Compulsory licences and ISDS in Covid-19 times: relevance of the new Indian investment treaty practice
Prabhash Ranjan*

As the world grapples with the Coronavirus disease (Covid-19)—the worst pandemic in the last 100 years—war-like efforts are being made to find a vaccine or a cure for the disease.1 Indeed, a few newly developed Covid-19 vaccines have already been approved for public use.2 At the same time, given the concerns of vaccine nationalism—countries pushing to get first access to Covid-19 vaccines3—many are filled with consternation about the timely and equitable access to medicines and vaccines.4 This concern has been outlined by countries like India and South Africa who in their recent proposal to the World Trade Organization (WTO) state: ‘As new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at an affordable price to meet global demand.’5

To ensure timely and equitable access to Covid-19 vaccines, drugs, and diagnostics, India and South Africa have proposed that, following Articles IX.3 and IX.4 of the Marrakesh Agreement establishing the WTO, certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement6 be temporarily waived or suspended to allow the prevention, containment, or treatment of Covid-19.7 Such a temporary suspension of the application of the TRIPS Agreement would give complete regulatory freedom to countries to deal with the production and distribution of Covid-19 vaccines, drugs, diagnostics without being concerned about the enforcement and protection of intellectual property rights. This radical proposal stems from the assumption that intellectual property rights such as patents, in certain circumstances, could act as

The author
- Prabhash Ranjan, LLM, PhD (London), is Senior Assistant Professor, South Asian University, New Delhi, India

This article
- Foreign investors are increasingly making use of investor-State dispute settlement (ISDS) to enforce their intellectual property rights.
- In this context, and taking into account the significance of compulsory licences (CLs) as a regulatory tool to fight the Covid-19 pandemic, this article studies India’s new investment treaty practice on the issuance of CLs.
- The article finds that India’s new investment treaty practice elucidates how India can issue CLs without worrying about investor-state dispute settlement claims.

* Email: pranjan1278@gmail.com. The author is grateful to Antarnihita Mishra for her assistance. The author also thanks the anonymous reviewers for their very useful comments.
1 WHO, ‘The Push for a Covid-19 Vaccine’ <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines accessed 20 October 2020>.
2 Benjamin Muller, ‘UK Approves Pfizer Coronavirus Vaccine, a First in the West’, The New York Times, New York (2 December 2020) <https://www.nytimes.com/2020/12/02/world/europe/pfizer-coronavirus-vaccine-approved-uk.html>; BBC, ‘Covid: US Approves Moderna as Second Vaccine’ (19 December 2020) <https://www.bbc.com/news/world-us-canada-55370999>.
3 Marco Hafner and others, COVID-19 and the Cost of Vaccine Nationalism (RAND Corporation 2020). <https://www.rand.org/pubs/research_reports/RRA769-1.html>.
4 WHO Countries Agree ‘equitable and timely access’ to coronavirus vaccine, ‘comprehensive evaluation’ of response, UN News <https://news.un.org/en/story/2020/05/1064442> accessed 20 October 2020; WHO, ‘The Push for a Covid-19 Vaccine’ accessed 20 October 2020;<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines accessed 20 October 2020>.
5 Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19, WTO, Communication from India and South Africa <https://docs.wto.org/dol2fe/Pages/SSdoc.aspx?filename=q:IP/W669.pdf&Open=True> accessed 20 October 2020 (hereinafter India and South Africa Submission).
6 Agreement on Trade-Related Aspects of Intellectual Property Rights (came into effect 1 January 1995) (‘TRIPS Agreement’). For a commentary on the TRIPS Agreement, see Carlos Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (Oxford 2007).
7 India and South Africa Submission (n 5).
barriers to accessibility of drugs and medicines.\(^8\) Several least developed and developing countries have endorsed the proposal at the WTO, while developed nations are not in favour.\(^9\)

Nonetheless, there is a consensus that countries need to collaborate to ensure timely and equitable distribution of drugs, vaccines and diagnostics for the treatment of Covid-19. To accomplish this objective various regulatory tools can be used in a manner that is consistent with the existing international law on intellectual property rights.\(^10\) This is especially relevant because several patent applications have already been filed for Covid-19 vaccines.\(^11\)

An important regulatory tool in this regard is a compulsory licence (CL)—the granting of a licence by a government to a third party to use the patent without the consent of the patent holder after paying a government-determined royalty to the patent owner.\(^12\) The possibility of issuing a CL is significant flexibility in the patent regime, especially in the context of pharmaceutical patents, because it allows governments to address public health needs by ensuring the availability of patented medicines at low-cost prices to those who cannot afford them.\(^13\)

Some countries have taken steps in this direction by adopting laws to expedite the issuance of CLs.\(^14\) Canada enacted a Covid-19 Emergency Response Act,\(^15\) through which it amended the Patent Act to accelerate the process of issuing CLs for public health purpose.\(^16\) Likewise, Chile adopted a resolution pronouncing that the Covid pandemic is a strong ground to validate the issuance of CL on Covid-19 related technologies.\(^17\) Ecuador has also adopted a resolution requiring the national government to establish compulsory licences and adopt other measures to ensure free and inexpensive access to medicines and other medical technologies to combat the Covid-19 pandemic.\(^18\) Germany, Europe’s largest economy, has also passed legislation, the Prevention and Control of Infectious Diseases in Humans Act, which empowers the health ministry to issue government use authorization under the patent law, after the declaration of a national epidemic by Bundestag, German federal legislature’s lower chamber.\(^19\) Israel has already issued a CL for the importation of Kaletra (lopinavir 200 mg/ritonavir 50 mg) for the treatment of Covid-19 patients.\(^20\)

In India too, several commentators have identified the prominence of CL for realizing public health objec-

---

8 Ellen FM ‘T Hoen, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond, WHO’ (2003) <https://www.who.int/intelectualproperty/topics/ip/tHoen.pdf?ua=1> accessed 22 October 2020; Helen Gabby, ‘Is the Patent System a Barrier to Inclusive Property? The Biomedical Perspective’ (2020) 11(1) Global Policy 46.

9 WTO, ‘Members Discuss Intellectual Property Response to the COVID-19 Pandemic’ <https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm> accessed 21 October 2020.

10 ‘COVID-19 Response’ (WHO, 19 May 2020) <https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf> accessed 8 July 2020.

11 Medecins Sans Frontieres, ‘Moderna’s Decision to Not Enforce COVID-19 Vaccine Patents during the Pandemic Isn’t Enough’ <https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-modernas-decision-not-enforce-covid-19-vaccine-patents-during> accessed 20 October 2020.

12 WTO, ‘Compulsory Licensing of Pharmaceuticals and TRIPS’ (September 2006) <https://www.wto.org/english/tratop_e/trips_e/pub lic_health_faq_e.htm> accessed 8 July 2020; See, Declaration on the TRIPS Agreement and Public Health (2001) WT/MIN(01)/DEC/2, art 9(b), that recognizes the importance of CLs as a flexible measure within the TRIPS Agreement to help countries achieve the objective of public health. CL is not the only regulatory tool available to States. States can also use other options. See generally Christopher Stothers and Alexandra Morgan, ‘IP and the Supply of Covid-19-Related Drugs’ (2020) Journal of Intellectual Property Law and Practice <https://academic.oup.com/jiplp/advance-article/doi/10.1093/jiplp/paa114/5882129> accessed 15 August 2020.

13 Sara M Ford, ‘Compulsory Licensing Provisions under TRIPS Agreement: Balancing Pills and Patents’ (2000) 15 American University Law Review 941; V Kuek, K Phillips and J C Kohler, ‘Access to Medicines and Domestic Compulsory Licensing: Learning from Canada and Thailand’ (2011) 6 Global Public Health 111; Margo A Bagley, ‘The Morality of Compulsory Licensing as an Access to Medicines Tool’ (2018) 102 Minnesota Law Review 2463.

14 Nirmalya Syam, ‘Countries Are Adapting Intellectual Property Laws to Prioritise Health During COVID-19’ (The Wire, 24 July 2020) <https://thewire.in/trade/intelectual-property-laws-covid-19> accessed 15 August 2020; Hilary Wong, ‘The Case for Compulsory Licensing during COVID-19’ (2020) Journal of Global Health <http://www.jogh.org/documents/issue202001/jogh-10-010358.html#R12> accessed 10 August 2020; Katarina Foss-Solbrekk, ‘Ensuring Global Access to Covid-19 Treatments’ (Oxford Business Law Blog, 23 June 2020) <https://www.law.ox.ac.uk/business-law-blog/blog/2020/06/ensuring-global-access-covid-19-treatments> accessed 11 August 2020.

15 The COVID-19 Emergency Response Act (2020).

16 Ibid, Pt 12.

17 Luis Gil Abinader, ‘Chilean Chamber of Deputies Approves Resolution for Compulsory Licenses for Patents Relating to the Coronavirus Virus’ (Knowledge Ecology International, 17 March 2020) <https://www.keionline.org/32385> accessed 10 August 2020; Wong (n 14); Syam (n 14).

18 ‘Resolution to require the National Government to Establish Compulsory Licenses and other Measures to Guarantee Free and Affordable Access to Pharmaceutical Products and Medical Technologies in the Declaration of Sanitary Emergency due to the Coronavirus Pandemic (COVID-19) and other Variations, as well as BioSafety Protocols and Instruments for Health Personnel, Postgraduates and Students of the Public Health System’ (Knowledge Ecology International) <https://www.keionline.org/ecuador-CL-coronavirus-resolution> accessed 12 August 2020.

19 Syam (n 14).

20 Thiru, ‘Israel Issues Compulsory License to allow the Government to Import Generic Versions of Kaletra’ (Knowledge Ecology International, 23 March 2020) <https://www.keionline.org/32303> accessed 12 August 2020.
Given this background of the rising importance of CL, from the perspective of states, it is imperative to understand what kind of legal challenges they can face if they make use of this regulatory tool. This question becomes even more important because patent owners, when it comes to drugs and medicines, in a large number of cases, are pharmaceutical companies who zealously protect their intellectual property. One obvious option for these companies will be to challenge the issuance of such CLs under the domestic laws of the country concerned. Another choice that many foreign pharmaceutical companies might like to employ, under international law, is to challenge the issuance of such CLs before investor-State dispute settlement (ISDS) tribunals. These ISDS tribunals derive their authority from bilateral investment treaties (BITs) or investment chapters of free trade agreements (FTAs). These BITs or investment chapters in FTAs allow foreign investors to directly bring claims against host States for alleged treaty breaches before ISDS tribunals—a three-member ad hoc arbitration tribunal—often without exhausting local remedies. Indeed, in the last few years, foreign investors have employed the ISDS regime to challenge the host State’s regulatory measures relating to IPRs. For example, Eli Lilly, an American pharmaceutical company challenged the invalidation of its patent by a Canadian federal court on the ground of ‘inutility’. Philip Morris, a tobacco company, challenged Australia’s legislation mandating plain packaging of tobacco products under the Hong Kong–Australia BIT. Philip Morris also brought a similar claim against Uruguay under the Switzerland–Uruguay BIT. Accordingly, the possibility of placing a CL on the market for an affordable generic version of remdesivir by other companies than the patent holder would be significantly reduced.

21 Jodie Liu, ‘Compulsory Licensing and Anti–Evergreening: Interpreting the TRIPS Flexibilities in Section 84 and 3(d) of the Indian Patents Act’ (2015) 56 Harvard International Law Journal 207; Yogesh Pai, ‘The Growing Irrelevancy of a TRIPS Challenge to India’s Patent Law’ in Won-Mog Choi (ed), International Economic Law: The Asia-Pacific Perspectives (Cambridge 2015); VK Unni, ‘Compulsory Licensing of Pharmaceutical Patents in India: Whether the Natco Decision Will Meet the Global Benchmark?’ (2015) 37 European Intellectual Property Review 296.

22 See Issuance of Compulsory Licenses for an Affordable Generic Version of Remdesivir, CPI(M) tells Govt, The Hindu (5 July 2020) <https://www.thehindu.com/news/national/issue-compulsory-licences-for-manufacture-of-an-affordable-generic-version-of-remdesivir-cpm-tells-govt/article31994596.ece> accessed 13 August 2020.

23 ‘India ‘Pharmacy of the World’ during Covid-19 Crisis, Say SCO Secy General’ Business Standard (Beijing, 21 June 2020) <https://www.business-standard.com/article/current-affairs/india-pharmacy-of-the-world-during-covid-19-crisis-says-sco-secy-general-120062100435_1.html> accessed 13 August 2020.

24 R Viswanathan, ‘India’s Exports to Latin America Increased to 13.2 Billion Dollars in 2019-20, the Highest in the Last Five Years’ Financial Express (14 July 2020) <https://www.financialexpress.com/economy/india-exports-to-latin-america-increased-to-13-2-billion-dollars-in-2019-20-the-highest-in-the-last-five-years/2023524/> accessed 13 August 2020.

25 Till the end of 2019, 3284 international investment agreements (IIAs) have been concluded, out of which 2895 are BITs. See, UNCTAD, World Investment Report 2020: International Production Beyond Pandemic (UNCTAD Report) (New York and Geneva, United Nations, 2020) 106.

26 Till the end of 2019, the cumulative number of known ISDS cases stands at 1023, see UNCTAD Report, ibid 110.

27 See, Carlos Correa and Jorge E Vinuales, ‘Intellectual Property Rights as Protected Investments: How Open are the Gates?’ (2016) 19 Journal of International Economic Law 91; Pratyush Nath Upreti, ‘Enforcing IPRs through Investor-State Dispute Settlement: A Paradigm Shift in Global IP Practice’ (2016) 19 The Journal of World Intellectual Property 53.

28 Upreti, ibid.

29 Philip Morris Asia Limited v The Commonwealth of Australia (Award on Jurisdiction and Admissibility of 17 December 2015) PCA Case No 2012-12; Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abul Hermanos S.A. v Oriental Republic of Uruguay (Award) ICSID Case No ARB/10/7 (8 July 2016).

30 Eli Lilly and Company v The Government of Canada (Notice of Intent to Submit a Claim to Arbitration under NAFTA Ch Eleven) ICSID Case No UNC/11/412 (7 November 2012); See also Apotex Holdings Inc and Apotex Inc v United States of America (Award) (ICISD Case No ARB(AF)/12/1 (25 August 2014); Les Laboratoires Servier, S.A.A., Biofarma, S.A.S., Arts et Techniques du Progrès S.A.S. v The Republic of Poland (Award) UNCITRAL (14 February 2012). See also Valentina S Vadi, ‘Towards a New Dialectics: Pharmaceutical Patents, Public Health and Foreign Direct Investments’ (2015) 5 New York University Journal of Intellectual Property and Entertainment Law 113; Henning Grosse Ruse-Khan, ‘Challenging Compliance with International Intellectual Property Norms in Investor-state Dispute Settlement’ (2016) 19 Journal of International Economic Law 241; Kathleen Liddell and Michael Waibel, ‘Fair and Equitable Treatment and Judicial Patent Decisions’ (2016) 19 Journal of International Economic Law 145.

31 Philip Morris v Australia (n 29); see Tania Voon, Andrew Mitchell and James Munro, ‘Intellectual Property Rights in International Investment Agreements: Striving for Coherence in National and International Law’ in Chin Leng Lim and Bryan Mercurio (eds), International Economic Law After the Crisis: A Tale of Fragmented Disciplines (Cambridge 2015).

32 Philip Morris v Uruguay (n 19). For more discussion on the interface between IPR and ISDS, see Carlos Correa, ‘Bilateral Investment Agreements: Agents of New Global Standards for the Protection of Intellectual Property Rights’ (2004) GRAIN <www.grain.org/article/entries/125-bilateral-investment-agreements-agents-of-new-global-standards-for-the-protection-of-intellectual-property-rights> accessed 13 August 2020; Lahra Liberti, ‘Intellectual Property Rights in International Investment Agreements: An Overview’ (2010) OECD Working Paper on International Investment <www.oecd.org/daf/inv/investment-policy/ WP-2010_1.pdf> accessed 13 August 2020; Rachel A Lavery, ‘Coverage of Intellectual Property Rights in International Investment Agreements: An Empirical Analysis of Definitions in a Sample of Bilateral Investment
pharmaceutical companies challenging the issuance of CL before ISDS tribunals is real, not conjectural.

International investment lawyers have pointed out that foreign investors can challenge the issuance of CL before an ISDS tribunal on the ground that it amounts to an indirect expropriation of their investments. In other words, foreign investors can argue that the issuance of a CL has led to substantial deprivation of their investment, thus constituting indirect expropriation under international investment law. As Bryan Mercurio argues, the prospect of challenging the issuance of CLs as expropriation before an ISDS tribunal is an attractive proposition for a patent holder for several reasons. First, it allows the patent holder to directly bring about a claim before an international tribunal bypassing the domestic courts of the host country. Secondly, if the claim were successful, it would provide higher compensation to the patent holder than what the host State would pay to her as remuneration for issuing the CL (see also Section II.2).

Whether the foreign investor will succeed in such a claim will depend on various factors, such as the duration for which the CL has been issued, whether the royalty paid to the patent owner is satisfactory, what impact the issuance of the CL had on the patent owner’s overall investment in the host State, what is the language of the treaty provision on expropriation in the BIT, whether the treaty permits deviation from the substantive treaty provisions like expropriation for public health purposes etc. Nonetheless, since IPRs are recognized as investments in BITs, the critical point is that foreign investors can bring such claims before ISDS tribunals. Thus, ISDS tribunals will enjoy jurisdiction to decide whether the issuance of a CL amounts to indirect expropriation or not. Foreign investors can also contest the issuance of a CL as a violation of the fair and equitable (FET) provision—a ubiquitous clause present in all BITs or other substantive provisions like national treatment.

The purpose of this article is to closely examine India’s investment treaty practice to see whether it provides a safe haven for the issuance of CLs from foreign investor’s claims for treaty breaches before an ISDS tribunal. In case a BIT or an investment chapter of an FTA exempts the issuance of CLs from the ambit of the substantive treaty standards, it would imply that the host State has greater regulatory autonomy to make use of CLs in the current times without worrying about ISDS claims. A survey of Indian BITs and FTA investment chapters shows that in the bulk of these treaties there is no specific mention of excusing the issuance of CLs from the application of the treaty’s substantive standards. In other words, if a foreign investor contests the issuance of a CL as a breach of any of the substantive provisions of the BIT, the outcome of such a challenge will depend on the numerous factors mentioned before.

However, there are some Indian BITs and FTA investment chapters that exempt the issuance of CLs from the application of the substantive treaty standards. In this article, we study such investment treaties by dividing the discussion into two parts. First, the article, in Section II, discusses those Indian BITs and FTA investment chapters where issuance of CL is outside the ambit of the expropriation provision. Next, the article, in Section III, focuses on the new Indian investment treaty practice, starting from the 2016 Indian model BIT, which provides that issuance of CL is outside the scope of the entire BIT. Section IV concludes by arguing that India’s recent treaty practice provides greater regulatory bandwidth to States in Covid-19 times to pursue public health objectives should countries wish to use CLs as the regulatory tool to increase accessiblity of Covid vaccines and drugs. Thus, India’s new investment treaty

Agreements and Free Trade Agreements’ (2009) 6 Transnational Dispute Management Journal 1; Christopher Gibson, ’A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation’ (2010) 25 American University International Law Review 368; Bryan Mercurio, ’Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements’ (2012) 15 Journal of International Economic Law 871; Lukas Vanhonnaeker, Intellectual Property Rights as Foreign Direct Investments: From Collision to Collaboration (Elgar 2015); Christophe Geiger (ed), Research Handbook on Intellectual Property and Investment Law (Elgar 2020).

33 Gibson, ibid.
34 See Prabhash Ranjan, ‘Issuance of Compulsory Patent Licenses and Expropriation in Asian BITs and FTA Investment Chapters: A Study of India, China, Malaysia and Thailand’ in Kung-Ching Liu and Julien Chaisse (eds), The Future of Asian Trade Deals and IP (Hart 2019).
35 Mercurio (n 32) 912–13.
36 ibid, 911–14; Ranjan (n 34).
37 ibid, 882–901; Liddell and Waibel (n 30).
38 India has signed more than 80 BITs. Recently, India unilaterally terminated several of its BITs, see ‘Bilateral Investment Treaties’ (Department of Economic Affairs) <https://dea.gov.in/bipfa>. However, these BITs contain a survival or a sunset clause due to which the treaty provisions shall continue to operate for a period of 10–20 years. For the evolution and detailed study of India’s BITs, see Prabhash Ranjan, India and Bilateral Investment Treaties: Refusal, Acceptance, Backlash (Oxford 2019). India has signed five FTAs containing investment chapters, see UNCTAD, ’India, Treaties with Investment Provisions’ <https://investmentpolicy.unctad.org/international-investment-agreements/countries/96/india&type=bits> accessed 14 August 2020. The FTAs that India has signed is known as Comprehensive Economic Cooperation/Partnership Agreements (CECAs/CEPAs). In this article, CECAs/CEPAs are being called free trade agreements or FTAs.
39 Prabhash Ranjan, ’Pharmaceutical Patents and Expropriation in Indian Bilateral Investment Treaties’ in Mahdev Mohan and Chester Brown (eds), Regulation and Investment Disputes: Asian Perspectives (Cambridge 2021 forthcoming).
40 India Model BIT 2016.
practice holds some lessons for other countries to deal with ISDS claims challenging the issuance of CLs. However, before discussing the treaty practice, Section I provides an overview of the Indian patent law on the issuance of CLs.

### I The Indian Patent Act and compulsory licences

The domestic law in India on the issuance of CLs on patents is contained in the Indian Patent Act. To understand India’s legal regime on the issuance of CLs under the Indian Patent Act on drugs, vaccines, etc., we divide the discussion into two parts. We first discuss the issuance of CLs for domestic use; next, we discuss the issuance of CLs to export the patented drug.

#### I.1 CLs for the domestic market

Section 84 of the Patent Act provides that CL in India can be issued at any time after the expiration of 3 years from the date of grant of a patent on the application of an interested person, by the patent’s controller, on the following grounds. First, the reasonable requirements of the public concerning the patented invention have not been satisfied. Second, that the patented invention is not available to the public at a reasonably affordable price. Third, that the patented invention is not worked in the territory of India. Critical to bear in mind that while the CL in case of section 84 is issued on the application of an interested person, the action of issuance of the CL shall be attributable to the Indian State since it is the patents controller who shall issue the licence. In the current Covid-19 scenario, due to the requirement that a CL under section 84 can be issued only 3 years after the grant of the patent, the practical utility of section 84 is restricted to issuing CL on an existing drug that may be helpful in some form to fight the pandemic. A CL under section 84 on a newly invented Covid-19 drug or vaccine may have to wait 3 years from the grant of the patent.

India issued its first CL in 2012, under section 84, in favour of a domestic generic pharmaceutical company called Natco Pharma, for a patent granted on a drug to treat kidney and liver cancer to Bayer. This CL was issued because of all the three reasons given in section 84. The drug was available to just 2 per cent of the population and thus it didn’t meet the reasonable requirements of the public. Further, the high price of the drug meant that it was not affordable. Moreover, there was a lack of local manufacturing i.e. the patented invention was not worked in India. The Supreme Court of India upheld the issuance of the CL.

A foreign pharmaceutical company cannot challenge the issuance of a CL under section 84 before an ISDS tribunal alleging that the CL has been granted in breach of any of the conditions given in section 84 or any other provision of the Indian Patents Act. The appropriate forum for such challenges will be a domestic court in India. For the foreign pharmaceutical company to challenge the issuance of a CL, either under section 84 or any other section, before an ISDS tribunal, it will have to show that the actions of the patent controller violate India’s BIT obligations. This is because the standard that the ISDS tribunal shall apply to judge the legality of the patent controller’s action is international law, not national law.

As already mentioned, the challenge before an ISDS tribunal can be made on the ground that the issuance of a CL has led to substantial deprivation of the investment and thus amounts to unlawful expropriation. Arguably, the issuance of a CL cannot be challenged as unlawful expropriation, even if its leads to substantial deprivation of investment, because remuneration must be provided to the patent holder. However, the standard of remuneration will play an important role in determining whether the issuance of a CL amounts to expropriation or not. As is well known, a State has the right to expropriate foreign investment provided it is for a public purpose, following due process and against due and fair compensation. An expropriation that satisfies all these requirements will be lawful. It will not constitute a breach of the BIT. However, if the compensation paid were not in accordance with the
treaty standard, it would amount to an unlawful expropriation, thus a breach of the BIT.

Applying this to the situation of issuance of CL, in case the remuneration paid to the patent holder is not as per the standard laid down in the BIT, the issuance of a CL could be challenged as expropriation. In order to fully understand this point, let us look at the remuneration provisions for issuance of a CL in the Indian Patent Act and in the TRIPS Agreement. We will then compare these provisions with the provision in the BIT that provides for compensation for expropriation.

In the Indian Patent Act, the criterion to determine remuneration for issuance of CL is given in section 90 (i): ‘... the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors’.52 In the TRIPS Agreement, Article 31(h) provides, ‘the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization’. Scholars argue that Article 31(h) of the TRIPS Agreement, which requires ‘adequate remuneration’ to be paid to the patent holder for issuance of a CL, provides enough flexibility to countries to develop their own rules to provide royalty rates keeping their local circumstances in mind.53 Thus, if a CL is issued on a patented drug or a vaccine, to make it accessible to the larger population, the royalty cannot be too high. Or else the purpose of ensuring the wider accessibility of the patented medicine will not be met. Section 90(i) of the Indian Patent Act, reflects these principles. Keeping these factors in mind, while issuing a CL to Natco Pharma on Bayer’s patented drug, India asked Natco to pay a quarterly royalty of 6 per cent of the net sales of the drug whereas Bayer had asked for a royalty of 15 per cent of net sales.54

If we compare the principles to determine remuneration in case of issuance of CLs under domestic law with the standard for compensation in case of expropriation under BITs, we will find that the former might not be consistent with the latter. For instance, Article 5 of the India-Germany BIT provides that compensation to be paid in cases of expropriation of foreign investment ‘shall be equivalent to the value of the expropriated or nationalised investment immediately before the date on which such expropriation or nationalisation became publicly known’. Furthermore, ‘interest shall be paid in a fair and equitable manner for the period between the date of expropriation or nationalisation and the date of actual payment of compensation’. In other words, the quantum of compensation should be equal to the value of the expropriated investment. Moreover, the BIT requires that ‘such compensation shall be effectively realisable without undue delay and shall be freely convertible and transferable’.

In short, the standard of compensation for expropriation recognized in most BITs is ‘prompt, adequate and effective’ compensation, which is akin to full compensation.55 This BIT standard of compensation imposes an onerous obligation on India in comparison to paying a royalty equivalent to 6 per cent of total sales to the patent holder (as in the case of Bayer). Thus, the foreign pharmaceutical company may challenge the issuance of a CL by the patent controller on the ground that the remuneration paid is less than what is required under the BIT, and thus constitutes a case of unlawful expropriation.

Another important provision in the Indian Patent Act as regards issuance of CLs is section 92(1). While, to issue a CL under section 84, a 3-year waiting period is required, under section 92(1) of the Indian Patent Act, a CL can be issued without waiting for 3 years in certain situations—i.e. in circumstances of national emergency or circumstances of extreme emergency, or in the case of public non-commercial use. The Covid-19 pandemic is definitely a public health emergency. It surely constitutes a circumstance of extreme emergency. If indeed India had to issue a CL on drugs and vaccines related to the Covid-19 pandemic, section 92(1) would be put to use.

Additionally, two other sections of the Indian Patent Act deserve attention. First, section 66 of the Indian Patent Act gives power to the central government to revoke a patent in the public interest. Thus, according to section 66, if the central government believes that a patent is ‘mischievous to the State’ or ‘generally prejudicial to the public’, the patent may be revoked.56 Second,
section 100 of the Patent Act gives power to the central government to use inventions for governmental purposes. 57

1.2 CL for the international/export market

Under the Indian Patent Act, a CL can be issued not just for the domestic market but also for the international/export market. Given India’s prowess as a major pharmaceutical producer, this aspect assumes much significance at the time of the Covid-19 pandemic. In this regard, a conspicuous provision of the Indian Patent Act is section 92A, which allows for CLs to be granted for the export of pharmaceutical products in certain exceptional circumstances. 58 As per this section, a CL can be issued for the manufacturing and export of patented pharmaceutical products to any country that has inadequate or no manufacturing capability in the pharmaceutical sector for the concerned product to address public health requirements. The issuance of a CL under section 92A also requires that the country to which India desires to export has also issued a CL or it has allowed the importation of the patented pharmaceutical products from India. This particular provision may come in handy in the current pandemic situation because of India’s manufacturing ability. India can issue CLs for the export of those potential Covid-19 vaccines and drugs that may be patented and manufactured in India currently59 or in the future. In fact, India has already assured countries like Nepal that they are a top priority for India as regards the supply of Covid-19 vaccines are concerned.60

Section 92A was inserted in the Indian Patent Act in light of the developments that took place after the adoption of the Doha declaration on TRIPS and Public Health (Doha Declaration). 61 Article 31(f) of the TRIPS Agreement states that a compulsory licence may be issued predominantly for the domestic market of the country issuing the licence. As a result, countries that have limited manufacturing ability in the pharmaceutical sector will not be able to benefit from the provision on compulsory licensing given in Article 31 of the TRIPS Agreement. This problem was recognized in paragraph 6 of the Doha declaration, which states: ‘we recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002’. Further to this, on 30 August 2003, the WTO’s General Council adopted a decision that waived the obligations imposed by Article 31(f) to allow countries to export drugs manufactured under compulsory licensing to be exported to countries that lacked the manufacturing ability.62 Finally, in 2005, the TRIPS Agreement was amended, which took effect on 23 January 2017, 63 to include Article 31 bis making the 2003 decision permanent. Notwithstanding this amendment in the TRIPS Agreement that makes it possible for countries like India to issue a CL under section 92A of the Indian Patent Act for export of patented drugs to countries that lack manufacturing capability, concerns have been expressed about the cumbersome process that countries need to follow to export such medicines.64 For instance, if a country issues a CL to export drugs to another nation that lacks manufacturing capability, the exporting country has to ensure that the drugs so manufactured are exported to that nation only; the medicines should be easily identifiable through different colour, or shape; only the amount necessary to meet the requirements of the eligible importing country are manufactured; the importing country has to notify to the WTO’s TRIPS Council; etc. 65 Due to these conditions, the generic manufacturers or any pharmaceutical company, Indian or foreign, might not have enough incentives to manufacture products under CLs for export.66

57 ibid, s 100.
58 ibid, s 92A.
59 Serum Institute of India, in collaboration with AstraZeneca and Oxford University, is manufacturing millions of doses of Covid-19 vaccine <https://www.thehindu.com/news/national/coronavirus-serum-institute-of-india-stocking-emergency-doses-of-covid-19-vaccine/article35156381.ece> accessed 5 January 2021.
60 ‘Nepal Is Top Priority for India for Supply of Covid-19 Vaccine: Shringla’, The Hindu Business Line (27 November 2020) <https://www.thehindubusinessline.com/economy/nepal-is-top-priority-for-india-for-supply-of-covid-19-vaccine-shringla/article31192890.ece> accessed 5 January 2021. India has now started exporting Covid-19 vaccines to several countries.
61 WTO, ‘Declaration on the TRIPS Agreement and Public Health’, WT/ MIN(01)/DEC/2, 20 November 2001.
62 Implementation of para 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 30 August 2003 <https://www.wto.org/english/tratop_e/trips_e/implem_par6_e.htm> (hereinafter 2003 August decision) accessed 30 December 2020.
63 TRIPS Agreement (as amended on 23 January 2017) <https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm> accessed 30 December 2020.
64 Oxfam International, ‘Patents versus Patients, Five Years after the Doha Declaration’, Oxfam Briefing Paper 95, November 2006. <https://www.asil.org/library/openrepository.com/bitstream/handle/10546/114562/bp95-patents-versus-patients-doha-q-and-a-141106-en.pdf?sequence=8&isAllowed=y> accessed 30 December 2020.
65 2003 August decision (n 62).
66 See Holger P Hestermeyer, ‘Canadian-Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines American Society of International Law’ (10 December 2007) <http://www.asil.org/
India and South Africa, in their recent proposal to the WTO appealing for a waiver of certain provisions of the TRIPS Agreement to make the treatment of Covid-19 widely available, articulate their disquiet over Article 31bis.67 They state in their proposal that ‘a particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31bis and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products’.68 Given the analysis above, it is unclear to what extent India will be able to make use of section 92A of the Indian Patent Act to ensure timely supply of Covid-19 vaccines and drugs to countries that lack the manufacturing capability. Satisfying the procedural requirements of Article 31bis will take time, which, in turn, will render a provision like section 92A redundant especially because expeditious delivery of vaccines and drugs is the crying need as the pandemic rages on.

We now turn to discuss those BITs and FTA investment chapters where issuance of CLs is outside the ambit of the expropriation provision.

II Issuance of CLs is exempted from the expropriation provision

After discussing the law on the issuance of CLs in the Indian Patent Act, in this section, we examine those Indian BITs and FTA investment chapters that specifically exclude issuance of CLs from the ambit of the provision on expropriation. We divide the discussion on this set of Indian investment treaties into two parts. First, we focus on treaty practice. Second, we study the implications of this practice from India’s regulatory right to make use of CL in corona times.

II.1 Treaty practice

The treaty practice in this set of Indian investment treaties can be classified into two categories. On the one hand, there are the following investment treaties: India–Colombia BIT,69 India–ASEAN investment agreement,70 India–Japan FTA71 investment chapter, India–Malaysia FTA.72 On the other hand, there are the following investment treaties: India–Singapore FTA investment chapter and India–Korea FTA investment chapter. The similarity and difference between these two groups of investment treaties shall become clear in the discussion that follows.

The first group of investment treaties exempt issuance of CLs from the ambit of expropriation provision subject to certain conditions. For instance, Article 6.7 of the India–Colombia BIT provides:

the Contracting Parties confirm that the issuance of compulsory licences granted in accordance with the TRIPS Agreement of the WTO is not covered under the provisions set out in this Article.

Similarly, Article 8(7) of the India–ASEAN investment agreement provides that ‘this article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights, in accordance with the TRIPS Agreement’. Likewise, Article 92.5 of the India–Japan FTA states, ‘this Article shall not apply with respect to the grant of compulsory licences concerning intellectual property in accordance with the TRIPS Agreement’. Finally, Article 10.7(6) of the India–Malaysia FTA investment chapter provides: ‘this Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights in accordance with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights’. Such formulation also exists in investment treaties signed by other countries.73

On the other hand, two investment treaties, the India–Singapore FTA investment chapter and India–Korea FTA investment chapter exempt, not just issuance of CLs but also revocation and limitation of IPRs from the ambit of the expropriation provision. For

70 Agreement on Investment under the Framework Agreement on Comprehensive Economic Cooperation between the Republic of India and the Association of South East Asian Nations (signed 12 November 2014) (‘ASEAN–India Investment Agreement’).
71 Comprehensive Economic Partnership Agreement between the Republic of India and Japan (signed 16 February 2011, entered into force 1 August 2011) (‘India–Japan FTA’).
72 Comprehensive Economic Cooperation Agreement between the Government of the Republic of India and the Government of Malaysia (signed 18 February 2011, entered into force 1 July 2011) (‘India–Malaysia FTA’).
73 EU–Canada Comprehensive Economic and Trade Agreement (signed 30 October 2016, entered into force 21 September 2017) (‘CETA’) art 8.12(5); Free Trade Agreement between the European Union and the Socialist Republic of Vietnam (signed 30 June 2019, entered into force 1 August 2020) (‘EU–Vietnam FTA’) art 2.7(4).
_instance, Article 6.5(6) of the India–Singapore FTA investment chapter provides: ‘this Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights to the extent that such issuance, revocation, limitation or creation is consistent with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights’. Article 10.12(6) of the India–Korea FTA investment chapter also provides: ‘this Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with the TRIPS Agreement’. Several new investment treaties signed by other countries also contain such formulation.  

II.2 Implications

This treaty practice is important and the following conclusions can be drawn from it. First, since these investment treaties explicitly put the issuance of CLs outside the ambit of the expropriation provision, they confer greater regulatory autonomy on India to issue CLs without being perturbed about the foreign investor challenging such issuance of CLs as expropriation of his investment. As mentioned earlier, the foreign investor will have all the incentive to challenge the issuance of CLs as expropriation because a successful challenge will mean a higher award than the ‘adequate remuneration’ received under a CL.  

Second, these treaties also provide that the expropriation provision shall not apply to the issuance of CLs, only if the licence has been issued in a manner consistent with the TRIPS Agreement of the WTO. As pointed out earlier, Article 31 of the TRIPS Agreement provides the conditions that have to be met when a State grants a CL. In other words, if a country fails to issue a CL in accordance with Article 31 of the TRIPS Agreement, the expropriation provision would continue to apply over the issuance of CLs. Thus, the ISDS tribunal would have jurisdiction over the claim that a CL issued amounts to an expropriation of foreign investment.

The germane issue here is that an ISDS tribunal, that has no expertise in WTO law, would determine whether the issuance of a CL is consistent with the TRIPS Agreement. To understand this better, let us assume that India issues a CL on a drug whose patent is owned by a foreign pharmaceutical company. Let us further assume that the foreign pharmaceutical company challenges the CL before an ISDS tribunal contending that the issuance of the CL amounts to expropriation because it has not been issued following the TRIPS Agreement. In such a scenario, the onus to decide whether the CL has been issued under Article 31 of the TRIPS Agreement shall vest on the ISDS tribunal.  

The ISDS tribunal shall have to satisfy itself that the host country has issued the CL by honouring the conditions given in Article 31 such as efforts were made at obtaining a voluntary licence first (this requirement may be waived in situations of national emergency); the licence has been issued predominantly for supply in the domestic market; the licence shall be terminated when the circumstances that led to the issuance of the licence cease to exist; etc. An important requirement that needs to be satisfied by the host country is to provide adequate remuneration to the patent holder as warranted by Article 31(h) of the TRIPS Agreement. The ISDS tribunal would therefore examine whether adequate remuneration has been provided or not. As discussed earlier, the term ‘adequate remuneration’ gives enough leeway to countries to develop their own compensation...
rules keeping the circumstances in mind. Since States would provide remuneration to the patent holder while issuing a CL, it would easily meet the requirement of Article 31(h). In sum, it can be concluded that if a State has issued a CL for a genuine public interest requirement such as addressing a public health need, on a non-discriminatory basis, after following due process and awarding adequate remuneration to the patent holder, the ISDS tribunal would not find the issuance of a CL to be inconsistent with the TRIPS Agreement.

Third, some BITs exempt issuance of CLs from the ambit of expropriation whereas some, like the India–Singapore FTA investment chapter, go a step ahead and also exempt revocation and limitation of IPRs from the scope of the expropriation rule. The meaning of the words, ‘revocation’ and ‘limitation’ are not given in the text of the treaties that talk about them. Some treaties like the Australia–Uruguay BIT that contain similar language as the India–Singapore FTA investment chapter, state that the term ‘revocation’ of IPRs includes the cancellation or nullification of those rights, and the term ‘limitation’ of IPRs includes exceptions to those rights. Let us assume that India, to make a medicine available for treating the coronavirus, revokes a patent for public interest under section 66 of the Indian Patent Act or starts using the invention for governmental purposes under section 100. Both these instances are different from issuing a CL. They would amount to revocation or limitation of IPRs. India would be able to defend such revocation and limitation of IPRs, provided it is consistent with the TRIPS Agreement, under the India-Singapore and India-Korea FTA investment chapters. However, if such revocation or limitation of IPRs is challenged under the first group of investment treaties like the India–Colombia BIT, India would not be able to rely on the CL exception.

Fourth, since these investment treaties exempt the issuance of CLs and other regulatory measures like revocation of patents only from the scope of expropriation, the foreign investor could still challenge these measures under other substantive obligations of the treaty such as FET and national treatment. In other words, presuming that an ISDS tribunal finds that a CL has been issued following the TRIPS Agreement, it can still examine whether such issuance violates any other substantive provision of the BIT such as FET, in case the investor claims so.

We now turn to discuss the new and emerging Indian treaty practice on the relationship between issuance of CLs and investment treaties.

III Issuance of CLs is outside the scope of the investment treaty

In this section, we discuss India’s 2016 Model BIT and the BITs that India has signed thereafter based on the 2016 Model. Like the previous section, we first discuss the treaty practice before discussing the implications of the same.

III.1 Treaty practice

Article 2.4(iii) of the 2016 Model BIT states, ‘this treaty shall not apply to the issuance of compulsory licences granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with the international obligations of Parties under the WTO Agreement’. Article 2.4(iii) of the India-Kyrgyzstan BIT 80 and Article 3.6(c) of India-Brazil BIT 81 contain similar language.

The language in the two other BITs that India signed after the 2016 Model BIT is slightly different. Article 2.4(iii) of the India-Belarus BIT 82 provides that the treaty ‘shall not apply to the issuance of compulsory licences granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with the national law and international obligations of the Party concerned’. Article 2.4(c) of the India–Taiwan BIT 83 provides that the treaty ‘shall not apply to the issuance of compulsory licences granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights under domestic law, to the extent that such issuance, revocation, limitation or creation is consistent with the obligations under the WTO Agreement.’

79 See also Australia–Hong Kong BIT and Singapore–Sri Lanka FTA Investment Chapter.
80 Bilateral Investment Treaty between the Government of the Kyrgyz Republic and the Government of the Republic of India (signed 14 June 2019) (‘India–Kyrgyzstan BIT’).
81 Investment Cooperation and Facilitation Treaty between the Federative Republic of Brazil and the Republic of India (signed 25 January 2020) (‘Brazil–India BIT’).
82 Treaty between the Republic of Belarus and the Republic of India on Investments (signed 24 September 2018, entered into force 5 March 2020) (‘Belarus–India BIT’).
83 Agreement between the India Taipei Association in Taipei And The Taipei Economic and Cultural Center in New Delhi on The Promotion and Protection of Investments (signed 18 December 2018, entered into force 14 February 2019) (‘India–Taiwan BIT’).
III.2 Implications

The following points are worth noting about the 2016 Indian Model BIT and other new investment treaties. Firstly, unlike the set of investment treaties examined in Section II, these BITs exclude the issuance of CLs, revocation, and limitation of IPRs, not just from the ambit of the expropriation provision, but also from the scope of the entire treaty. Thus, all the substantive provisions of the BIT are inapplicable to regulatory acts about the issuance of CLs, revocation, and limitation of IPRs.

Secondly, the inapplicability of the treaty to the issuance of CLs, revocation, and limitation of IPRs is contingent on the fact that these regulatory acts must have been carried out following the international obligations of the country under the WTO agreement. This is the language given in four, out of the five, treaties, i.e. the 2016 Model BIT, India–Kyrgyzstan BIT, India–Brazil BIT, and the India–Taiwan BIT.

It is important to note that, unlike the previous set of treaties studied in Section II of the article, these sets of treaties talk of the WTO Agreement and do not mention the TRIPS Agreement. This will not make any substantive difference because, within the WTO agreement, the IP obligations are contained in the TRIPS Agreement. The language in the India–Belarus BIT is marginally different from the four BITs mentioned above. The India-Belarus BIT provides that issuance of CLs, revocation, and limitation of IPRs will be outside the scope of the BIT provided these regulatory acts are consistent with national law and international obligations. The two minor differences are: first, there is only mention of international obligations with no reference to the WTO Agreement; second, there is an additional requirement of ensuring consistency with national laws of the country that has, for example, issued the CL.

The third key point to note about these set of treaties is that like in the set of investment treaties analysed in Section II of the article, the ISDS tribunal shall continue to exercise jurisdiction even in the current set of treaties. To understand this better, let us assume that India issues a CL on a drug needed for the treatment of Covid-19. Let us further postulate that a foreign pharmaceutical company challenges this issuance of CL as a violation of one of the substantive provisions of the BIT alleging that the CL has been granted in a manner that is inconsistent with India’s international law obligations. In a situation such as this, the ISDS tribunal will determine whether India’s regulatory measure is consistent with India’s international law obligations (in the case of India–Belarus BIT, consistency with domestic law shall also be assessed). In case the tribunal concludes that the regulatory action of granting CL is inconsistent with India’s international law obligations, the provisions of the BIT, i.e. all the substantive obligations would apply to the issuance of such CL.

Fourth, as regards the consistency of IP-related regulatory measures (issuance of CL, revocation, and limitation of IPRs) vis-à-vis international IP law, these treaties seem to place the WTO’s TRIPS Agreement on a higher pedestal in comparison to the investment treaties. By stating that, if the issuance of CL and other regulatory measures related to IPRs are consistent with the WTO’s TRIPS Agreement, the BIT shall not apply, these treaties make it abundantly clear that the TRIPS Agreement has a higher normative value than BITs as far as country’s international IPR obligations are concerned.

Fifth, this type of treaty practice of putting the issuance of CLs and other regulatory actions on IPRs outside the ambit of the entire BIT is unique to India. While several countries exempt the issuance of CLs from the ambit of expropriation, as enunciated in Section II, there are no examples of excusing the issuance of CLs or revocation of IPRs from the scope of the entire investment treaty.

IV Conclusion

Foreign investors are increasingly making use of ISDS to enforce their IPRs. This aspect of IPR enforcement assumes central importance in Covid-19 times, when many nations wish to make use of regulatory tools like CLs to increase the accessibility of vaccines and medicines for people who cannot afford them. It is possible that, especially while the pandemic is raging, pharmaceutical companies supplying Covid-19 vaccines may choose not to enforce their patents. However, as time progresses, the possibility of these companies enforcing their patents cannot be ruled out. Thus, in the coming months, countries would have to explore policy options like using CLs to make the vaccines and drugs widely accessible. Thus, countries need to pay close attention to their BIT obligations.

As is well known, there is a backlash against international investment law and the ISDS regime for espousing vague and indeterminate legal principles for the protection of foreign investors. This criticism of international investment law and the ISDS regime has
ushed in a new kind of investment treaty practice where there is a greater thrust on the codification of the State’s right to regulate. The objective is to reduce uncertainty and not give a free pass to ISDS tribunals to interpret broad and vague investment treaty provisions in a manner that may restrict the host State’s right to regulate.

India’s new emerging investment treaty practice on CL is relevant when viewed in this larger context. Most Indian BITs do not contain an exception related to the issuance of CLs, which puts such regulatory actions at grave risk of an ISDS challenge. Thus, providing that the entire BIT is inapplicable to the issuance of CLs, gives greater regulatory bandwidth to the host State to issue CLs either for the production of a patented medicine for domestic purpose or for export as stated in section 92A of the Indian Patent Act. It also firewalls revocation and limitation of IPRs from the substantive provisions of the BIT. It may be argued that such firewalling of IP-related regulatory conducts from the BIT might lead to the State abusing its powers against the rights of the IP holders. This argument is not valid since all such regulatory actions, for it to fall outside the scope of the BIT and thus the jurisdiction of an ISDS tribunal, have to meet the standards laid down in the WTO Agreement.

Other countries must look closely at India’s emerging investment treaty practice on CLs and try to cement this rule in their BITs as well. This will help countries ward off risks of ISDS challenges to regulatory measures aimed at protecting public health especially at times when the world is passing through the worst pandemic in the last century.