 Some countries also responded to COVID problems through executive action. One example was President Trump’s September 2020 Executive Order to lower drug prices. Under the Centers for Medicare and Medicaid Services Most Favored Nation Rule, which was adopted under that order, the price for covered drugs was to be set at an amount comparable to the lowest price, adjusted for purchasing power, paid by any country in the OECD that has a GDP per capita that is at least 60 per cent of the US GDP per capita. Although not specifically tied to the pandemic, the covered medicines included drugs.
authorized to treat patients with suspected or confirmed cases of COVID-19.\textsuperscript{36} Similarly, the Australian health minister used emergency powers to address price-gouging.\textsuperscript{37}

11.11 Adjudication offered another avenue for improving access to COVID-related knowledge and products. For example, many national patent laws include an experimental use exception.\textsuperscript{38} While these are usually limited to non-commercial research efforts,\textsuperscript{39} a court could reason that actions taken to respond to a pandemic qualify, even if the defendant contemplated commercialization at a later date. Courts could also refuse to grant injunctive relief to right holders when defendants engaged in infringing acts with important social benefits.\textsuperscript{40} Furthermore, as commentators in the US suggested, courts might agree that government scientists played an important enough role in developing COVID treatments to be considered co-inventors.\textsuperscript{41} Under US patent law, such an action would give the US the rights of a co-owner and allow it to use the inventions for the public benefit without any obligation to account to joint inventors.\textsuperscript{42}

C. Investor Disputes

11.12 It is not clear that any, or which of, these measures were (or will be) implemented. However, it is evident that if countries take one or more of these approaches to obtain coronavirus-related knowledge and products, their actions will significantly impact the value of related IP assets. Thus, any such action could lay the groundwork for claims of indirect expropriation under most IIAs.\textsuperscript{43} For example, although compulsory licences, crown use, and denials of injunctive relief all require compensation, it is unlikely that most states could afford to remunerate right holders an amount anywhere close to what they could charge for diagnostics, medicines, or vaccines in an open market in the middle of a pandemic. Trade measures and price controls could similarly significantly lower the price at which right holders would otherwise sell.\textsuperscript{44} Expanding experimental use exceptions or asserting government ownership would go even further and deprive right holders of markets in which they would otherwise enjoy exclusivity.

11.13 Some of these actions could also form the basis for claims that fair and equitable treatment (or justice) was denied. As noted, the COVID-related compulsory licences that were enacted do not require consulting right holders or include other guarantees typically found in such provisions. Some measures involve abrupt changes in the law. For example, the US had been in the process of narrowing the scope of experimental use.\textsuperscript{45} Suddenly expanding it would arguably undermine right holders’ expectations of greater exclusivity. So too, a sudden decision to impose price controls, regard US scientists as co-inventors and co-owners of important patents, or change the exhaustion rules. Some measures might also be challenged on the ground that they were arbitrary, for example, because they were adopted before a need had materialized. Or it might be said that they discriminate against foreign investors. Opting into the TRIPS amendment mentioned earlier is even more fraught because several WTO members agreed to modify the Agreement on the explicit understanding that many of the countries with large markets would not participate as importers.\textsuperscript{46}

11.14 One might have thought that the pandemic would not constitute a meaningful stress test; that the exigencies of the situation would dissuade investors from lodging ISDS claims on COVID-related actions; or that essential security exceptions in IIAs would discourage them from challenging states’ responses to the pandemic. However, these prospects for avoiding arbitration may be largely illusory. The year 2020 was barely half over when the first notice of a pandemic-related dispute was filed.\textsuperscript{47} It did not involve IP, but there is no reason to believe investors would consider IP assets off the table. Moreover, there are several reasons to think that security exceptions might fail to provide states with comprehensive protection against the costs and risks associated with ISDS. There may be
older IIAs that do not include such an exception or have provisions strictly limited to military threats.48 Some security exceptions exclude claims for discriminatory treatment.49 Some may be regarded not as exceptions to protection but rather as defences and would therefore be considered with other merits issues.50 Furthermore, these provisions, particularly in older IIAs, may not be regarded as self-judging.51 Or because IIAs are subject to the Vienna Convention’s requirement of good faith, arbitrators may decide they have the authority to determine whether the state could reasonably regard the security exception as triggered and to decide whether the actions it took were necessary.52

11.15 To be sure, during the pandemic, tribunals are likely to agree that the host country had the authority to act and that whatever measures were taken were necessary. In January 2020, the WHO Director-General declared a Public Health Emergency of International Concern (PHEIC).53 As Fred Abbott cogently argued, its statement would likely be considered objective evidence that limiting IP rights was ‘necessary for the protection of its essential security interests … taken in time of … emergency in international relations’, which is the formulation of the security exception in the TRIPS Agreement.54 While this provision is not expressly aimed at health, Abbott reasoned that because the PHEIC deals with transmissions across national borders, which affect international trade and travel, and because the misallocation of resources could lead to hostilities, it would fit within that language.

11.16 But it is not clear that all ISDS tribunals would be willing to consider measures narrowly drawn to deal with military threats as capacious enough to include pandemics. In addition, some arbitrators may not be willing to adopt the views of the WHO. Thus, in Philip Morris’s challenge to Uruguay’s tobacco packaging regime, Uruguay relied on the WHO Framework Convention on Tobacco Control to claim that its measures were scientifically valid and therefore not arbitrary. The tribunal accepted the argument. However, a reference it made to Uruguay’s ‘limited technical and economic resources’ suggests that more evidence may be required of nations not similarly situated.55

11.17 Even if tribunals were to accept that the PHEIC (or the obvious evidence of a global pandemic) provides a basis for relying on a security exception, the host state might nonetheless encounter problems. One is temporal. Even after the pandemic is over as a scientific matter (eg once the WHO decides that transmission rates have declined enough to end the emergency),56 state interests in IP assets may well endure. For example, states may wish to enjoy continued access to vaccines in order to inoculate future generations, administer boosters, and treat populations initially resistant to immunization. States may also need to use protected technologies to continue monitoring the virus to determine whether it has mutated, watch for long-term effects in infected patients, and follow the vaccinated population to ensure that the immunity endures. As noted above, some of the voluntary efforts and special measures taken during the pandemic were time-limited, but states may find the duration too short to deal with all the problems the pandemic caused. Furthermore, they may wish to continue using the products, processes, and data created during the period when pledges, special research exemptions, or crown use measures were in effect. Thus, ISDS tribunals could be put in a position where they must decide how long a host state can continue to assert a security exception.57 Argentina’s ISDS experience defending actions taken in response to its financial crisis suggests that the outcome in such a case is highly uncertain.58

11.18 Furthermore, even if a tribunal were to find that security exceptions apply beyond the pandemic period, necessity may become increasingly hard to establish. Once a population achieves herd immunity, continued use of protected technologies may be regarded as discretionary. It may become similarly difficult to consider monitoring activities—which will likely be incorporated into routine healthcare—as necessary enough to satisfy
these exceptions. In addition, the uncoordinated approach that countries took to the coronavirus led to the discovery of multiple treatments, diagnostics, and vaccines. This was certainly advantageous from a public health perspective in that it led to inventions that served different populations with different medical conditions and localities with differing abilities to store, deliver, and administer materials. However, with so many alternatives available, a host country may have trouble persuading a tribunal that its specific choice of a diagnostic, treatment, or vaccine was necessary. Of course, states should not be permitted to assert necessity when it no longer exists. However, because the progress of pandemics is so uncertain, there could easily be a gap between what a state viewed as necessary when it took action and what a tribunal considers as necessary in hindsight. In sum, it is unlikely that all the claims arising from the pandemic will be decided on the basis of a security exception.\(^\text{59}\)

11.19 Of course, a state can always claim that it did not indirectly expropriate the investor’s assets or deny it fair and equitable treatment. As to expropriation, a state might argue that its actions did not inflict a significant enough loss to be actionable. The Philip Morris tribunal accepted that argument with regard to limitations on the use of tobacco trademarks. However, at least partly, it did so because it considered the value of the investor’s assets as a whole. It did not evaluate the loss of value in each trademark separately.\(^\text{60}\) Although the tribunal failed to explain why it took that approach, it might have been relevant that Philip Morris’s trademarks all involved tobacco products and were all subject to the challenged regulatory regime. That commonality would not be as true of a pharmaceutical firm’s entire portfolio of intellectual property rights. If COVID-related IP assets are viewed separately from a firm’s entire holdings, it is hard to believe that the loss in value, coming amid the extraordinary demand generated by the pandemic, would not be considered significant enough to constitute indirect expropriation.

11.20 A state can attempt to invoke the police powers doctrine to assert that, under customary international law, it is free to protect health without regard to obligations regarding expropriation.\(^\text{61}\) Although this view has not been universally adopted,\(^\text{62}\) it was accepted by the Philip Morris tribunal.\(^\text{63}\) Still, Uruguay was required to demonstrate that the challenged measure was for a bona fide purpose, proportionate, potentially effective, and not arbitrary.\(^\text{64}\) Once again, defending actions taken during the throes of the pandemic may be straightforward. Furthermore, as we saw, some of the measures enacted expressly mention proportionality. But as the pandemic recedes in time, a state may have a harder time making its case. In particular, given the many diagnostics, treatments, and measures developed, a state may have a difficult time showing that any one choice of technology was not arbitrary.

11.21 As noted last year, many modern IIAs include explicit public health safeguards.\(^\text{65}\) But even those leave considerable room for an investment challenge. For example, the EU–Canada Comprehensive Economic and Trade Agreement (CETA) provides that measures do not amount to indirect expropriation if they protect ‘legitimate public welfare objectives such as health’—except when the effect is ‘severe’.\(^\text{66}\) However, the Agreement does not define ‘legitimate’ or ‘severe’. Over time, legitimacy may come into question. And many of the actions taken during the pandemic would, if implemented, have a very severe impact. Or consider the Armenia–Singapore Agreement. Like many other modern agreements, it includes a General Exceptions clause that provides that nothing in the Agreement should be construed to prevent a party from adopting measures ‘necessary to protect ... health’.\(^\text{67}\) Although that formulation is quite broad, over time, it may become harder to prove that a particular action is necessary.
11.22 Many modern IIAs also carve out from the expropriation guarantee actions that are ‘in accordance with the TRIPS Agreement’. But as Simon Klopschinski, Christopher S Gibson, and Henning Grosse Ruse-Khan have convincingly demonstrated, there is a great deal of uncertainty concerning the interrelationship between investment protection and international intellectual property law and between the decisions of WTO panels and ISDS tribunals. For example, if a waiver were enacted and a state relied on it to suspend an IP right, would an ISDS tribunal consider the action to be ‘in accordance with the TRIPS Agreement’? As contemplated as of this writing, the waiver would apply to actions taken ‘for the prevention, containment and treatment of COVID-19’. Would an ISDS tribunal regard that language as broad enough to allow a state to suspend rights over advances in general use, such as a patent on a method to manufacture the vials in which vaccines are stored, as opposed to a method to manufacture vaccine? Moreover, would an ISDS tribunal regard itself as bound by a WTO decision on these matters?

11.23 Even if it is assumed that a host state will rely on the Agreement itself rather than on the waiver, there are several open issues. Thus, a state might try to import into ISDS the security exception in the TRIPS Agreement and argue that it limits what states are obliged to provide to right holders. It is, however, clear from the report of the Saudi Arabia—IP Panel that the WTO does not regard this provision as entirely self-judging. Although Fred Abbott is probably right that in the immediate aftermath of the pandemic invoking this exception will be straightforward, the same temporal and necessity stumbling blocks discussed earlier could arise here as well.

11.24 Other measures may also be vulnerable to attack. The TRIPS Agreement contemplates compulsory licensing, crown use, and damages instead of injunctive relief. However, in these cases, compensation is required—for a compulsory licence, ‘adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization’; for damages, ‘adequate to deter further infringerments’. Given what consumers would be willing to pay to avoid the potentially horrendous effects of the coronavirus, states may have a difficult time justifying the adequacy of what they (or their populations) can afford to spend or even the amount the WHO remuneration guidelines suggest.

11.25 Under TRIPS, compulsory licensing also requires prior efforts to obtain authorization. There is an exception in national emergencies or other extreme urgency. But on its face, it is not clear that this provision is self-judging. Nevertheless, in the Doha Round of WTO negotiations, the Ministerial Conference issued a Declaration on Public Health which included a statement that each member has ‘the freedom to determine the grounds upon which [compulsory] licences are granted’ and ‘the right to determine what constitutes a national emergency or other circumstances of extreme urgency [within the meaning of TRIPS compulsory license provision]’. Unfortunately, the status of the Doha Declaration is unresolved. That issue arose in the WTO dispute over Australia’s tobacco packaging legislation. Although the Panel reasoned that the Declaration constituted a subsequent agreement among WTO members within the meaning of the Vienna Convention, the Appellate Body did not endorse that view. Thus, a tribunal might disregard the Declaration and decide for itself whether a state can rightfully invoke the exception. Alternatively, the arbitrators might decide that TRIPS is subject to a good faith commitment under the Vienna Convention, thereby allowing the tribunal to consider the state’s action. In addition, a tribunal may be troubled by the lack of individualized adjudication and right of review, both of which are required by TRIPS.
11.26 As to denials of injunctive relief, while the language of TRIPS makes it clear that courts can refuse to award injunctive relief, it also requires them to grant a remedy that will deter further infringements, which is generally understood to implicate monetary damages. Because that result is functionally equivalent to a compulsory licence, should courts systematically refuse to enjoin defendants from using coronavirus-related inventions, investors could arguably raise the objections applicable to compulsory licences.

11.27 States may also be required to defend their use of expanded research exceptions and the continued use of the materials created in reliance on such exceptions—and, perhaps, continued use of materials developed under a time-limited voluntary licence or patent pledge. In Canada—Pharmaceuticals, a WTO Panel upheld as within the TRIPS patent exceptions provision, a Canadian research exception which allowed generic drug companies to use patented pharmaceuticals to generate the data needed to obtain regulatory approval. However, the decision was predicated on a finding that the period of exclusivity that was truncated by the exception was not ‘a natural or normal consequence of enforcing patent rights’ but rather was an ‘unintended consequence of the conjunction of the patent laws with regulatory laws’. Outside that circumstance, the Panel took a very hard line. It held that the Agreement was violated by another exception in Canadian law, which allowed generic companies to stockpile patented medicines in order to be ready to distribute them as soon as the patent expired. Although, as Canada pointed out, the object and purpose of TRIPS include disseminating technology and promoting social welfare, the Panel reasoned that relying on such statements to give special considerations to health interests would be ‘equivalent to renegotiation of the basic balance of the Agreement’.

11.28 Unauthorized use of copyrighted materials, such as the reproduction and distribution of scientific articles, is even more vulnerable to challenge. Unlike the TRIPS exception for patents, the provision applicable to copyright appears to leave no room for public interest considerations. In the one WTO dispute applying that provision, US—110(5), a Panel rejected the argument that such consideration could be implied.

11.29 That said, the Canada—Pharmaceuticals and US—110(5) reports may no longer reflect the WTO’s views. They were decided before (and likely inspired) the Doha Declaration, which emphasized the relevance of the TRIPS Agreement’s objectives and principles. As we saw, the status of the Declaration is unknown. However, in the Australia—Plain Packaging case, the Appellate Body acknowledged that the object and purpose of the Agreement were relevant to treaty interpretation. Thus, weight should now be given to public health interests in analysing TRIPS flexibilities. Therefore, an ISDS tribunal may conclude that notwithstanding the earlier cases, a state’s use of IP assets to further health interests, especially in response to an emergency, is within the carve-out. Certainly, both the WTO and an ISDS tribunal were solicitous of public health concerns in the cases on tobacco packaging.

11.30 State actions that undercut data exclusivities and trade secrets also pose problems. TRIPS requires protection for undisclosed information. For data used to obtain regulatory approval for pharmaceuticals, it includes an exception for use that is ‘necessary to protect the public’. However, the question as to whether the condition is self-judging arises here as well. Moreover, many free trade agreements include more restrictive data exclusivity measures, and the necessity exceptions in these provisions may not be self-judging even if the one in the TRIPS Agreement is. Furthermore, there is no obvious exception applicable
to trade secrets. Indeed, the scope of obligations regarding technology transfer is currently pending at the WTO.99

11.31 Finally, it is uncertain how an ISDS tribunal would consider matters that TRIPS does not cover, such as price caps and ownership, or issues it expressly leaves to the states, such as basic rules on exhaustion.100 Because these issues were omitted, they could be regarded as outside carve-out for TRIPS-compliant measures. As a result, price controls and changes in rules on ownership could be vulnerable to expropriation claims. Alternatively, it could be argued that the omissions regarding these issues represent an affirmative decision by the WTO that states should enjoy autonomy on them and that in the spirit of the carve-out, a tribunal should defer to a state’s judgment.

11.32 A host state may have considerably more trouble dealing with claims based on the guarantee of fair and equitable treatment (FET). IIAs do not typically carve out TRIPS-compliant measures from this protection, and to the extent that FET commitments focus tribunals on the expectations of investors, the guarantee has considerable scope to intrude on a state’s right to regulate. In a few cases, investor expectations may be based on an explicit representation. Consider, for example, the amendment to TRIPS that makes it possible for a state to issue a compulsory licence to manufacture pharmaceutical products on behalf of another WTO country.101 The WTO’s decision to amend the Agreement was based, in part, on the understanding that ‘some Members will not use the system as importing Members’.102 That reservation arguably gave right holders a legitimate expectation that they would retain control over manufacture in the large markets of the members who opted out. Thus, a tribunal could find that opting back in constitutes a violation of an FET commitment.

11.33 But even without explicit promises, a tribunal may give state action considerable scrutiny. Indeed, the Lilly v Canada tribunal took a rather expansive view of the protectability of investor expectations, suggesting that dramatic changes in the law could constitute FET violations.103 As Susy Frankel and I argued, that rule seems wrong in the context of IP, where (as investors know) states must continually readjust the balance between public and proprietary interests in light of technological, social, and cultural developments.104 And as Klopschinski and his co-authors pointed out, the Lilly tribunal decided the investor’s claim on its facts. Canada won because Lilly could not, as a factual matter, demonstrate that the change in question was dramatic. Thus, the tribunal never decided the legal question whether investors have protectable expectations concerning the speed at which the law changes.105 For the same reason, it did not discuss how (or whether) a dramatic change can be justified. Given the exigencies of the pandemic, it seems unlikely that a tribunal would find against a state on an argument about the abruptness of changes instituted as a response. Similarly, a tribunal is likely to reject the converse argument that a state cannot anticipate the problems the pandemic might cause but must rather wait for a particular problem (such as the lack of vaccine) to materialize before it can act. Nonetheless, the temporal question remains as to whether a state can continue to use products and knowledge acquired during the pandemic after it is over. That is, a tribunal could find that investors cannot hold legitimate expectations that states will ignore a pandemic or fail to anticipate its consequences. At the same time, a tribunal could decide that investors have protectable expectations that states will not use a pandemic as an excuse to make permanent changes in their legal regimes.

11.34 FET provisions also protect investors from arbitrary actions and discriminatory treatment. As noted above, over time, arbitrariness may pose an increasingly difficult question. However, a claim based on discrimination is unlikely to succeed. To be sure, an investor might argue that pandemic-related measures discriminate against foreigners because life sciences IP assets are largely owned by right holders in a small group of
developed counties. However, the *Lilly v Canada* tribunal rejected a similar claim on the ground that intentional discrimination cannot be inferred from the fact that most pharmaceutical firms are not owned by Canadians.\textsuperscript{106} Similar reasoning should prevail here.

**D. Conclusion**

11.35 The COVID-19 pandemic may, unfortunately, not be the last such event. Because no state can end a pandemic on its own—because no one is safe until everyone is safe,\textsuperscript{107} it is in every nation’s interest that the knowledge and products needed to respond to this new challenge are widely available and that the discoveries made are broadly shared. That can require a high degree of cooperation among states, between states and the WHO, and among international organizations. But IP rights are held privately. Thus, more attention must be paid to IIAs, and how the actions states may wish to take will be perceived by arbitrators, even if states take these actions collectively and by agreement.

11.36 This thought experiment exposes potential weaknesses in the safeguards intended to protect sovereign authority over health. It demonstrates that, at a minimum, a state responding to a pandemic must shoulder the risk that investors will challenge their actions, that these disputes will be costly to defend, and that they could result in high awards. In earlier work, Susy Frankel and I suggested that one way to ameliorate this problem is through localization: IP rights should be regarded as an in-state investment only when the work to develop or manufacture the underlying knowledge product takes place in the host state.\textsuperscript{108} That approach would allow countries with lower inventive or manufacturing capabilities to take measures that enable them to benefit from other countries’ discoveries and productive capacity without worrying about the possibility of investment disputes. But even if that position were adopted, more is required. Countries should reexamine the security exceptions within their IIAs to ensure that they have the flexibility needed to take action during a health emergency as well as in its immediate aftermath. States should also evaluate the specific public health safeguards built into IIAs to determine whether pandemic-related measures can be defended without requiring detailed, expensive, and potentially unavailable evidence.

11.37 More would also be desirable at the international level. Efforts underway to give the WHO greater authority should be accompanied by modifications of IIAs to include explicit references to its expertise regarding the existence of a health crisis, actions needed to deal with health issues arising during the crisis, the identification of essential medicines, appropriate approaches to compensation, and the special needs of developing countries.\textsuperscript{109}

11.38 Most important, this thought experiment demonstrates why IP presents a somewhat unique problem to investment law, a problem that goes well beyond the localization issue alluded to above. Knowledge is a public good, and the pandemic exposes how high a price society may pay when it is privatized. Because that price is determined by the balance national laws strike between access interests and incentivization goals, investors’ expectations should be regarded as effectively set by the degree to which international law constrains that calculus. As a result, a system that allows ISDS tribunals to make their own decisions about what international intellectual property law requires, divorced from the system that enforces these constraints, makes little sense.\textsuperscript{110} That ISDS could effectively render nugatory a WTO decision to waive TRIPS obligations is a particularly stark example of this disjuncture. But it is almost as odd that ISDS tribunals can make their own decisions about the effect of the Doha Declaration or the meaning of TRIPS flexibilities. Or that they could regard a move from one TRIPS-compliant regime to another as a denial of fair and equitable treatment if it was made too suddenly. If states continue to protect IP assets in
IIAs, it behooves them to clarify the relationship between these agreements and the other regimes that shape the excludability of knowledge.

Footnotes:

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1 The pending cases included BeIN Corp v Kingdom of Saudi Arabia, Notice of Arbitration, UNCITRAL, 1 October 2018 <https://www.italaw.com/cases/6862> accessed 15 June 2021 (rights to broadcast copyrighted works) and Theodore David Einarsson and others v The Government of Canada, Notice of Arbitration, UNCITRAL, 18 April 2019 <https://www.italaw.com/cases/8154> accessed 15 June 2021 (copyrights in seismic maps and data). The Award in Bridgestone Licensing Services, Inc and Bridgestone Americas, Inc v Republic of Panama, Final Award, ICSID Case No ARB/16/34, 14 August 2020, which was predicated on trademark rights located in Panama, was decided on grounds unrelated to intellectual property law. Finally, Uber gave Colombia notice that it would bring an action under the United States–Colombia Trade Promotion Agreement, Uber Technologies, Inc and Uber Colombia, SAS v Colombia, Notice of Dispute, 30 December 2019 <https://www.italaw.com/cases/7823> accessed 15 June 2021. However, the case has not progressed publicly beyond that stage.

2 Philip Morris Brands Sàrl, Philip Morris Products SA and Abal Hermanos SA v Oriental Republic of Uruguay, Award, ICSID Case No ARB/10/7, 8 July 2016 (Philip Morris v Uruguay); Eli Lilly and Company v Government of Canada, Final Award, ICSID Case No UNC/14/2, 16 March 2017 (Eli Lilly v Canada); and Philip Morris Asia Ltd v The Commonwealth of Australia, Award on Jurisdiction and Admissibility, UNCITRAL PCA Case No 2012-12, 17 December 2015.

3 ibid.


5 Rochelle Cooper Dreyfuss, ‘ISDS and Intellectual Property in 2019: The Case of the Dog that Didn’t Bark’ in Lisa E Sachs, Lise J Johnson and Jesse Coleman (eds), Yearbook on International Investment Law & Policy 2019 (Oxford University Press 2020) 249, 253–54 (giving examples of legislation that was withdrawn or postponed until ISDS challenges to similar legislation in other states was resolved in favour of the state) (hereafter Dreyfuss, ‘ISDS and IP’).


See eg Contreras and others (n 8).


ibid, s 19.4(6).

TRIPS (n 12) art 31.


Executive Order 13948 on Lowering Drug Prices by Putting America First, 85 Federal Regulation 59649 (3 September 2020).


Madey v Duke University, 307 F.3d 1351 (Fed. Cir. 2002)


In prior case law, US scientists were regarded as not participating in the act of conceiving the first treatment for AIDS, Burroughs Wellcome Co v Barr Labs, 40 F.3d 1223 (Fed. Cir. 1994). But see James Krellenstein and Christopher J Morten, The U.S. Government’s Apparent Co-Ownership of Patents Protecting Remdesivir (20 May 2020) <https://static1.squarespace.com/static/5e937abfbd7a75746167b39c/t/5ecd88c5699191ae9bad9ea/1590528109403/The+U.S.+Government%27s+Apparent+Co-

42 *Ethicon, Inc v US Surgical Corp*, 135 F.3d 1456 (Fed. Cir. 1998).


44 The extent to which trade measures, such as export controls, violate trade agreements is beyond the scope of this chapter.

45 *Madey v Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).


49 ibid 93 citing art 12.2 of the 2003 BIT between India and Hungary.


51 The ‘self-judging’ concept means that states in the IIA intend to create for themselves a right to determine solely the legitimacy of extraordinary measures. UNCTAD, ‘National Security’ (n 48) 39–42.


55 Philip Morris v Uruguay (n 2) [393].


58 José E Alvarez, The Public International Law Regime Governing International Investment (Hague Academy of International Law 2011) 266–84; Federico Lavopa, ‘Crisis, Emergency Measures and the Failure of the ISDS System: The Case of Argentina’ in Kinda Mohamadieh, Anna Bernardo, and Lean Ka-Min (eds), Investment Treaties: Views and Experiences from Developing Countries (South Centre 2015) 193.


60 Philip Morris v Uruguay (n 2) [282]-[283].

61 See eg American Law Institute, Restatement (Third) of the Foreign Relations Law of the United States, s 712, comment (g) (1987).


63 Philip Morris v Uruguay (n 2) [291]. See also Chemtura Corp v Canada, UNCITRAL, Award, 2 August 2010 [266].

64 Philip Morris v Uruguay (n 2) [305]-[306], [390]; Dreyfuss and Frankel, ‘Reconceptualizing’ (n 4) 387–88. Some modern IIAs include an express right to regulate, Dreyfuss, ‘ISDS and IP’ (n 5) 257. But these may similarly leave room for a tribunal to consider whether the state’s policy objectives are legitimate and whether the measures adopted are sufficiently related to its objectives.

65 Dreyfuss, ‘ISDS and IP’ (n 5) 255–59.

66 Comprehensive Economic and Trade Agreement between Canada of the One Part, and the European Union and its Member States, of the Other Part (signed 30 October 2016, provisionally applied 21 September 2017) annex 8-A(3).

67 Armenia–Singapore Agreement on Trade and Investment (signed 1 October 2019) art 3.26(a).

68 For example, US–Korea Free Trade Agreement (KORUS) (signed 30 June 2007, entered into force 15 March 2012) art 11.6(5). The reference to TRIPS applies only to compulsory licences. Other actions must be consistent with the IP provisions of the Agreement. Some of these are very similar to TRIPS. Thus, a dispute would also raise questions about the relationship between TRIPS provisions and the provisions in the IP chapters of trade agreements. See also Treaty between the Government of the United States of America and


70 Council for TRIPS, ‘Revised Waiver’ (n 15) [1].

71 TRIPS (n 12) art 73.


73 TRIPS (n 12) arts 31, 44.

74 ibid art 31(h).

75 ibid art 41(1).


77 TRIPS (n 12) art 31(b).

78 ibid.

79 WTO, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (20 November 2001) paras 5(b) and (c) (hereafter Doha Declaration).


82 TRIPS (n 12) arts 31 (a), (i), and (j).

83 The provision requires only that courts have the authority to order a party to desist from infringement, TRIPS (n 12) art 44.

84 TRIPS (n 12) art 41.1.


86 TRIPS (n 12) art 30.

ibid [7.57].

TRIPS (n 12) arts 7 and 8.

*Canada—Pharmaceuticals* (n 87) [7.26].

TRIPS (n 12) art 13.


Doha Declaration (n 79) paras 4 and 5(a), stressing the importance of TRIPS arts 7 and 8.

*Australia—Plain Packaging* (n 81) [6.657].

ibid; *Philip Morris v Uruguay* (n 2).

TRIPS (n 12) art 39.

ibid art 39.3.


*China—Certain Measures on the Transfer of Technology*, DS549 (consultations requested 1 June 2018).

TRIPS (n 12) art 6.

TRIPS (n 12) art 31.

WTO General Council, Amendment to the TRIPS Agreement, WT/L/641 annex (1)(b) (decision of 6 December 2005). These members are Australia, Canada, the European Communities, Iceland, Japan, New Zealand, Norway, Switzerland, and the US.

*Eli Lilly v Canada* (n 2) [349]–[350].

Dreyfuss and Frankel, ‘Reconceptualizing’ (n 4) 385–87. We also argued that because states do not tend to regard changes in the scope of IP rights as regulatory takings, see eg *JT International SA v Commonwealth* [2012] HCA 43 (Australia), an investor should not be permitted to claim a legitimate expectation that IP law would not change, ibid 385–87,

Klopschinski and others (n 69) [6.39]

*Lilly v Canada* (n 2) [440]–[441].


Dreyfuss and Frankel, ‘Reconceptualizing’ (n 4) 404–09.

110 See generally Henning Grosse Ruse-Khan, ‘Protecting Intellectual Property under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?’ in Kate Miles and Chester Brown (eds), Evolution in Investment Treaty Law and Arbitration (Cambridge University Press 2011) 486.