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### A Survey of Intellectual Property Issues between the United States and India under the Special 301 Report

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# A Survey of Intellectual Property Issues Between the United States and India under the Special 301 Report

"It is now clear that substantial and consistent progress has been made by India and overall, Indian laws relating to patents and their application do not deny adequate and effective protection of IPR, nor do they deny fair and equitable market access to the U.S. pharmaceutical industry which relies on intellectual property protection."

- Indian Pharmaceutical Alliance

#### Seemantani Sharma†

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<sup>&</sup>lt;sup>1</sup> Dilip G. Shah, *Indian Pharmaceutical Alliance*, USTR: 2018 SPECIAL 301 SUBMISSION (2018), https://www.regulations.gov/document?D=USTR-2017-0024-0003 [https://perma.cc/THF6-P67Z].

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#### I. Introduction

On April 30, 2018, the U.S. Trade Representative (USTR) once again placed India as a priority watch list country under the 2018 Special 301 Report despite the progressive steps undertaken by the Indian Government to improve its Intellectual Property (IP) regime by promulgating the National Intellectual Property Rights (IPR) Policy in June 2016.<sup>2</sup> The 2018 Special 301 Report is a twin tale of

<sup>&</sup>lt;sup>2</sup> See Dep't of Indus. Policy & Promotion, National Intellectual Property

doubles; it is the second Special 301 Report (the Report) of the Trump Administration and the second one post India's National IPR Policy. One of the primary reasons for devising the National IPR Policy was to cater to the U.S.' and other developed countries' vehemence against India's laggard IP regime.<sup>3</sup> According to India's former Minister of State for Commerce and Industry, Nirmala Sitharaman, the absence of a National IPR Policy was the primary reason for India's recurrent placement on the Special 301 Report as a priority watch list country; however, commentators have strongly contested this claim on the grounds that India had a nuanced IP policy even before the release of the official National IPR Policy.<sup>4</sup>

The release of the National IPR Policy was perceived to bridge the long-standing discord between New Delhi and Washington D.C. on the issue of intellectual property rights.<sup>5</sup> Despite this, the 2018 Special 301 Report indicates that the U.S.' view on India's IP regime has not softened. A partial explanation for this cautionary pessimism could be attributed to the Trump Administration's

RIGHTS POLICY (2016), http://dipp.nic.in/sites/default/files/National\_IPR\_Policy\_English.pdf [https://perma.cc/BUG4-YV5R].

- 3 See K.M. Gopakumar, National IPR Policy: A Reality Check, DECCAN HERALD (June 5, 2016), http://www.deccanherald.com/content/550549/national-ipr-policy-reality-check.html [https://perma.cc/TZ7P-L93U]. The National Democratic Alliance decided to devise the National IPR Policy in the aftermath of the Special 301 Report released in 2014 when the USTR placed India on the Priority Watch List along with nine other countries. See Sunil Mani, Doesn't India Already Have an IPR Policy?, 49 ECON. & POL'Y WEEKLY (Nov. 22, 2014), https://www.epw.in/journal/2014/47/commentary/doesnt-india-already-have-ipr-policy.html [https://perma.cc/DR89-L4SM].
- 4 See IPR Policy Soon, Says Minister, (Sept. Hindu http://www.thehindu.com/business/Industry/govt-to-come-out-with-ipr-policysitharaman/article6391438.ece [https://perma.cc/C5GP-AFYK]; see also Rupali Samuel, Academics, Diplomats, Scientists, Lawyers, Public Health Orgs Issue Open Letter to PM Proposed IPPolicy Review, SPICY IΡ (Sept. 23, 2014), https://spicyip.com/2014/09/academics-diplomats-scientists-lawyers-public-health-orgsissue-open-letter-to-pm-on-proposed-ip-law-review.html [https://perma.cc/EU2M-8JG8].
- 5 See Dinesh Abrol, Who Gains From Modi Government's Intellectual Property Rights Policy?, WIRE (May 22, 2016), https://thewire.in/37795/who-gains-from-the-modi-governments-intellectual-property-rights-policy/ [https://perma.cc/9QT4-YVK2]; see also Patralekha Chatterjee, Will India, US Bridge Over Intellectual Property Rights?, INTELL. PROP. WATCH (Dec. 10, 2014), https://www.ip-watch.org/2014/12/10/will-india-us-bridge-divide-over-intellectual-property-rights/ [https://perma.cc/HM7B-9SVB]; see also Seemantani Sharma, Despite Modi's New IPR Policy, US Continues to Cry Foul over Indian Laws, WIRE (Mar. 31, 2017), https://thewire.in/external-affairs/national-ipr-policy-cautionary-pessimism-continues-washington-d-c [https://perma.cc/TK4V-PUUG].

overtly self-protectionist stance vis-à-vis U.S. corporate interests.<sup>6</sup> This protectionist stance is laid out at the outset of the 2018 Special 301 Report where it states:

A top trade priority for the Administration is to use all possible sources of leverage to encourage other countries to open their markets to U.S. exports of goods and services, and provide adequate and effective protection and enforcement of U.S. intellectual property (IP) rights. Toward this end, a key objective of the Administration's trade policy is ensuring that U.S. owners of IP have a full and fair opportunity to use and profit from their IP around the globe.<sup>7</sup>

In the past, the USTR would remove a country, such as Hong Kong, from the Special 301 watch list when it took substantial steps to improve its IP framework.8 Similarly, Arab countries such as Egypt and Lebanon were upgraded from the priority watch list to the watch list by the USTR in the 2008 Special 301 Report when they made significant improvements to their IP regimes.<sup>9</sup> In this vein, this article takes the specific case of Hong Kong to argue that India should strive to improve its substantive IP regime which will go a long way in saving it from needless humiliation by the USTR. Part II gives an overview of the Special 301 process. It also highlights the influence exerted by U.S. industry groups on the USTR as part of the Special 301 process. Part III examines India's designation under the Report since it was first released in 1989. Part IV highlights the key issues with respect to India's designation under the Report. Part V examines India's future under the 2019 Special 301 Report. Part VI concludes.

<sup>6</sup> Off. of the U.S. Trade Representative, 2017 National Trade Estimate Report, WASH. INT'L TRADE ASS'N (Apr. 3, 2017), http://americastradepolicy.com/2017-national-trade-estimate-report/#.WTH\_BWiGO00 [https://perma.cc/7YR2-2SWK].

<sup>7</sup> OFF. OF THE U.S. TRADE REPRESENTATIVE, 2018 SPECIAL 301 REPORT 5 (2018), https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf [https://perma.cc/46BV-6G6X].

<sup>8</sup> Press Release, Office of the U.S. Trade Representative, USTR Announces Results of Special 301 Annual Review (Apr. 30, 1999), https://ustr.gov/sites/default/files/1999%20Special%20301%20Report.pdf [https://perma.cc/TX3A-WRRU].

<sup>&</sup>lt;sup>9</sup> Dr. Mohamed Salem Abou El Farag, What Is New in the United States Trade Representative's Special 301 Report for Arab Countries, 46 INT'L L. 683, 684–85 (2012).

## II. Special 301 Report and the Protection of Intellectual Property in Foreign Countries

#### A. What is the Special 301 Report?

Special 301 is a set of provisions of the Omnibus Trade and Competitiveness Act of 1988 (1988 Trade Act) for protecting intellectual property rights of American corporations in foreign countries.<sup>10</sup> It empowers the USTR to identify those foreign countries that deny "adequate and effective protection of intellectual property rights"11 or deny "fair and equitable market access to U.S. persons who rely upon intellectual property protection."<sup>12</sup> It owes its genesis to a study conducted by the U.S. International Trade Commission (USITC) which estimated that in the year 1986, American corporations lost between \$43 and \$61 billion due to intellectual property piracy in foreign countries.<sup>13</sup> On May 25, 1989, Carla Hills, the U.S. Trade Representative, observed that inadequate protection of intellectual property rights not only harmed the U.S. economy but also "undermined the creativity, invention and investment that are essential to economic and technological growth in all countries."<sup>14</sup> The looming threat to U.S. industries was recognized by both chambers of Congress which stressed the need for comprehensive and effective programs to address the growing problem of piracy and counterfeiting faced by U.S. firms and industries in foreign markets. This problem is not an isolated one affecting just one or two industries. It is a problem confronted by virtually all sectors of the U.S. economy, including manufacturers of semiconductors and other high technology products, motion

Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107 (1988) [hereinafter 1988 Trade Act]. See Judith H. Bello & Alan F. Holmer, "Special 301": Its Requirements, Implementation, and Significance, 13 FORDHAM INT'L L.J. 259, 263–65 (1990), for more on the legislative history of the 1988 Trade Act.

<sup>11 19</sup> U.S.C. § 2242(a)(1)(A) (2016).

<sup>12</sup> Id. at (a)(1)(B).

<sup>13</sup> U.S. INT'L TRADE COMM'N, FOREIGN PROTECTION OF INTELLECTUAL PROPERTY RIGHTS AND THE EFFECT ON U.S. INDUSTRY AND TRADE H-3 (1988); see Off. OF THE U.S. TRADE REPRESENTATIVE, FACT SHEET "SPECIAL 301" ON INTELLECTUAL PROPERTY (1989), https://ustr.gov/sites/default/files/1989%20Special%20301%20Report.pdf [https://perma.cc/59VJ-6T8Y].

<sup>14</sup> FACT SHEET "SPECIAL 301" ON INTELLECTUAL PROPERTY, supra note 13.

pictures, computer software, books, records, auto parts, pharmaceuticals, and chemicals. It also is a problem encountered in developed and developing countries alike.<sup>15</sup>

Even though they were frequently at odds with each other during the Reagan era, both the President and Congress were cognizant of the losses incurred by American corporations due to IP piracy in foreign countries.<sup>16</sup> Nevertheless, they were committed to adequately protect IP rights of American businesses by aggressively pursuing the protection of American IP through international trade negotiations and amendments to existing U.S. trade laws.<sup>17</sup> Therefore, in addition to the amendments made to "generic" section 301,<sup>18</sup> the Generalized System of Preferences (GSP),<sup>19</sup> the Caribbean Basin Economic Recovery Act,<sup>20</sup> and the Export-Import Bank Act,<sup>21</sup> President Reagan signed the 1988 Trade Act along with the newly enacted Special 301 provisions.<sup>22</sup> In signing the 1988 Trade Act, President Reagan stated that Special 301 will "strengthen the ability of U.S. firms to protect their patented, copyrighted, or trademarked goods from international thievery."<sup>23</sup>

#### B. Legislative History of Section 301

The Special 301 requirements derive from both the House and Senate omnibus trade bills. The House and Senate bills were similar, with only three notable differences between the two. First, only the Senate bill covered denial of fair and equitable market access to U.S. persons who relied on IP protection.<sup>24</sup> Second, the House bill authorized a six-month extension in Special 301

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15 H.R. REP. No. 100-40, at 163 (1987).
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<sup>16</sup> Bello & Holmer, supra note 10, at 260.

<sup>17</sup> *Id*.

<sup>18 19</sup> U.S.C. § 2411 (2016).

<sup>19 19</sup> U.S.C. § 2462 (1988).

<sup>20 12</sup> U.S.C. § 2702 (2011).

<sup>21 12</sup> U.S.C. § 635 (1988).

Mitchell Locin, *Trade Law Gets Reagan Signature*, CHI. TRIB. (Aug. 24, 1988), https://www.chicagotribune.com/news/ct-xpm-1988-08-24-8801250297-story.html [https://perma.cc/2Q3A-BQLU].

<sup>23</sup> Id.

Ultimately, the House conceded to the Senate on this issue, and the market access provisions were included. *See* Omnibus Trade Act of 1987, S. 490, 100th Cong. § 302 (1987); Omnibus Trade and Competitiveness Act of 1987, S. 1420, 100th Cong. § 302 (1987).

investigations involving complex issues while the Senate bill allowed for a maximum of three-month extension.<sup>25</sup> Finally, the Senate bill left the statutory authority for action exclusively with the President while the House bill provided for transfer of authority to the President, subject to direction.<sup>26</sup>

### C. How Does the USTR Categorize Countries under Special 301?

The Special 301 report classifies countries into three categories depending upon the laxity of IP protection extended by countries or imposition of barriers to market access. The worst offenders in these categories are classified as a "priority foreign country," followed by those on the "priority watch list," and lastly those on the "watch list." A priority foreign country is a statutory category under Section 182 of the Trade Act of 1974.<sup>27</sup> A country is designated as a priority foreign country if its acts, practices, or policies are highly "onerous or egregious," and "deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access to U.S. persons who rely upon intellectual property protection."28 Further, these countries fail to enter into good-faith negotiations or make significant progress in bilateral or multilateral negotiations to effectively and adequately protect IP.<sup>29</sup> Priority foreign countries can attract retaliatory actions in the form of trade sanctions through imposing tariffs or import restrictions, or withdrawing concessions granted under preferential agreements.<sup>30</sup> The President may also direct the USTR to retaliate in any area of trade or foreign relations that is within the President's competence.<sup>31</sup> The next-in-line category is the priority watch list country, which is a non-statutory category. These countries have "serious intellectual property rights deficiencies"32 but not to the level of a priority foreign country. The last category is the watch

<sup>25</sup> H.R. 3, 100th Cong. § 173 (1987); see H.R. REP. No. 40 (1987).

<sup>26 19</sup> U.S.C. § 2411(a)(l)-(b)(2) (2017).

<sup>27 19</sup> U.S.C. § 2242(a)(2) (2017).

<sup>28 19</sup> U.S.C. § 2242(a)(1).

<sup>29 19</sup> U.S.C. § 2242(b)(1).

<sup>30 19</sup> U.S.C. § 2411(c)(1)(A)-(B).

<sup>31 19</sup> U.S.C. § 2411(a)(ii).

<sup>32</sup> Sam F. Halabi, *Multipolarity, Intellectual Property, and the Internationalization of Public Health Law*, 35 MICH. J. INT'L L. 715, 743 (2014).

list, which includes countries whose IP laws are problematic but not to the extent of a priority watch list country. The status of a watch list or a priority watch list country can be resolved by entering into bilateral negotiations or, if in the opinion of the USTR, the designated country has made satisfactory improvements to its IP regime. For example, Hong Kong was removed from the Special 301 watch list of countries in 1999 after it made satisfactory improvements to curb copyright piracy.<sup>33</sup> USTR first placed Hong Kong on the Special 301 list in April 1996 due to high rates of piracy in the Hong Kong Special Administrative Region despite the USTR's repeated request for increased protective measures for curbing copyright piracy.<sup>34</sup> Similarly, if a country fails to satisfactorily improve its IP regime, it is downgraded to a lower category. India was downgraded to a priority foreign country from a priority watch list country in 1991 due to inadequate levels of patent protection, including a short term of patent protection and overly-broad compulsory licensing provisions.<sup>35</sup>

USTR can designate a country as a priority foreign country after consulting the Register of Copyrights, the Under Secretary of Commerce for Intellectual Property, and the Director of the U.S. Patent and Trademark Office.<sup>36</sup> It is also required to take into account information from such sources as may be available to it or such information as may be submitted to it by interested persons.<sup>37</sup> Under this provision, the USTR often consults industry groups about their specific grievances regarding a country's IP regime.<sup>38</sup> The industry groups play a pivotal role in determining the fate of a

<sup>33</sup> Matthew K. Miller, Hong Kong Removed from U.S. Trade Representative's Special 301 Watch List, 5 B.U. J. Sci. & Tech. L. 12 (1999).

<sup>34</sup> Simon Beck, *Hong Kong off Piracy 'Watch List*,' S. CHINA MORNING POST, Feb. 21, 1999, at 1, 1999 WL 2521394.

<sup>35</sup> See INT'L INTELL. PROP. ALLIANCE, 2018 SPECIAL 301 REPORT ON COPYRIGHT PROTECTION AND ENFORCEMENT app. B (2018), https://iipa.org/files/uploads/2018/02/2018SPEC301HISTORICALCHART.pdf [https://perma.cc/US7M-3YHY], for a history of Special 301 decisions; see also Off. of The U.S. Trade Representative, Fact Sheet: "Special 301" on Intellectual Property 2 (1991) (containing the 1991 Special Report).

<sup>36 19</sup> U.S.C. § 2242(b)(2)(A) (2017).

<sup>37 19</sup> U.S.C. § 2242(b)(2)(B).

<sup>38</sup> See Paul C.B. Liu, U.S. Industry's Influence on Intellectual Property Negotiations and Special 301 Actions, 13 PAC. BASIN L.J. 87, 102 (1994) (describing the role of the International Intellectual Property Association (IIPA) in the Special 301 process).

country under the Special 301 Report.<sup>39</sup> The overarching influence of the industry groups on the outcome of the report is so extensive that it has developed the moniker of a "public law devoted to the service of private corporate interests."<sup>40</sup>

Though the USTR has substantial discretion in designating a country as a priority foreign country, there must be factual basis for such designation.<sup>41</sup> There is no consultation requirement for designating a country as a priority watch list or a watch list country as they are non-statutory categories.<sup>42</sup> Nevertheless, the USTR always consults the industry and lobby groups before recommending a country to be listed under the Report.<sup>43</sup>

#### D. Role of Lobbying Groups in the Special 301 process

The role of U.S. industries and lobby groups on the Special 301 process is so significant that it has been deemed a "public law devoted to the service of private corporate interests."44 The Special 301 process is largely influenced by six industrial lobby groups: (i) Manufacturers the Pharmaceutical Research and America (PhRMA): (ii) the International Intellectual Property Alliance (IIPA); (iii) the U.S. Chambers of Commerce's Global Innovation Property Center (GIPC); (iv) the Biotechnology Industry Organization (BIO); (v) the Business Alliance (BSA); and (vi) the National Association of Manufacturers (NAM).<sup>45</sup> The Alliance for Free Trade with India (AFTI) and the U.S.-India Business Council (USIBC) also exert a significant influence over the process with respect to India's designation under the Report. Based on the record from 2009 through 2018, it is clear that almost all the major lobby groups recommended India to be

<sup>39</sup> Id.

 $_{\rm 40}~$  Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? 89 (2002).

<sup>41</sup> Bello & Holmer, supra note 10, at 262.

<sup>&</sup>lt;sup>42</sup> Preeti Sinha, *Special 301: An Effective Tool Against Thailand's Intellectual Property Violations*, 1 PAC. RIM L. & POL'Y J. 281, 286–87 (1992).

DRAHOS & BRAITHWAITE, supra note 40, at 89.

<sup>45</sup> See Liu, supra note 38, at 88–89. According to Liu, the most active and influential industry participants in the Special 301 process were International Intellectual Property Alliance (IIPA), Business Software Alliance (BSA), International Anti-Counterfeiting Coalition (IACC), Pharmaceutical Manufacturers Association (PMA), International Trademark Association (INTA), Microsoft Corporation, and Nintendo Corporation.

categorized as a priority watch list country under each year's Special 301 Report.<sup>46</sup>

TABLE 1: LIST OF RECOMMENDATIONS BY INDUSTRY GROUPS BY YEAR

Year	Priority Watch List	Watch List	Priority Foreign Country
2018	BSA, BIO, IIPA, PhRMA, AFTI, IACC, NAM		
2017	IIPA, AFTI, BSA, NFTC, PhRMA, USCC, NAM, IACC		
2016	Trademark Working Group, NAM, BSA, IIPA, AFTI, USIBC, BIO, IACC, ASCAP		
2015	CASBAA, <sup>47</sup> AFTI, ASCAP, BSA, IACC, SIA, NAM, PhRMA, BIO		

<sup>46</sup> See Previous Special 301 Reports, Off. of the U.S. Trade Representative (June 30, 2018), https://ustr.gov/issue-areas/intellectual-property/special-301/previous-special-301-reports [https://perma.cc/4RHJ-TSXM].

<sup>47</sup> See Cable & Satellite Broad. Assoc. of Asia, Comment Letter on 2015 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974, at 8 (Feb. 6, 2015), https://www.regulations.gov/document?D=USTR-2014-0025-0007 [https://perma.cc/7TT2-TJTE] (noting that the CASBAA supported removing India from the priority watch list after completion of the digitization process).

2014	IIPA,	NFTC	·,
	American Seed	BIO, U	JSCC,
	Trade	AFTI	
	Association,		
	National Center		
	for Policy		
	Analysis, IACC,		
	SIA <sup>48</sup>		
2013	SIA, IIPA,		
	PhRMA, BIO <sup>49</sup>		

48 Apart from these organizations, other organizations like the Center for Medicine in the Public Interest and Intellectual Property Owners Association (IIPO) did not propose India to be designated as priority watch list or watch list countries, but expressed concerns over India's IP regime. For Center for Medicine in the Public Interest's testimony, see Ctr. for Med. in the Publ. Interest, *Comment Letter on 2014 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974*, at 2–7 (Feb. 7, 2014), https://www.regulations.gov/document?D=USTR-2013-0040-0016

[https://perma.cc/5MZD-ULHL]. For IIPO's comments, see Phillip S. Johnson, Intellectual Prop. Owners Assoc., *Comment Letter on 2014 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974* (Feb. 7, 2014), https://www.regulations.gov/document?D=USTR-2013-0040-0023

[https://perma.cc/L2KV-YBQ4]. For NAM's comments, see Nat'l Assoc. Mfrs., Comment Letter on 2014 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974 (Feb. 7, 2014), https://www.regulations.gov/document?D=USTR-2013-0040-0011 [https://perma.cc/5P6E-FZYD]. For Trademark Working Group's comments, see Special 301 Trademark Working Grp., Comment Letter on 2014 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974 (Feb.6, 2014), https://www.regulations.gov/document?D=USTR-2013-0040-0007 [https://perma.cc/RWQ9-C7QT].

Apart from these organizations, some other organizations such as the U.S. Chambers of Commerce and the National Foreign Trade Council did not propose India to be designated as priority watch list or watch list countries but expressed concerns over India's IP regime. For U.S. Chamber of Commerce's written submission, see U.S. Chamber of Commerce, Comment Letter on 2013 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974 (Feb. 8, 2013), https://www.regulations.gov/document?D=USTR-2012-0022-0042 [perma.cc/3Z4M-MEXD]. For National Foreign Trade Council's written submission, see Nat'l Foreign Trade Council, Comment Letter on 2013 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974 (Feb. 8, 2013), https://www.regulations.gov/document?D=USTR-2012-0022-0018

[https://perma.cc/M3TE-V6YX]. CASBAA supported removing India from the priority watch list after completion of the digitization process. See Cable & Satellite Broad. Assoc. of Asia, Comment Letter on 2013 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974 (Feb. 8, 2013), https://www.regulations.gov/document?D=USTR-2012-0022-0005

2012	SIA, BIO,		
	PhRMA <sup>50</sup>		
2011	SIA, BIO,		
	IIPA		
	CASBAA,		
	PhRMA		
	NAM		
2010	NAM, IIPA	Sports	
	BIO,	Coalition	
	CASBAA <sup>51</sup>		
2009	BIO, PhRMA		
	IIP, CASBAA		

### 1. The Pharmaceutical Research and Manufacturers of America (PhRMA)

Pharmaceutical Research and Manufacturers of America (PhRMA), formerly known as the Pharmaceutical Manufacturers Association (PMA), is a trade group representing leading biopharmaceutical companies in the United States since 1958.<sup>52</sup> Its avowed mission is to "conduct effective advocacy for public policies that encourage the discovery of important, new medicines for patients by biopharmaceutical research companies."<sup>53</sup> PhRMA has been an ardent proponent of the Special 301 law and for allowing private corporations to bring complaints against foreign

<sup>[</sup>https://perma.cc/PHF2-552U].

Apart from these organizations, some other organizations such as Croplife America did not propose India to be designated as a priority watch list or watch list country, but expressed concerns over India's seed protection regime. *See* Letter from Douglas T. Nelson, Exec. Vice President, Gen. Counsel, Sec'y, Croplife America, to Paula Karol Pinha, Dir. for Intellectual Prop. and Innovation, Off. of the U.S. Trade Representative (Feb. 10, 2012) https://www.regulations.gov/document?D=USTR-2011-0021-0017 [https://perma.cc/3PZX-K92S].

<sup>51</sup> See id.

<sup>52</sup> About, PHRMA, https://www.phrma.org/about [https://perma.cc/3KTT-P52J].

 $_{53}\ Our\ Mission,$  PHRMA, https://www.phrma.org/about/our-mission [https://perma.cc/JGB3-RHAP].

sovereign nations.<sup>54</sup> Since the inception of the Report, PhRMA has played an active role in the Special 301 process. Per a study conducted by American University's Program on Information Justice and Intellectual Property (PIJIP), 75% of the nations singled out by PhRMA to be placed on the 2008 Special 301 Report were in that year's report.<sup>55</sup> Since 2009, almost all the grievances listed out by PhRMA with respect to India's IP regime have made their way to the respective year's report.<sup>56</sup>

### 2. The International Intellectual Property Alliance (IIPA)

The IIPA is a "private sector coalition, formed in 1984, of trade associations representing U.S. copyright-based industries working to improve international protection and enforcement of copyrighted materials and to open up foreign markets closed by piracy and other market access barriers." Members include:

- a. Association of American Publishers (AAP)<sup>58</sup>
- b. Entertainment Software Association (ESA)<sup>59</sup>
- c. Independent Film & Television Alliance (IFTA)<sup>60</sup>

<sup>54</sup> Liu, *supra* note 38, at 107.

<sup>55</sup> PROGRAM ON INFO. JUSTICE AND INTELL. PROP., AM. UNIV. WASH. COLL. OF LAW, *PIJIP SNAPSHOT OF INDUSTRY INFLUENCE ON THE 2008 SPECIAL 301 REPORT* (2008), https://seemantanisharma.files.wordpress.com/2016/05/pjip-snapshot-of-industry-influence.pdf [https://perma.cc/CYY5-2SCY].

<sup>56</sup> See Table 2 (providing a synoptic view of the grievances expressed by PhRMA and its inclusion in the Special 301 Report).

<sup>57</sup> INT'L INTELL. PROP. ALLIANCE, https://iipa.org/about/ [https://perma.cc/ZDE7-2NRQ].

The Association of American Publishers (APA) is the national trade association of the American publishing industry representing nearly over 400 hundred-member associations including major commercial, digital learning, education and professional publishers alongside independents, non-profits, university presses, and scholarly societies. See Ass'n of Am. Publishers, http://publishers.org/about/overview [https://perma.cc/4MZ9-BKPS].

The Entertainment Software Association (ESA) is the trade association representing the video games industry in the U.S. It was formed in April 1994 as the Interactive Digital Software Association and renamed on July 16, 2003. See ENT. SOFTWARE ASS'N, http://www.theesa.com/about-esa/overview/ [https://perma.cc/9D4F-JWXC]; INTERACTIVE DIGITAL SOFTWARE ASS'N, https://www.c-span.org/organization/?30736/Interactive-Digital-Software-Association [https://perma.cc/U3UG-GUWT].

<sup>60</sup> The Independent Film & Television Alliance (IFTA) is a trade association representing companies that finance, produce, and license independent film and television

- d. Motion Picture Association of America (MPAA)<sup>61</sup>
- e. Recording Industry Association of America (RIAA)<sup>62</sup>

Collectively, IIPA's five member associations represent over 3,200 U.S. companies producing and distributing copyright-based materials throughout the world, making it the most powerful copyright lobbying organization in the world.<sup>63</sup> These include: (i) entertainment and educational software (including interactive video games for consoles, handheld devices, personal computers and the Internet); (ii) motion pictures, television programming, DVDs, home video and digital representations of audio-visual works; (iii) music, records, CDs, and audiocassettes; and (iv) fiction and non-fiction books, instructional and assessment materials, and professional and scholarly journals, databases, and software in all formats.<sup>64</sup>

The IIPA has been at the forefront in the enactment of the Special 301 law. In order to make a successful case against intellectual property pirates, it submitted an economic report on piracy titled, "Piracy of US Copyrighted Works in Ten Selected Countries" to Congress in 1985.65 That same report was also submitted to the USTR in response to its request for information concerning the use of the Special 301 and the GSP.66 The report marked the beginning of a symbiotic relationship between the two organizations. Since the enactment of the Special 301 law, the IIPA has submitted comments for designating a country under each of the three categories.67 Its influence on the USTR is so extensive that in the 2008 Special 301 Report, 86% of the nations singled out by IIPA were in that year's report.68 Since 2009, almost all the grievances

programming worldwide. INDEP. FILM & TELEVISION ALLIANCE, http://www.ifta-online.org/what-ifta [https://perma.cc/S64Q-M4ML].

<sup>61</sup> The Motion Picture Association of America (MPAA) is a trade association representing the six major Hollywood studios. *See* MOTION PICTURE ASS'N OF AM., https://www.mpaa.org/our-story/ [https://perma.cc/GW74-BHK9].

The Recording Industry Association of America (RIAA) is a trade association representing the recording industry in the U.S. RECORDING INDUS. ASS'N OF AM., https://www.riaa.com/about-riaa/ [https://perma.cc/37VM-P88V].

<sup>63</sup> INT'L INTELL. PROP. ALLIANCE, supra note 57.

<sup>64</sup> Id.

<sup>65</sup> DRAHOS & BRAITHWAITE, supra note 40, at 94.

<sup>66</sup> Id.

<sup>67</sup> Id.

<sup>68</sup> PROGRAM ON INFO. JUSTICE AND INTELL. PROP., AM. UNIV. WASH. COLL. OF LAW,

listed out by IIPA with respect to India's IP regime have made their way onto the respective year's report.<sup>69</sup>

## 3. The United States Chambers of Commerce's Global Innovation Property Center

The Global Innovation Property Center (GIPC) is the principal institution of the United States Chamber of Commerce handling all issues relating to intellectual property. It protects the intellectual property of three million U.S. businesses of all sizes, sectors, and regions. Its members range from mom-and-pop shops and local chambers to leading industry associations and Fortune 500 corporations. The GIPC is a relatively new entrant to the list of organizations testifying before the USTR for designating a country under the Special 301 Report. It testified before the USTR for the first time in 2012. As an arm of the U.S. Chamber of Commerce, the GIPC is a mouthpiece for U.S corporate interests. It is therefore not surprising that almost all the grievances listed by the GIPC with respect to India's IP regime have made their way onto the respective year's report.

#### 4. The Biotechnology Industry Organization (BIO)

The Biotechnology Industry Organization (BIO) is a trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations.<sup>75</sup> Its

supra note 55.

<sup>69</sup> See Table 3 (providing a synoptic view of the grievances expressed by IIPA and its inclusion in the Special 301 Report).

<sup>70</sup> GLOBAL INNOVATION PROP. CTR., http://www.theglobalipcenter.com/about/mission-and-goals/ [https://perma.cc/B8Q9-EUE2].

 $_{71}$  About the U.S. Chamber, U.S. Chamber of Com., https://www.uschamber.com/about/about-the-us-chamber [https://perma.cc/6A4M-2VGJ].

<sup>72</sup> *Id*.

<sup>73</sup> See U.S. Chamber's Global Intell. Prop. Ctr., Comment Letter on 2012 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974, at 3–4 (Feb. 10, 2012), https://www.regulations.gov/document?D=USTR-2011-0021-0043 [https://perma.cc/G2K3-NKYJ].

<sup>&</sup>lt;sup>74</sup> See Table 4 (providing a synoptic view of the grievances expressed by GIPC and its inclusion in the Special 301 Report).

<sup>75</sup> BIOTECHNOLOGY INNOVATION ORG., https://www.bio.org/about

members include major American pharmaceutical companies such as Merck & Co., Amgen, and GlaxoSmithKline (GSK).<sup>76</sup> Participants are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.<sup>77</sup> The BIO promotes the biotechnology industry's heavy reliance on patents and, since 2010, it has testified before the USTR only with respect to a country's patent regime.<sup>78</sup> It exerts significant influence over USTR on patent-related issues as almost all grievances expressed by it appear on the respective year's report.<sup>79</sup>

#### 5. The Business Software Alliance (BSA)

The Business Software Alliance (BSA) is a trade group established by Microsoft Corporation in 1988 representing a number of the world's largest software makers.<sup>80</sup> Its primary purpose is to "protect the continuous growth of the American software industry."<sup>81</sup> Even though it is a member of the IIPA, it has been testifying independently before the USTR since 2015.<sup>82</sup> As a member of the IIPA, it also exerts significant influence over the USTR as far as the patent-related grievances and enforcement issues

[https://perma.cc/G94U-VGRK].

<sup>76</sup> See Bio Member Directory, BIOTECHNOLOGY INNOVATION ORG., https://www.bio.org/bio-member-directory [https://perma.cc/7U66-3UCS] (providing a complete list of BIO members).

<sup>77</sup> BIOTECHNOLOGY INNOVATION ORG., supra note 75.

<sup>78</sup> See 2013 Special 301 Submission: BIO Provides Input on Biotech IP Challenges Around the Globe, BIOTECHNOLOGY INNOVATION ORG. (Feb. 8, 2013), http://tinyurl.com/nf2wmw8 [https://perma.cc/PR6X-P9E3]; see also Letter from Lila Feisee, Managing Dir., Intellectual Prop. Biotechnology Indus. Org., to Jennifer Choe Groves, Senior Dir. for Intellectual Prop., Innovation and Chair of the Special 301 Committee., Office of the U.S. Trade Representative (Jan. 15, 2010) https://www.regulations.gov/document?D=USTR-2010-0003-0273

<sup>[</sup>https://perma.cc/LX7W-FVCD] (discussing BIO's 2010 comment on Biotech IP challenges around the globe).

<sup>&</sup>lt;sup>79</sup> See Table 5 (providing a synoptic view of the grievances expressed by BIO and its inclusion in the Special 301 Report).

<sup>80</sup> About BSA, SOFTWARE ALLIANCE, http://www.bsa.org/about-bsa [https://perma.cc/MP84-SNFX].

<sup>81</sup> Liu, supra note 38, at 103.

<sup>82</sup> See Letter from Jared Ragland, Senior Dir., Bus. Software All., to Susan F. Wilson, Dir. for Intellectual Prop. and Innovation, Off. of the U.S. Trade Representative (Feb. 6, 2015), https://www.regulations.gov/document?D=USTR-2014-0025-0035 [https://perma.cc/PPU4-R6SD].

are concerned.83

#### 6. The Alliance for Free Trade with India (AFTI)

The Alliance for Free Trade with India (AFTI) is a trade coalition of diverse organizations representing a range of U.S. industries adversely impacted by India's IPR policies and practices.84 It was formed in June 2013 in support of increased action to address the barriers to trade and investment faced by American companies due to erosion of intellectual property rights. 85 Members include major trade groups such as the National Association of Manufacturers (NAM), GIPC, Croplife America, PhRMA, Motion Picture Association of America (MPAA), Recording Industry Association of America (RIAA), BIO, and Solar Energy Industries Association (SEIA), amongst others. 86 It testified before the USTR for the first time in 2014. Since then, it has played a pivotal role in the Special 301 process. For the year 2018, it once again urged USTR to place India as a priority watch list country and asserted that India had failed to protect the interests of U.S. IP holders.<sup>87</sup> Its influence on the Special 301 report is to such an extent that all grievances expressed by it are replicated by the USTR in the respective year's report.88

#### 7. US-India Business Council (USIBC)

The US-India Business Council (USIBC) is a business advocacy organization formed in 1975 to strengthen economic and commercial ties between the United States and India.<sup>89</sup> Its primary mission is to serve as a direct link between business and government

<sup>83</sup> See Table 7 (providing a synoptic view of the grievances expressed by AFTI and its inclusion in the Special 301 Report).

 $_{84}$  All. For Free Trade with India, http://aftindia.org/ [https://perma.cc/YB96-4HKK].

<sup>85</sup> Id.

<sup>86</sup> *Id*.

<sup>87</sup> Asit Ranjan Mishra, *Donald Trump's Trade War May Extend to IPR 'Violators*,' LIVEMINT (Mar. 9, 2018), https://www.livemint.com/Politics/7WVhXJsE2uua0ejBBTNgzH/Donald-Trumps-tradewar-may-extend-to-IPR-violators.html [https://perma.cc/6NHV-5MCH].

 $_{88}$  See Table 7 (providing a synoptic view of the grievances expressed by AFTI and its inclusion in the Special 301 Report).

 $_{\rm 89}$  U.S.-INDIA BUS. COUNCIL, http://www.usibc.com/home [https://perma.cc/LE5C-AH3Z].

leaders. Its members are major U.S. and Indian business conglomerates such as Amazon,<sup>90</sup> Facebook,<sup>91</sup> Shell India,<sup>92</sup> and PepsiCo.<sup>93</sup> Since 2014, it has actively been guarding against the risk of a downgrade from a priority watch list country to a priority foreign country by the USTR though it does advocate for grievances with respect to India's IP regime on behalf of its members.<sup>94</sup>

#### 8. National Association of Manufacturers

NAM is the nation's largest manufacturing industrial trade association, representing 11,000 small and large manufacturing

- 90 Sunita Sohrabji, *U.S. India Business Council Partners Investing \$69 Billion in India Updated*, INDIA WEST (June 15, 2016), https://www.indiawest.com/news/global\_indian/u-s-india-business-council-partners-investing-billion-in-india/article\_69d05e7a-3327-11e6-8f28-e3bd242c6ca5.html [https://perma.cc/32TR-XJ6D].
- 91 Centralised Platform Needed for Data Privacy Laws: Facebook, THE HINDU BUS. LINE (Sept. 6, 2018), https://www.thehindubusinessline.com/info-tech/social-media/centralised-platform-needed-for-data-privacy-laws-facebook/article24884483.ece [https://perma.cc/DAR6-EY2K].
- 92 Haider Kazim, *India Has a Pivotal Role in Global Order: USIBC*, INDO AM. NEWS (July 9, 2015), http://www.indoamerican-news.com/india-has-a-pivotal-role-in-global-order-usibc/ [https://perma.cc/C3YA-F8WZ].
- 93 Former USIBC Chair John Chambers Announces Launching of U.S.-India Strategic Partnership Forum, INDIA WEST (Aug. 7, 2017), https://www.indiawest.com/news/global\_indian/former-usibc-chair-john-chambers-announces-launching-of-u-s/article\_cf6f8d60-7c9f-11e7-810d-77aa168b8a1f.html [https://perma.cc/8U5R-EQF9].
- 94 Varghese K. George, USIBC Working Hard to Protect India's IPR Status, HINDU (Feb. 21, 2016), http://www.thehindu.com/business/Industry/usibc-working-hard-toprotect-indias-ipr-status/article8264688.ece. [https://perma.cc/YN78-52T3]; see also US Not Placing India Under the Punitive Priority Foreign Country Most Sensible Thing to Experts, ECON. TIMES, (May https://economictimes.indiatimes.com/news/economy/policy/us-not-placing-india-underthe-punitive-priority-foreign-country-most-sensible-thing-to-doexperts/articleshow/34469787.cms [https://perma.cc/7C5P-PSZ4]; see also IPR: US Trade Body Bats for India Despite Tough Resistance, REDIFF BUS. (Mar. 14, 2014), http://www.rediff.com/money/report/ipr-us-trade-body-bats-for-india-despite-toughresistance/20140314.htm [https://perma.cc/2KT3-HCGN]; see also Amit Sengupta, India Assures the US It Will Not Issue Compulsory Licenses on Medicines, WIRE (Mar. 12, 2016), https://thewire.in/health/india-assures-the-us-it-will-not-issue-compulsorylicences-on-medicines [https://perma.cc/JE4V-CZJP]; see also USIBC Step Up Lobbying to Prevent Downgrade of India's IPR Status, INDIA WRITES NETWORK, http://www.indiawrites.org/diplomacy/usibc-step-up-lobbying-to-prevent-downgrade-ofindias-ipr-status/ [https://perma.cc/LYV7-G386].

companies in every industrial sector.<sup>95</sup> It employs more than 12 million men and women with an annual contribution of \$2.25 trillion to the U.S. economy.<sup>96</sup> It has been testifying before the USTR since 2010.<sup>97</sup> Its influence on the Special 301 report is so extensive that all grievances expressed by it are replicated by the USTR in the respective year's report.<sup>98</sup>

#### III. India and Special 301

#### A. Indian Economy and Polity

As a nation of approximately 1.35 billion people, India rose out of extreme poverty to become the world's fastest growing economy with a growth potential of 7.8% as of 2018.99 According to the International Monetary Fund (IMF), India has the world's seventh largest economy, closely behind the United Kingdom and France, and this trend is likely to continue.100 After India gained independence from British rule in 1947, the process of rebuilding the Indian economy started.101 Being predominantly an agrarian economy, heavy investments were made to develop irrigation

<sup>95</sup> NATIONAL ASS'N OF MANUFACTURERS, http://www.nam.org/[https://perma.cc/9TWX-ASQJ].

<sup>96</sup> *Id*.

<sup>97</sup> See Table 9.

 $_{98}$  Id. (providing a synoptic view of the grievances expressed by NAM and its inclusion in the Special 301 Report).

<sup>99</sup> India Population, Worldometers, http://www.worldometers.info/world-population/india-population/ [https://perma.cc/NL32-3J48]; see also Population of India, POPULATION OF THE WORLD, https://www.livepopulation.com/country/india.html [https://perma.cc/L6SB-VA8X]. For India's GDP and growth potential, see The Fastest-Growing and Shrinking Economies in 2018, Economist (Jan. 5, 2018), https://www.economist.com/blogs/graphicdetail/2018/01/daily-chart-3

<sup>[</sup>https://perma.cc/YW7U-ZYX3]; see also Salvatore Babones, India May Be the World's Fastest Growing Economy, but Regional Disparity is a Serious Challenge, FORBES (Jan. 10, 2018), https://www.forbes.com/sites/salvatorebabones/2018/01/10/india-may-be-the-worlds-fastest-growing-economy-but-regional-disparity-is-a-serious-challenge/#3749e0f353ac [https://perma.cc/RPH8-9W8A].

Rob Smith, *The World's Biggest Economies in 2018*, World Econ. F. (Apr. 18, 2018), https://www.weforum.org/agenda/2018/04/the-worlds-biggest-economies-in-2018/ [https://perma.cc/8TT6-PGQL]; *see About Indian Economy Growth Rate & Statistics*, INDIA BRAND EQUITY FOUND., https://www.ibef.org/economy/indian-economy-overview [https://perma.cc/Q7HH-UCV9].

<sup>101</sup> Sangaralingam Ramesh, China's Lessons for India: Volume I: The Political Economy of Development 25 (2017).

facilities, construct dams, and develop infrastructure. Equal importance was also given to the establishment of modern industries, scientific and technological institutions, and development of space and nuclear programs. Despite these efforts, the country did not witness rapid economic development due to a lack of capital, skilled labor, and infrastructure as well as cold war politics, hefty defense expenditures, and a large population. 104

However, during the 1980s, the Indian economy improved significantly with an annual rate of growth of 5.5%. 105 A high rate of private savings and investment was a major factor in India's improved economic growth, but by the mid-1980s the government had to rely on foreign lenders due to saturation in the private savings market.<sup>106</sup> This situation led to a balance of payment crisis in 1990 primarily due to the collapse of the former Soviet Union, which was a major market for Indian exports, and the first Gulf War, which reduced employment opportunities for Indians in the Middle East, resulting in a depletion of remittances from non-resident Indians to India.<sup>107</sup> This crisis ultimately led to the introduction of the New Economic Policy (NEP) in July 1991 under Prime Minister P.V. Narasimha Rao and then-Finance Minister Manmohan Singh's leadership.<sup>108</sup> The NEP 1991 aimed at rapid liberalization, globalization, and privatization (LGP) of the Indian economy. 109 Under the liberalization scheme, India abolished the licensing system for most industries except those of strategic significance such as alcohol, cigarettes, industrial explosives, defense products,

<sup>102</sup> Id.

<sup>103</sup> Id. at 48.

<sup>104</sup> Id. at 33.

Natalia George, *Reforms Shape India's Economy (1980-90)*, YAHOO (Aug. 14, 2011), https://www.yahoo.com/news/Reforms-shape-India-economy-yahoofinancein-2531391639.html [https://perma.cc/2DRG-995B].

<sup>106</sup> See id.

<sup>107</sup> Ramesh, supra note 101, at 33.

Hemant Singh, *New Economic Policy of 1991: Objectives, Features, and Impacts*, JAGRAN JOSH (Feb. 21, 2018), https://www.jagranjosh.com/general-knowledge/new-economic-policy-of-1991-objectives-features-and-impacts-1448348633-1 [https://perma.cc/A3LM-9KSM].

ACCOMPLISHED? WHAT REMAINS TO BE DONE? (2001), http://www.columbia.edu/~ap2231/Policy%20Papers/OPB2.pdf [https://perma.cc/X2GA-Q5X9].

drugs and pharmaceuticals, hazardous chemicals, and certain others reserved for the public sector. 110 It also relaxed restrictions on foreign direct investment (FDI) and on industrial production.<sup>111</sup> Prior to the NEP 1991, foreign companies required prior written approval of the Indian Government before investing money into the country. 112 However, post-NEP 1991, automatic renewals were granted for FDI inflows into the country. 113 Similarly, the pre-NEP 1991 regime required government approval to set up industries in cities, which was relaxed by the NEP 1991.<sup>114</sup> Apart from these measures, the liberalization scheme also reformed the existing antitrust regulations, introduced public sectoral reforms, and opened the door for foreign technology imports.<sup>115</sup> India's high economic growth in the 1990s and 2000s is attributed to liberalization while critics have blamed it for increased poverty, inequality, and economic degradation.<sup>116</sup> The privatization scheme of the NEP 1991 was primarily marked by the disinvestment of public sector undertakings, granting greater autonomy to the public sector, and the de-reservation of the public sector.<sup>117</sup> This circumstance has ultimately boosted the productivity of the once-ailing public sector initiatives and the growth of competent private enterprises particularly in the insurance, banking, civil aviation, telecom, and power sector. 118 Globalization under the NEP 1991 opened India's domestic markets for inflow of foreign goods by reducing customs duties on imports, accession to international organizations such as the WTO, and liberalization of Foreign Exchange Regulation Act to

<sup>110</sup> Singh, supra note 108.

<sup>111</sup> Id

<sup>112</sup> PANAGARIYA, *supra* note 109, at 2.

<sup>113</sup> See id. (finding that Indian foreign investment regime is as liberal as in other Asian countries).

<sup>114</sup> See id. at 3 (finding private telecommunication firms have thrived in urban development).

Subho Mukher, *Benefits of Liberalisation and Globalisation of Indian Economy*, ECON. DISCUSSION, http://www.economicsdiscussion.net/globalization/benefits-of-liberalisation-and-globalisation-of-indian-economy/10929 [https://perma.cc/UE7P-UJE4].

Ramesh, supra note 101, at 39.

<sup>117</sup> Singh, supra note 108.

Anant Kousadikar & Trivender Kumar Singh, *Advantages and Disadvantages of Privatisation in India*, 3 INT'L J. OF ADVANCED SYS. AND SOC. ENGINEERING Res. 18, 21 (2013).

enable foreign currency transactions.<sup>119</sup> Because of these measures, India's economy has progressed immensely at an annual rate of 6-8% with major contribution from the tertiary or the services sector industry.<sup>120</sup> The growth of the tertiary and the manufacturing sectors since 1951 has been to such an extent that India is referred to as "the back office of the world."<sup>121</sup> Despite this, over 58% of rural Indian households depend on agriculture even though the overall share of the primary sector, which includes agriculture, livestock, forestry, and fishery, is estimated to be only 20.4% of the Gross Value Added (GVA) during the financial year 2016-17, which marks a reduction from 59% in 1951.<sup>122</sup>

#### B. U.S.-India Relations

Since India's independence in 1947 until the end of the Cold War in 1991, economic and political relations between the U.S. and India have been in flux. During the Cold War, the U.S. was skeptical of India's "non-aligned" foreign policy and close relations with the Soviet Union, this, coupled with India's testing of nuclear weapons, resulted in poor relations between the two countries.<sup>123</sup>

<sup>119</sup> *Id*.

<sup>120</sup> PANAGARIYA, supra note 109, at 3.

Preetam Kaushik, *Transforming India: From 'The World's Back Office' To 'The World's Factory*,' Bus. Insider (Sept. 24, 2014), https://www.businessinsider.in/transforming-india-from-the-worlds-back-office-to-the-worlds-factory/articleshow/43330488.cms [https://perma.cc/9WUC-TW3L].

<sup>122</sup> INDIA BRAND EQUITY FOUNDATION, Agriculture in India: Information about Indian Agriculture & Its Importance, https://www.ibef.org/industry/agriculture-india.aspx [https://perma.cc/N8YV-4ZRJ]; see also Rural India No Longer an Agrarian Economy: Study, ECON. TIMES 24, (Apr. https://economictimes.indiatimes.com/news/economy/agriculture/rural-india-no-longeran-agrarian-economy-study/articleshow/12852101.cms [https://perma.cc/486L-GP7L]; see also Shekhar Gupta, Why Rural India Matters: Agriculture's Share in Economic GDP May Be Low but in Electoral, Political Equivalent of GDP, It is about 60 Per Cent, INDIA 2015), https://www.indiatoday.in/magazine/nationalinterest/story/20150615-agriculture-rural-india-gdp-economy-narendra-modi-shekhargupta-819842-2015-06-05 [https://perma.cc/RP6E-6KPA].

Bradley Dunseith, *The US – India Economic Relationship*, INDIA BRIEFING (June 28, 2017), https://www.india-briefing.com/news/us-india-economic-relationship-14559.html/ [https://perma.cc/85SB-HUB6]; *see also* RAVI TOMAR, INDIA-US RELATIONS IN A CHANGING STRATEGIC ENVIRONMENT (2002), https://www.aph.gov.au/About\_Parliament/Parliamentary\_Departments/Parliamentary\_L ibrary/pubs/rp/rp0102/02RP20 [https://perma.cc/Q55E-XR97]. For more on U.S.-India bilateral relations, see Stephen P. Cohen, *India and America: An Emerging Relationship*, BROOKINGS (2010), https://www.brookings.edu/wp-content/uploads/2016/06/kyoto.pdf

However, in the post-Cold War era, economic and political relations between the U.S. and India have undergone a sea change, with each side eager to foster better economic and trade relations. Former President Barack Obama called the U.S.-India partnership one of the defining partnerships of the 21st century, one which was vital to U.S. strategic interests in the Asia-Pacific region and across the globe.<sup>124</sup> Similarly, during Prime Minister Narendra Modi's "nofrills" visit to the United States in June 2016, a joint statement issued by the heads of the two states called the two countries "[e]nduring [g]lobal [p]artners in the 21st [c]entury." This legacy of enduring partnership between the two countries has been carried forward by President Trump who has referred to Prime Minister Modi as a friend. 126 Prime Minister Modi has commended President Trump for speaking highly about India and stated that relations between the two countries had the potential to rise beyond bilateral ties. 127 Despite this positive rhetoric, areas of conflict exist between the two countries. India has criticized the U.S. for its withdrawal from the Paris Agreement on Climate Change (Paris Climate

[https://perma.cc/D5HE-PHLJ].

<sup>124</sup> Indo-US Ties Can Be Defining Partnership of 21st Century: Obama, ECON. TIMES (Dec. 1, 2017), https://economictimes.indiatimes.com/news/politics-and-nation/indo-us-ties-can-be-defining-partnership-of-21st-century-obama/articleshow/61882179.cms [https://perma.cc/2A97-DGPS]; see also U.S. Relations with India, U.S. DEPT. OF STATE (Aug. 15, 2018), https://www.state.gov/r/pa/ei/bgn/3454.htm [https://perma.cc/X5VA-BQG8] (stating that U.S. is India's largest trade and economic partner).

https://www.mea.gov.in/Portal/ForeignRelation/India\_US\_brief.pdf [https://perma.cc/X9VT-C7Y7]; see also US-India Relations to Expand Beyond Trade, Says Admiral Harry Harris, The Am. BAZAAR (Mar. 16, 2018), https://www.americanbazaaronline.com/2018/03/16/us-india-relations-to-expand-beyond-trade-says-admiral-harry-harris-433070/ [https://perma.cc/52TY-YMA6] (stating that U.S. Navy Admiral Harry B. Harris, Jr. believed that the U.S.-India relationship was poised to become the most consequential relationship of the 21st century).

<sup>126</sup> Ved Nanda, A Growing Relationship Between the U.S. and India, DENVER POST (Feb. 2, 2018), https://www.denverpost.com/2018/02/02/a-growing-relationship-between-the-u-s-and-india/ [https://perma.cc/5YBA-YQM5]; see also India-US Partnership Has Never Been More Important: John Chambers, MONEY CONTROL (June 29, 2017, 09:03 AM IST), https://www.moneycontrol.com/news/business/india-us-partnership-has-never-been-more-important-john-chambers-2314329.html [https://perma.cc/CEC5-F5EC] (quoting statements by John Chambers, Executive Chairman of CISCO and Chairman of U.S.-India Business Council, emphasizing the crucial nature of the India-U.S. partnership).

<sup>127</sup> Nanda, supra note 126.

Agreement).<sup>128</sup> Justifying its departure, the U.S. later criticized India for demanding billions of dollars to fulfill its own commitments under the Paris Climate Agreement.<sup>129</sup> India has also expressed concerns over President Trump's possible restrictions on H1-B visas.<sup>130</sup> The U.S. trade deficit of 24.4 billion dollars with India has been a talking point for President Trump, despite a substantial decrease in the trade deficit in 2017.<sup>131</sup> The U.S. has also criticized India for market access barriers, high tariffs on several American products being imported into India, and on intellectual property issues, which has been a major area of discord between the two countries since at least 1989.<sup>132</sup>

#### C. Broad Trends

The USTR's Special 301 Report on intellectual property has been critical of India since its first release on May 25, 1989, which listed India as a priority watch list country.<sup>133</sup> The major reasons

<sup>&</sup>lt;sup>128</sup> Mathew Car, Abhay Singh & Anindya Upadhyay, *India Criticizes Rich Nations on Broken Climate Promises*, BLOOMBERG (May 23, 2018), https://www.bloomberg.com/news/articles/2018-05-24/india-disappointed-by-richnations-climate-treaty-track-record [https://perma.cc/73ZC-ACFD].

ANALYSIS (June 21, 2017), https://idsa.in/idsacomments/modi-meets-trump-what-to-expect asajjanhar 210617 [https://perma.cc/WC4Y-3E75].

Meeran Karim, Modi & Trump's Meeting Went Great, Unless You Are an Indian Worried about H1-B Visas, SLATE (June 27, 2017), http://www.slate.com/blogs/the\_slatest/2017/06/27/modi\_and\_trump\_didn\_t\_talk\_about\_visas\_at\_white\_house\_meeting.html [https://perma.cc/W555-7RRG]; see also Rishi Iyengar, Trump Meets Modi: Trade, Visas and Climate Could Make for Tough Talking, CNN Bus. (June 26, 2017), http://money.cnn.com/2017/06/25/news/economy/trump-modi-visit-india-h1b-trade-climate/index.html [https://perma.cc/Q8RG-G6EM].

Trade Deficit with India Decreased in 2017; Concerned over Trade Barriers: US, ECON. TIMES (Apr. 5, 2018), https://economictimes.indiatimes.com/news/economy/foreign-trade/trade-deficit-with-india-decreased-in-2017-concerned-over-trade-barriers-us/articleshow/63621099.cms [https://perma.cc/LN88-GJL7] (stating that trade deficit between India and the U.S. dropped by almost 6% in 2017 compared to 2016).

<sup>132</sup> For the first special 301 report, see FACT SHEET "SPECIAL 301" ON INTELLECTUAL PROPERTY, *supra* note 13.

<sup>133</sup> Id. See also Arvind Panagariya, India as Scapegoat: U.S. Action under Super-301, TIMES OF INDIA (June 23, 1989), http://www.columbia.edu/~ap2231/ET/toi1-section-301-india%20as%20a%20scapegoat-june23-89.htm [https://perma.cc/BB98-DZZ5]; see also Seemantani Sharma, Will 2016 Usher a New Era for US-India IPR Relations? QRIUS (July 16, 2016), https://qrius.com/new-era-us-india-ipr-relations/ [https://perma.cc/2ATG-BY49].

cited for categorizing India as a priority watch list country include: lack of effective patent protection for all classes of inventions; discrimination against foreign trademarks; lack of effective protection for well-known marks and service marks, rampant copyright piracy; and concern over the lack of constructive participation in multilateral intellectual property negotiations. 134 Since then, except for the years 1991-1993, India has always been designated as a priority watch list country, mandating USTR's urgent attention, and just falling short of trade sanctions.<sup>135</sup> The relations between India and the U.S. became particularly tense in 1991 when the USTR designated India as a priority foreign country for the first time.<sup>136</sup> Then-U.S. Trade Representative Carla Hills cited India's patent regime, which provided for a very short term of patent protection, and overly broad compulsory licensing provisions as primary reasons for classifying India as a priority foreign country.<sup>137</sup> Despite the threat of retaliation, the Indian government under the leadership of P.V. Narasimha Rao refused to negotiate with the U.S. on patent issues even though it made several concessions in the domain of copyright and trademark law to fulfill the U.S.' demands. 138 However, no substantive changes were made to provisions related to patent protection for pharmaceutical products.<sup>139</sup> On November 2, 1991, the USTR extended the date for releasing the Special 301 Report to February 28, 1992, when it

<sup>134 1989</sup> SPECIAL 301 REPORT, supra note 132.

<sup>135</sup> See Clinton Ritchey, India's Weak Patent Rights Hurt U.S. Pharmaceutical Trade, NAT'L CTR. FOR POL'Y ANALYSIS (July 1, 2014), http://www.ncpathinktank.org/pub/ib145 [https://perma.cc/S79X-QJQ5]. For categorization under each year's special 301 report, see also INT'L INTELL. PROP. ALLIANCE, APPENDIX B: CHART OF COUNTRIES' SPECIAL 301 PLACEMENT (1989-2017) & IIPA 2018 SPECIAL 301 RECOMMENDATIONS (Feb. 8, 2018), https://iipa.org/files/uploads/2018/02/2018SPEC301HISTORICALCHART.pdf [https://perma.cc/9TDD-TZRV].

<sup>136</sup> See Theodore H. Davis, Jr., Sino-American IPR Trade War Narrowly Averted, 13 IPL NEWSL. 3, 4 (1995). For the U.S.' strategy for designating countries under the special 301, see Theodore H. Davis, Jr., Combatting Piracy of Intellectual Property in International Markets: A Proposed Modification of the Special 301 Action, 24 VAND. J. TRANSNAT'L. L. 505, 523 (1991).

<sup>137</sup> FACT SHEET: "SPECIAL 301" ON INTELLECTUAL PROPERTY, supra note 35.

Aparna Vishwanathan, Special 301: Analysis of Intellectual Property Dispute Between India and US, 35(1/2) J. OF INDIAN L. INST. 127, 128 (1993); see also Geoffrey Allen Pigman, United States Trade Policies at Loggerheads: Super 301, the Uruguay Round and Indian Services Trade Liberalization, 3 REV. INT'L POL. ECON. 728, 742 (1996) (stating that Indian negotiators had refused to negotiate over Super 301).

<sup>139</sup> Id.

proclaimed that the Indian patent regime unduly burdened American corporations. As a result on April 29, 1992, with the release of the 1992 Special 301 Report, USTR retaliated by suspending duty-free treatment of U.S. \$60 million-worth of pharmaceutical imports from India under General System of Preferences (GSP) of the General Agreement on Tariffs and Trade (GATT).<sup>140</sup> Hills stated that the President's action was directed at Indian firms which benefited from inadequate protection of patented U.S. pharmaceuticals.<sup>141</sup> India vehemently defended its position by arguing that heightened patent protection for pharmaceuticals would increase drug prices beyond the reach of common Indian citizens. 142 India further claimed that the excessively-long term of protection for pharmaceutical products had not led to innovative therapeutic advances, and the patent monopoly had led to exorbitant drug prices which in turn resulted in windfall profits for the American pharmaceutical companies.<sup>143</sup> Despite this, the then newly-appointed U.S. Trade Representative Mickey Kantor once again placed India as a priority foreign country under the 1993 Special 301 Report on account of a lack of adequate and effective protection for U.S. intellectual property or fair and equitable market access for relevant U.S. products. 144 However, the situation normalized in 1994 when the USTR moved India from priority foreign country to a priority watch list primarily on the basis of positive amendments to its copyright law. 145 Since the

<sup>140</sup> Id.; see also Diane Kroeger May, Pharmaceutical Crisis in India: Transcending Profits with Human Rights, 10 Wis. Int'l L.J. 40, 52 (1991); see also Timothy C. Bickham, Protecting U.S. Intellectual Property Rights Abroad with Special 301, 23 AIPLA Q. J. 195, 213 (1995) (stating that the U.S. President suspended duty-free entry privileges equivalent to \$60 million under GSP from India).

<sup>141</sup> Eduardo Lachica, *Taiwan Added to List of Worst Patent Violators*, WALL St. J., Apr. 30, 1992, at A2.

<sup>142</sup> May, supra note 140, at 57.

<sup>143</sup> Id. at 56.

<sup>144</sup> For the 1993 Special Report, see Off. of the U.S. Trade Representative, USTR Announces Three Decisions: Title VII, Japan Supercomputer Review, Special 301 (1993) [hereinafter 1993 Special Report]. Michael Kantor served as the United States Trade Representative from 1993 till 1996. *See* Off. of the U.S. Trade Representative, https://ustr.gov/about-us/history/list-past-ustrs [https://perma.cc/7UN4-JWPM].

<sup>145 1993</sup> Special Report, *supra* note 144. *See also* OFF. OF THE U.S. TRADE REPRESENTATIVE, USTR ANNOUNCES TWO DECISIONS: TITLE VII AND SPECIAL 301 5 (1995) [hereinafter 1995 Special Report] (stating the reasons why the U.S. administration had moved India from a priority foreign country to a priority watch list country).

implementation of the new copyright law and the mailbox provisions of the TRIPS Agreement was still pending, India was still retained as a priority watch list country. 146 This situation continued from 1995 until 1998, during which USTR categorized India as a priority watch list primarily for its failure to implement Articles 70.8 and 70.9 of the TRIPS Agreement. 147 It was only when India successfully implemented the mailbox provisions by enacting the Patents (Amendment) Act, 1999 on March 26, 1999 that the USTR expressed satisfaction over India's compliance with Articles 70.8 and 70.9 of the TRIPS Agreement under the 1999 Special 301 Report.<sup>148</sup> Nevertheless, USTR still placed India on the priority watch list under the 1999 Special 301 Report due to its noncompliance with other provisions of the TRIPS Agreement and due to rampant copyright piracy.<sup>149</sup> Since then, India has recurrently been placed as priority watch list country largely on account of deficiencies related to its patent system, rampant copyright piracy, lack of effective protection for foreign trademarks, and nonratification of major international IP treaties. These issues will be explored-in depth in the next section.

[https://perma.cc/5QZZ-9W8A].

<sup>146 1995</sup> Special Report, supra note 144.

<sup>147</sup> For the 1995 special report, see 1995 Special Report, supra note 144. For the 1996 Special 301 Report, see Off. of the U.S. Trade Representative, USTR Announces Two Decisions: Title VII and Special 301 10 (1996). For the 1997 Special 301 Report, see Off. of the U.S. Trade Representative, USTR Announces Results of Special 301 Annual Review 9 (1997). For the 1998 Special 301 Report, see Off. of the U.S. Trade Representative, USTR Announces Results of Special 301 Annual Review 12 (1998).

The United States had initiated a WTO dispute settlement proceeding against India in 1997 for its failure to provide a "mailbox" system for filing patent applications. In December 1997, the WTO Appellate Body upheld a panel ruling in favor of the U.S. with slight modifications wherein it found that India had failed to comply with its obligations under Articles 70.8 and 70.9 of the TRIPS Agreement. On February 13th, 1998 India committed to fulfill its obligations under the ruling of the Appellate Body by amending its patent law no later than April 19th, 1999. *See* WORLD TRADE ORG., INDIA—PATENT PROTECTION FOR PHARMACEUTICAL AND AGRICULTURAL CHEMICAL PRODUCTS (1997), https://www.wto.org/english/tratop\_e/dispu\_e/cases\_e/ds50\_e.htm
[https://perma.cc/8QBU-5Z9P]; *see also* WORLD TRADE ORG., INDIA—PATENTS (US), https://www.wto.org/english/tratop\_e/dispu\_e/cases\_e/lpagesum\_e/ds50sum\_e.pdf

<sup>149</sup> OFF. OF THE U.S. TRADE REPRESENTATIVE, USTR ANNOUNCES RESULTS OF SPECIAL 301 ANNUAL REVIEW 11 (1999) (stating that India's patent and trademark laws had continued to fall short of the TRIPS standards and that it had failed to take adequate enforcement action to control high levels of piracy of videos, video CDs, cable systems, computer software, and sound recordings).

#### IV. Key Issues under Special 301 Report

#### A. Patent Related Issues

1. Failure to Provide Patent Protection for Pharmaceutical and Agricultural Chemical Products

India's failure to provide patent protection for pharmaceutical and agricultural chemical products has been a major area of discord between the two countries since at least 1994 when the TRIPS Agreement was concluded. Until then, India had successfully resisted U.S. pressure to amend its patent law in order to provide for patent protection for pharmaceutical and agricultural chemical products. With the coming-into-force of the TRIPS Agreement on January 1, 1995, India had no choice but to implement the patent "mailbox" provisions of the TRIPS Agreement. In the 1995 Special 301 Report, the USTR (as expected) placed India as a priority watch list country on account of India's failure to fully implement the patent "mailbox" provisions of the TRIPS Agreement. This unsurprisingly became a contentious issue between the two In the 1996 Special Report, USTR expressed its unequivocal intention to initiate a WTO dispute settlement proceeding against India. 151 On July 2, 1996, the United States requested formal consultations with India under the aegis of the WTO dispute settlement mechanism on the alleged absence of patent protection for pharmaceutical and agricultural products under the Indian patent law.<sup>152</sup> After successive rounds of failed consultations, the United States requested the establishment of a panel to investigate the dispute. In response to the request, a WTO Dispute Panel ("Panel") was established on November 20, 1996. 153 The report of the panel found that India had failed to comply with Articles 70.8(a) and 63(1) and (2) of the TRIPS Agreement by failing to preserve novelty and priority with respect to applications

<sup>150</sup> India had failed to fully implement the mail-box provisions as the Indian Parliament was unable to pass the 1995 Patents Amendment Bill. See David K. Tomar, A Look into the WTO Pharmaceutical Patent Dispute Between United States and India, 17 WIS. INT'L. L.J. 579, 585 (1999).

<sup>&</sup>lt;sup>151</sup> USTR Announces Two Decisions: Title VII and Special 301, *supra* note 147.

<sup>152</sup> Request for Consultations by the United States, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/1 (July 9, 1996).

<sup>&</sup>lt;sup>153</sup> Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 1.1, WTO Doc. WT/DS50/R (Sept. 5, 1997).

for product patents for pharmaceutical and agricultural chemical inventions.<sup>154</sup> It also held that India did not comply with Article 70.9 of the TRIPS Agreement by failing to establish a system for the grant of exclusive marketing rights. 155 On October 15, 1997, India decided to appeal the decision of the Panel to the Appellate Body of the WTO (the Appellate Body). 156 Appellate Body upheld the Panel's decision on Articles 70.8 and 70.9, but ruled that Article 63(1) was not within the Panel's terms of reference. 157 Subsequent to the decision of the Appellate Body, and the first meeting of the Dispute Settlement Body (DSB) on April 22, 1998, the two parties eventually decided to set a deadline of April 19, 1999.<sup>158</sup> On March 26, 1999 India successfully complied with the decision of the DSB by enacting the Patents (Amendment) Act, 1999.<sup>159</sup> The newly enacted Section 2(2) of the Patents (Amendment) Act, 1999 instituted the mailbox requirement of Article 70.9 of the TRIPS Agreement which enabled entities to submit product patent applications for pharmaceuticals and agricultural chemicals to the patent office that would be held until examination in 2005.<sup>160</sup> Section 24A of the Patents (Amendment) Act, 1999 also granted exclusive marketing rights to pharmaceutical and agricultural chemical products in accordance with Article 70.9.<sup>161</sup> The enactment of Section 4 of the Patents (Amendment) Act, 2005 which deleted Section 5 of the erstwhile Patents Act, 1970 brought India fully into compliance with Article 27(1) of the TRIPS Agreement by giving patent protection to pharmaceutical and agricultural products.<sup>162</sup> Since the enactment of the Patents

<sup>&</sup>lt;sup>154</sup> *Id.* ¶¶ 8.1–8.2.

<sup>155</sup> *Id* 

<sup>&</sup>lt;sup>156</sup> Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 3, WTO Doc. WT/DS50/AB/R (adopted Dec. 19, 1997).

<sup>157</sup> *Id*. at ¶ 97.

<sup>&</sup>lt;sup>158</sup> DS50: India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, World Trade Org.,

https://www.wto.org/english/tratop\_e/dispu\_e/cases\_e/ds50\_e.htm [https://perma.cc/J78R-UTJY].

<sup>159</sup> Status Report by India, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/10/Add.4 (Apr. 16, 1999).

<sup>160</sup> The Patent (Amendment) Act, 1999, No. 17 of 1999, INDIA CODE (1999), sec. 2(2).

<sup>161</sup> Id. at sec. 24(A).

<sup>162</sup> Section 5 of the Patents Act, 1970 (prior to the 2005 amendments) provided that in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the methods or processes of manufacture of such substances could be obtained. *See* Patents Act, 1970, No. 39 of 1970, INDIA CODE (1970).

(Amendment) Act, 2005 the USTR has expressed satisfaction over India's patent law—at least on account of pharmaceutical and agricultural chemical products. However, grievances regarding patentability criteria and compulsory licenses prevail. 163

#### 2. Narrow Patentability Criteria

Since 2010, USTR has expressed concerns over Section 3(d) of the Indian Patents Act, 1970. This provision aims to prevent "evergreening"<sup>164</sup> of pharmaceutical patents by prohibiting the patenting of new forms of existing pharmaceutical substances that do not demonstrate significantly enhanced "efficacy."<sup>165</sup> The concern stemmed, *inter alia*, from rejection of a patent application covering Novartis' famed anticancer drug Gleevec by the Indian Patent Office (IPO) in 2008.<sup>166</sup>

During the 1990s, Novartis filed a series of patent applications in the United States for an anti-cancer drug containing "imatinib." These patent applications covered pharmaceutically acceptable salts and was subsequently granted by the United States Patent & Trademark Office (USPTO). Novartis then filed a patent application for the "beta crystalline" form of the imatinib mesylate salt which was also accepted by the USPTO. 169 In 2001,

For more on the Patents (Amendment) Act, 2005, see Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act*, 2005, 1 INDIAN J.L. & TECH. 15 (2005). See also Manoj Pillai, *The Patents (Amendment) Act*, 2005 and TRIPS Compliance – A Critique, 10 J. of INTELL. PROP. RTS. 235 (2005).

- 163 See Off. of the U.S. Trade Representative, 2006 Special 301 Report 28 (2006), (stating that India improved its patent regime by passing the legislation in early 2005 to provide for product patents for pharmaceuticals and agricultural products. However, while this was an important step, the new legislation had important omissions which detracted from India's patent regime).
- 164 Evergreening is a "practice whereby pharmaceutical companies extend the patent life of a medicine by obtaining additional 20-year patents for minor reformulations or other iterations of the medicine, without necessarily increasing the therapeutic efficacy." *See Evergreening: An Abuse of the Patent System*, LAWCTOPUS (Jan. 16, 2015), https://www.lawctopus.com/academike/evergreening-an-abuse-of-the-patent-system/ [https://perma.cc/5B9H-DSQY].
- $_{\rm 165}$  See Off. of The U.S. Trade Representative, 2010 Special 301 Report 26 (2010).
- 166 See Shamnad Basheer & T. Prashant Reddy, The "Efficacy" of Indian Patent Law: Ironing Out the Creases in Section 3(d), 5 SCRIPTED 232, 235 (2008).
  - <sup>167</sup> Novartis v. the Union of India & Others, (2013) 13 SCR 148, 165 (India).

<sup>168</sup> *Id*.

<sup>169</sup> Id. at 169.

the U.S. Food and Drug Administration (FDA) approved the active ingredient imatinib mesylate for use as a blockbuster cancer drug, which was later marketed by Novartis as Gleevec. 170 At least 40 patents were obtained for the beta crystalline form of imatinib mesylate all over the world.<sup>171</sup> At that time, Indian patent law did not grant product patents; therefore, no patents were granted for imatinib mesylate. 172 Subsequently, in 2005, Indian patent law was amended which allowed for product patents.<sup>173</sup> Novartis sought patent protection for the beta crystalline form of imatinib mesylate under a "mailbox application," which was rejected by the Assistant Controller of Patents of the IPO on grounds that it failed to satisfy novelty and non-obviousness requirements.<sup>175</sup> Novartis then appealed the decision of the IPO to the Madras High Court, which was ultimately transferred to the then newly-formed Intellectual Property Appellate Board (IPAB), a specialized tribunal established to hear appeals from various intellectual property offices around the country.<sup>176</sup> The IPAB also rejected the patent application on grounds that the invention was not a new substance, but an amended form of a known compound and Novartis was unable to show increase in efficacy as laid down in section 3(d) of the Indian Patents Act. 177 Novartis then appealed the decision of the IPAB directly to the Supreme Court of India through the Special Leave Petition, under a time constraint as the patent if granted on appeal would have expired by 2018.<sup>178</sup> In a landmark ruling, the Indian Supreme Court rejected Novartis' appeal for patent protection for a newer version of Gleevec. In Novartis AG v. Union of India & Others, the Indian Supreme Court held that the prior patents and literature did not constitute prior art against the beta crystalline form of imatinib mesylate and did not meet the

<sup>170</sup> FDA Gives Fast Approval to Gleevec in Treatment of CML, CANCER NETWORK (June 1, 2001), http://www.cancernetwork.com/chronic-myeloid-leukemia/fda-gives-fast-approval-gleevec-treatment-cml [https://perma.cc/XJ4R-NCFC].

<sup>&</sup>lt;sup>171</sup> Lisa Kilday, Global IP Reaction to India's Rejection of the Novartis Drug Patent, IP WATCHDOG (May 28, 2013), http://www.ipwatchdog.com/2013/05/28/global-ip-reaction-to-indias-rejection-of-the-novartis-drug-patent/id=40778/ [https://perma.cc/CDW3-CFVJ].

Novartis v. the Union of India & Others, *supra* note 167, at 171.

<sup>173</sup> Id. at 171.

<sup>174</sup> For more on mailbox application, see supra Part IV(A)(1).

<sup>&</sup>lt;sup>175</sup> Novartis v. the Union of India & Others, *supra* note 167, at 171–72.

<sup>&</sup>lt;sup>176</sup> *Id.* at 172.

<sup>177</sup> Id. at 173.

<sup>&</sup>lt;sup>178</sup> Id. at 174.

requirements of an "invention" as laid down in the Indian Patents Act. The Supreme Court's decision hinged upon the interpretation of Section 3(d) of the Patents Act, 1970 wherein Section 3(d) set qualifying standards for pharmaceuticals products, leaving "the door open for true and genuine inventions but at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds." It further held that Section 3(d) of the Patents (Amendment) Act, 2005 set the invention threshold higher than that required under old provisions of Patents Act, 1970. This restrictive interpretation of Section 3(d) of the Patents Act, 1970 has been touted as evidence of India's weak patent regime by the USTR. However, this restrictive interpretation was imperative for safeguarding India's public health needs as it would have led to evergreening of pharmaceutical patents. Would have led to evergreening of pharmaceutical patents.

#### 3. Compulsory Licenses & Local Working Requirement

Since 1991, USTR has criticized India's compulsory licensing provisions as stipulated under Section 84 and Section 92 of the Patents Act, 1970 for their lack of clarity and for being overly broad in contravention of the TRIPS Agreement.<sup>184</sup> Under Section 84(1)(c) of the Patents Act, 1970 a compulsory license can be issued by the Controller General of Patents if the patent is not "worked" in the territory of India.<sup>185</sup> The situation worsened in 2012 when India

<sup>179</sup> Id. at 151.

<sup>180</sup> Id. at 152.

<sup>181</sup> Id. For more on the Indian Supreme Court's interpretation of Section 3(d) of the Patents Act, 1979, see Joli Patel, Comment, India's Crack down on the Practice of Pharmaceutical Evergreening: The 2013 Novartis Decision, 85 UMKC L. Rev. 503, 530 (2017). See also Swaraj Paul Barooah, India's Pharmaceutical Innovation Policy: Developing Strategies for Developing Country Needs, 5 Trade L. & Dev. 150, 168 (2013).

<sup>182</sup> Even in the 2018 Special 301 Report, the USTR has mentioned that American corporations were concerned about India's narrow patentability standards. *See* OFF. OF THE U.S. TRADE REPRESENTATIVE, 2018 SPECIAL 301 REPORT 49 (2018).

<sup>183</sup> For more on evergreening, see supra Part IV(A).

<sup>184</sup> See Fact Sheet "Special 301" on Intellectual Property, supra note 35, at 2. For India's compulsory licensing provisions, see Katherine W. Sands, Prescription Drugs: India Values Their Compulsory Licensing Provision—Should the United States Follow in India's Footsteps?, 29 Hous. J. Int'l L. 191, 199 (2006); see also Janice M. Mueller, The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation, 68 U. Pitt. L. Rev. 491, 587 (2007).

<sup>185</sup> The Patents Act, 1970, No. 39 of 1970, INDIA CODE, sec. 84(1)(c).

issued its first compulsory license on a pharmaceutical product primarily because of the innovator's failure to "work" the patent in India. By an order of the Controller General of Patents, German pharmaceutical company Bayer's patented drug Nexavar was allowed to be used by the Indian generic drug manufacturer Natco Pharma Ltd. The order of the Controller General of Patents was subsequently upheld by IPAB, which caused a stir with the multinational pharmaceutical companies and in turn the USTR. Even to date, the USTR has threatened India for its lax compulsory licensing regime, which India has firmly refuted on grounds of its public health needs. 189

#### 4. Computer-Related Inventions (CRI) Guidelines

In 2016 and 2017, the USTR had objected to the much-publicized and contested guidelines related to computer-related inventions due to its unpredictability and opacity leading up to the comment process.<sup>190</sup> For many years the patentability of computer-

<sup>186</sup> See id. (enabling the issuance of a compulsory license if a patented invention has not been worked in the territory of India).

<sup>187</sup> See Shamnad Basheer, Breaking News: India's First Compulsory License Granted!, SPICYIP (Mar. 12, 2012), https://spicyip.com/2012/03/breaking-news-indias-first-compulsory.html [https://perma.cc/NT8W-S96Z]; see also Maricel Estavillo, India Grants First Compulsory License, For Bayer Cancer Drug, INTELL. PROP. WATCH (Mar. 12, 2012), http://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/ [https://perma.cc/ZHC6-TMWA].

the IPAB order, see GNAIPR, http://www.gnaipr.com/CaseLaws/IPAB%20Order.pdf [https://perma.cc/BV6M-ATWP]; see also Patralekha Chatterjee, India's First Compulsory License Upheld, but Legal Fights Likely to Continue, INTELL. PROP. WATCH (Mar. 4, 2013), http://www.ipwatch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/ [https://perma.cc/CG5F-9RHG].

There were rumors that India had agreed to not issue compulsory licenses. However, these rumors have been refuted by the Indian government. *See* Zeba Siddiqui, *U.S. Industry Body Says India Agreed to Not Issue 'Compulsory' Drug Licenses*, REUTERS (Mar. 8, 2016), https://www.reuters.com/article/india-patents-usa/u-s-industry-body-says-india-agreed-to-not-issue-compulsory-drug-licences-idUSKCN0WA18Q [https://perma.cc/84U3-V5KL]. For the Government notification, see Press Release, Press Info. Bureau, Gov't of India, Clarification on Media Reports Regarding Compulsory License (Mar. 22, 2016), http://pib.nic.in/newsite/PrintRelease.aspx?relid=138271 [https://perma.cc/4LYC-W8RH].

As a matter of fact, even the Indian stakeholders have criticized these guidelines. See Tanveer Kaur, CRI Guidelines May Impact the Innovation Ecosystem, HINDU BUS. LINE (Nov. 21, 2016), https://www.thehindubusinessline.com/info-tech/cri-guidelines-may-impact-the-innovation-ecosystem/article9370958.ece [https://perma.cc/HH9S-

related inventions in India has remained unclear as Section 3(k) of the Patents Act 1970 excludes computer programs as patentable subject matter.<sup>191</sup> This situation had resulted in an ambiguity on whether software inventions were patentable in India or not. On June 28, 2013 the IPO, to resolve this ambiguity, published the draft guidelines for examination computer-related of applications.<sup>192</sup> The IPO, after stakeholders, published the final guidelines on August 21, 2015. However, these draft guidelines were abruptly suspended by the IPO by giving a public notice on December 14, 2015. There was no reason given whatsoever for suspending the existing guidelines.<sup>194</sup> It is because of this unpredictability and opacity on the part of the IPO that the USTR lashed out against India in the 2016 Special 301 Report. After much hue and outcry by the various stakeholders, the IPO issued the revised guidelines on computer-related inventions in June 2017. 195 The revised version of the guidelines was published on June 30, 2017 and was based on the recommendation of an expert committee established by the Department of Industrial Policy & Promotion (DIPP), the nodal government agency handling intellectual property matters. 196 The committee examined various representations and held intense stakeholder consultations in order to consider a diverse

2KMT]; see also India's Patent Office Says No to Software Patents, But Copyrights Still Valid, FIRSTPOST (Feb. 23, 2018), https://www.firstpost.com/tech/news-analysis/indiaspatent-office-says-no-to-software-patents-but-copyrights-still-valid-3677597.html [https://perma.cc/KQW7-X75B]; see also Sadhana Chathurvedula, India's Patent Office to Software Patents, Again. LIVEMINT (Feb. https://www.livemint.com/Industry/mBXAAoBm4yCf0Rhl3mUrCK/Indias-patentoffice-says-no-to-software-patents-again.html [https://perma.cc/ZVP4-8PAX]. For the guidelines related to computer related inventions, see OFF. OF THE CONTROLLER GEN. OF PATS., DESIGNS & TRADEMARKS, GUIDELINES FOR EXAMINATION OF COMPUTER RELATED INVENTIONS http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/Revised Guidelines for Exa

http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/Revised\_\_Guidelines\_for\_Examination\_of\_Computer-related\_Inventions\_CRI\_\_.pdf [https://perma.cc/27R9-CKK4].

<sup>191</sup> The Patents Act, supra note 185, at sec. 3(k).

<sup>192</sup> For the timeline related to the issuance of the guidelines, see Joginder Singh, International Report - Latest Guidelines for Examination of Computer-Related Inventions, IAM (Aug. 2, 2017), https://www.iam-media.com/latest-guidelines-examination-computer-related-inventions [https://perma.cc/82SE-UNN3].

<sup>193</sup> Id.

<sup>194</sup> Id.

<sup>195</sup> *Id* 

<sup>196</sup> For more on Department of Industrial Policy & Promotion (DIPP), see DEPT. OF INDUS. POL'Y & PROMOTION, http://dipp.nic.in/ [https://perma.cc/68C8-DKRX].

range of views. Unlike its predecessors, the revised guidelines have removed the "novel hardware" requirement as a prerequisite for seeking patents.<sup>197</sup> It is because of this that the USTR and other stakeholders have applauded the revised guidelines even though how effectively the IPO implements this policy is yet to be seen.<sup>198</sup> There is hope the IPO will effectively implement the revised policy. Otherwise, India should be prepared to be decried by the USTR in future special 301 reports.<sup>199</sup>

#### 5. Administrative Issues

Apart from the substantive grievances related to India's patent regime, the USTR has also expressed concerns regarding certain administrative issues such as the backlog of patent applications at the IPO, lengthy patent opposition proceedings, shortage of patent examiners, and excessive reporting requirements.<sup>200</sup> The National IPR Policy has attempted to address some of these issues. Clause 4.3 of Objective 4 of the National IPR Policy states that steps shall be taken towards restructuring, modernizing and, upgrading the

<sup>197</sup> Singh, supra note 192.

the June 2017 issuance of Computer-Related Invention Patent Examination Guidelines which eliminated the "novel hardware" requirements). The Guidelines were also welcomed by the Indian IT industry. See Guidelines for Computer Related Inventions Makes IT India Happy, Selvam & Selvam (Feb. 26, 2016), https://selvams.com/blog/guidelines-for-computer-related-inventions-makes-it-india-happy/ [https://perma.cc/5ZBE-JRV6].

<sup>199 2018</sup> SPECIAL 301 REPORT, *supra* note 182, at 51 (2018) (stating that the U.S. hoped that the Indian Patent Office would fully implement the guidelines in a manner that gave full recognition to the software sector).

<sup>200</sup> See Off. of the U.S. Trade Representative, 2012 Special 301 Report 35 https://ustr.gov/sites/default/files/2012%20Special%20301%20Report 0.pdf [https://perma.cc/D5GK-XQ9H] (stating that India should continue to work on its patent opposition proceedings). See also Off. of the U.S. Trade Representative, 2017 Special 301 https://ustr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.P DF [https://perma.cc/EVN5-TA3Q] [hereinafter 2017 SPECIAL REPORT] (stating that across all industries, patent applicants face costly and time-consuming patent opposition hurdles, long timelines for receiving patents, and excessive reporting requirements); see also Snehal Fernandes, India Takes Five Years to Look at Patent Applications, Reveals Economic HINDUSTAN TIMES Survey, https://www.hindustantimes.com/mumbai-news/india-takes-five-years-to-look-at-patentapplications-reveals-economic-survey/story-q1u11vKeg8lLtPqtdEtniM.html [https://perma.cc/4MG5-JXMB].

various intellectual property offices.<sup>201</sup> Similarly, it calls for steps expediting the examination of patent applications and fixing a timeline for grant of registrations and disposal of opposition matters.<sup>202</sup> Lastly, it supports augmenting the manpower, infrastructure facilities, and technological capabilities of the intellectual property offices and of the enforcement agencies.<sup>203</sup> Pursuant to the National IPR Policy, DIPP in conjunction with the Office of the Controller General of Patents, Designs & Trade Marks released the Patent (Amendment) Rules in 2016, which permit patent applicants to apply for expedited examination of patent applications subject to payment of applicable fees.<sup>204</sup> The release of the Patent (Amendment) Rules in 2016 has been a welcome step towards expediting the review of patent applications, though India still has a long way to go.<sup>205</sup>

## B. Copyright-Related Issues

### 1. Overly Broad Exceptions

USTR has criticized India's copyright regime for its broad limitations and exceptions in light of the decision of the Delhi High Court in the DU Photocopy Case.<sup>206</sup> In *Chancellor*, *Masters & Scholars of the University of Oxford & Ors. v. Rameshwari* 

<sup>201</sup> See Dept. of Indus. Pol'y & Promotion, National Intellectual Property Rights Policy 11 (May 12, 2016), http://dipp.nic.in/sites/default/files/National\_IPR\_Policy\_English.pdf [https://perma.cc/2QRZ-KP8V].

<sup>202</sup> *Id.* at 12 (citing clauses 4.14 and 4.16.1).

<sup>203</sup> Id. (citing clause 4.4).

<sup>205</sup> In 2017, the USTR lauded the Patent (Amendment) Rules, 2016 for its IP protection and enforcement progress. See 2017 SPECIAL REPORT, supra note 205, at 43 (2017); see also Patralekha Chatterjee, Is India's Expedited Examination of Patents a Big Deal?, INTELL. PROP. WATCH (Sep. 4, 2017), http://www.ip-watch.org/2017/09/04/indias-expedited-examination-patents-big-deal/ [https://perma.cc/4E8B-BXCY]; see also Shishir Arya, Patent Office Hopes to Halve Backlog by March 2018, TIMES OF INDIA (Feb. 23, 2017), https://timesofindia.indiatimes.com/city/nagpur/patent-office-hopes-to-halve-backlog-by-march-2018/articleshow/57299413.cms [https://perma.cc/E9BQ-KCDS].

<sup>206</sup> See 2017 SPECIAL REPORT, supra note 205, at 42 (2017), https://ustr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.P DF [https://perma.cc/EVN5-TA3Q] (stating that overly-broad exceptions for certain uses have raised concerns about the strength of copyright protection).

Photocopy Services & Anr, the Delhi High Court ruled that the preparation of course packs<sup>207</sup> did not constitute infringement of copyright of those books as long as the inclusion of the text photocopied (irrespective of the quantity) was used solely for educational purposes.<sup>208</sup> The suit (which was subsequently withdrawn) was filed by three publishers (Oxford, Cambridge, and Taylor & Francis) against a photocopy shop named Rameshwari Photocopy Service located on the premises of Delhi University.<sup>209</sup> The publishers alleged that the photocopy shop was illegally photocopying and selling substantial excerpts from their books that were part of the prescribed syllabus as course packs and thereby infringing their copyright in their works under Sections 51 and 14 of the Indian Copyright Act, 1957.<sup>210</sup> On September 16, 2016, Justice Rajiv Sahai Endlaw of the Delhi High Court dismissed the entire suit of the plaintiffs on grounds that purported actions of the defendants (the photocopy shop) did not amount to copyright infringement under Section 52(1)(i) of the Indian Copyright Act, 1957 which provides that any reproduction of a copyrighted work by a teacher or pupil in the course of educational instruction does not constitute copyright infringement.<sup>211</sup> This decision caused an uproar amongst American publishers, resulting in India remaining

<sup>207</sup> For example, compilation of photocopies of the relevant portions of different text books prescribed in the syllabus, and their distribution to students by educational institutions.

Chancellor, Masters & Scholars of the University of Oxford & Ors. v. Rameshwari Photocopy Services & Anr, Unreported Judgments 2016, 16 [hereinafter DU Photocopy Case]. For more on the DU Photocopy case, see *Chancellor, Masters & Scholars of the Univ. of Oxford & Ors. v. Rameshwari Photocopy Servs. & Ors.*, SPICYIP, https://spicyip.com/resources-links/du-photocopy-case [https://perma.cc/7YKY-R9EP]; V.N. Muralidharan, *Educational Institutions and Copyright Laws*, 22 J. OF INTELL. PROP. RTS. 266 (2016); *see also* Lawrence Liang, *A Blow for the Right to Knowledge*, HINDU (Sept. 19, 2016), http://www.thehindu.com/opinion/lead/A-blow-for-the-right-to-knowledge/article14987252.ece [https://perma.cc/B6BZ-NFZY]; *Copyright and Copymaking*, HINDU (Sept. 21, 2016), http://www.thehindu.com/opinion/editorial/Copyright-and-copy-making/article14990268.ece [https://perma.cc/4Z36-G8G2]; *see also* Prasang Shukla, *DU Photocopy Case: Fair Dealing or Raw Dealing?*, IP OSGOODE (Nov. 14, 2016), https://www.iposgoode.ca/2016/11/du-photocopy-case-fair-dealing-or-raw-dealing/ [https://perma.cc/DQ2Q-KNSQ].

<sup>209</sup> DU Photocopy Case, supra note 208, at 1.

<sup>210</sup> See The Chancellor, Masters & Scholars of the Scholars of the University of Oxford & Ors. v. Rameshwari Photocopy Services & Ors., supra note 208.

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on the USTR's 2017 "Special 301 Report" priority watch list. 212

### 2. Lack of Optical Disc Law

Since 2005, USTR has lashed out against India for lack of an optical disc law.<sup>213</sup> Unfortunately, there is no optical disc piracy law to date even though a draft optical disc law, which was drafted in consultation with the disc-manufacturing companies and the Federation of Indian Chamber of Commerce (FICCI), has been pending before the Ministry of Information and Broadcasting (MIB) since 2007.<sup>214</sup> The legislation was proposed by the music industry due to rampant optical disc piracy.<sup>215</sup> However, at the time, MIB had rejected the idea on the grounds that more work needed to be done on the supply side by releasing the films on digital platforms such as simultaneous releases in theatres, on disks, and online.<sup>216</sup> Hopefully in the near future India will enact an optical disc piracy law which will not only boost investment in India's media and entertainment industry but also will spare it of the needless ignominy by the USTR.<sup>217</sup>

<sup>212 2017</sup> SPECIAL REPORT, supra note 205, at 49.

<sup>213</sup> See Off. of the U.S. Trade Representative, 2005 Special 301 Report 2 (2005).

<sup>214</sup> See Ashish Sinha & Meera Vankipuram, Optical Disc Law Proposed, Bus. STANDARD (Feb. 5, 2013), https://www.business-standard.com/article/economypolicy/optical-disc-law-proposed-107033001003 1.html [https://perma.cc/D7RS-DLQC]; see Presley Thomas, IMI Demands New Act to Fight Music Piracy, HINDUSTAN TIMES (Jan. 20, 2007), https://www.hindustantimes.com/india/imi-demands-new-act-tofight-music-piracy/story-wVAe9nXQmsygVF8K7FgRSO.html [https://perma.cc/665N-SPWZ]. Even a 2008 research report titled, "The Effects of Piracy and Counterfeiting on India's Entertainment Industry" had noted an urgent need for the adoption of an optical disc law. See Neelam Verjee, Indian Piracy Industry Packs a \$4 Bn Punch, LIVEMINT 2008), https://www.livemint.com/Home-Page/fK0Vy2kErBH96TaNJR2ijM/Indian-piracy-industry-packs-a-4-bn-punch.html [https://perma.cc/CJ2F-Q7AU]. For more on Optical Disc Law of India, see SLIDESHARE, https://www.slideshare.net/altacitglobal/optical-disc-law-of-india [https://perma.cc/T4HW-63G8].

<sup>215</sup> See id.

<sup>216</sup> Lawrence Liang & Ravi Sundaram, *India*, *in* MEDIA PIRACY IN EMERGING ECONOMIES 374 (Joe Karaganis ed., 2011); *see also* Nikhil Pahwa, *@FICCI Frames: Asha Swarup, Secretary Ministry of I&B on Mobile TV, Copyright and Optical Disk Law*, GIGAOM (Mar. 25, 2008), https://gigaom.com/2008/03/25/419-ficci-frames-asha-swarup-secretary-ministry-of-ib-on-mobile-tv-copyrigh/ [https://perma.cc/QPP6-VFME].

<sup>217</sup> THE INDIAN ENTERTAINMENT AND MEDIA INDUSTRY: UNRAVELLING THE POTENTIAL 15 (2006), https://www.pwc.in/assets/pdfs/ficci-pwc-indian-entertainment-and-media-industry.pdf [https://perma.cc/9GPY-PPBP].

#### 3. Non-Accession to the WIPO Internet Treaties

Since 2003, the USTR has criticized India for not ratifying to the WIPO Internet Treaties (the Treaties).<sup>218</sup> The Treaties were adopted by the WIPO member states in 1996 in order to set international norms for preventing unauthorized access to and use of creative works on the internet or other digital networks.<sup>219</sup> The Indian Copyright Act of 1957 was amended in 2012 to comply with the Treaties, however India did not accede to these treaties until recently.<sup>220</sup> It was only on July 4, 2018, that the Union Cabinet chaired by Prime Minister Modi approved India's accession to the WIPO Internet Treaties.<sup>221</sup> This six-year delay from the enactment of the Copyright Amendment Act in 2012 and the Union Cabinet's decision to accede to the Treaties is inexplicable especially because as far as back in 2008, the Copyright Law Division of WIPO had persuaded India to accede to the Treaties for its own benefit.<sup>222</sup> Further, an independent study commissioned by WIPO on the state of the audiovisual industry in selected African countries concluded, in the specific context of Kenya, that acceding to the Treaties had the potential to boost Kenya's domestic audiovisual industry.<sup>223</sup> It would seem that this study would have allayed the concerns of the

http://www.wipo.int/copyright/en/activities/internet\_treaties.html [https://perma.cc/ZGK8-RZM8].

 <sup>218</sup> OFF. OF U.S. TRADE REP., 2003 SPECIAL 301 REPORT 13–14 (2003).
 219 See WIPO Internet Treaties, WIPO,

<sup>220</sup> See Devika Agarwal & Radhika Agarwal, Needless Pressure to Change Copyright Laws, HINDU BUS. LINE (May 4, 2016), https://www.thehindubusinessline.com/opinion/needless-pressure-to-change-copyright-laws/article8557036.ece [https://perma.cc/9VL9-AV7K] (stating that one of the possible reasons for the lack of accession is that the anti-circumvention provisions under Section 65 A of the Copyright (Amendment) Act, 2012 do not comply with Article 11 of the WIPO Copyright Treaty).

Press Release, Gov't of India, Cabinet Approves Accession to WIPO Copyright Treaty, 1996 and WIPO Performance and Phonograms Treaty, 1996 (July 4, 2018), http://pib.nic.in/newsite/PrintRelease.aspx?relid=180389 [perma.cc/N76T-4XTJ].

*WIPO Calls on India to Sign Internet Treaties on Copyright*, ECON. TIMES (Jul. 15, 2008), https://economictimes.indiatimes.com/tech/internet/wipo-calls-on-india-to-sign-internet-treaties-on-copyright/articleshow/3237397.cms [https://perma.cc/W293-D2B9].

Tarja Koskinen-Olsson, World Intell. Prop. Assoc., Study on Collective Negotiation of Rights and Collective Management of Rights in the Audiovisual Sector 28 (2014), http://www.wipo.int/edocs/mdocs/mdocs/en/cdip\_14/cdip\_14\_inf\_2.pdf [perma.cc/QX9T-PXX6].

Indian government and the civil society about the unsuitability of the Treaties for developing countries such as India.<sup>224</sup> Nevertheless, India's position in the international copyright community is very different from other developing countries, a fact conceded by none other than Jagdish Sagar, India's chief negotiator for the copyright provisions of the TRIPS Agreement. In a leading memoir on the negotiating history of the TRIPS agreement, without mincing any words on India's incompatible position on international copyright issues, Sagar stated, "[w]hatever the politics of our relationship with other developing countries in regard to other and broader issues, we did not then, and certainly do not now, have common interests with many of them in the sphere of copyright."225 Therefore, even assuming that there is some merit in the argument that the Treaties are ill-suited for developing countries, that argument holds little ground for India. In 2002 when the Treaties entered into force, India's internet penetration rate stood at an abysmal 1.5\%.<sup>226</sup> However, as of 2016, 34.8% of India's population has access to digital networks.<sup>227</sup> Therefore, technological backwardness as a reason for not acceding to the Treaties becomes irrelevant.<sup>228</sup> Finally, one of the avowed benefits of acceding to the Treaties is that it allows domestic creators to compete on a fair level.<sup>229</sup> It is likely that for these reasons that India has finally decided to accede to the Treaties, and it is hoped that USTR will applaud India for this change in the next special 301 report.

<sup>224</sup> See Arul George Scaria & Anubha Sinha, RCEP IP Chapter: A Serious Threat to Access to Knowledge/Cultural Goods?, LIVE LAW (July 27, 2017), http://www.livelaw.in/rcep-ip-chapter-serious-threat-access-knowledge-cultural-goods/[perma.cc/GFZ9-S43F].

<sup>225</sup> Jagdish Sagar, Copyright: An Indian Perspective, in The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations 342 (Jayashree Watal & Antony Taubman eds., 2015); see also Arpan Banerjee, Copyright Piracy and the Indian Film Industry: A "Realist" Assessment, 34 Cardozo Arts & Ent. L.J. 609, 640 (2016).

<sup>226</sup> India Internet Users, INTERNET LIVE STATS, http://www.internetlivestats.com/internet-users/india/ [perma.cc/Z3YS-46US].

<sup>227</sup> Id.

<sup>228</sup> See Banerjee, supra note 225, at 640.

WORLD INTELL. PROP. ORG., THE ADVANTAGES OF ADHERENCE TO THE WIPO COPYRIGHT TREATY (WCT) AND THE WIPO PERFORMANCES AND PHONOGRAMS TREATY 4, http://www.wipo.int/export/sites/www/copyright/en/activities/pdf/advantages\_wct\_wppt. pdf [https://perma.cc/28DE-LWES].

#### C. Trademark and Trade Secret Related Issues

 Non-Ratification of Singapore Treaty on the Law of Trademarks

Since 2016, USTR has urged India to accede to the Singapore Treaty on the Law of Trademarks (the Singapore Treaty) which sets out a multilateral framework for the registration of non-traditional trademarks.<sup>230</sup> The main objective of the Singapore Treaty (the Treaty) is to create a dynamic international framework for the harmonization of administrative trademark registration procedures. It is based on the Trademark Law Treaty of 1994 (TLT 1994), but is much wider in scope and addresses more recent developments in the field of communication technologies. Among other things, the Treaty settles the longstanding question of whether threedimensional marks are protectable—an outstanding issue under Article 15.1 of the TRIPS Agreement.<sup>231</sup> There are primarily five differences between the TLT 1994 and the Treaty. First, TLT 1994 covers only visible two-dimensional marks (with limited coverage for three-dimensional marks) while the Singapore Treaty covers all forms of marks, including holograms, motion marks, and nonvisible (audible and olfactory) marks.<sup>232</sup> Second, the Treaty revises the rules governing communications made by mark holders, applicants, or other interested persons to the trademark offices with which those interested persons must work. Third, the Treaty provides appropriate relief measures when an interested party fails to comply with certain time limits such as the date of filing and opposition.<sup>233</sup> Fourth, the Treaty includes guidelines governing official recording of trademark licenses.<sup>234</sup> Last, the Treaty created a Trademark Law Treaty Assembly within WIPO to oversee future

<sup>230</sup> OFF. OF THE U.S. TRADE REPRESENTATIVE, 2016 SPECIAL 301 REPORT 39 (2016), https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf [https://perma.cc/5P8T-Y8M7].

Marrakesh Agreement Establishing the World Trade Organization annex 1C, Apr. 15, 1994, 1867 U.N.T.S. 154, https://treaties.un.org/doc/Publication/UNTS/Volume%201867/volume-1867-A-31874-English.pdf [https://perma.cc/FM9Y-KE4H].

<sup>232</sup> Trademark Law Treaty art. 2(1)(a), Oct. 27, 1994, 112 Stat. 3064, 2037 U.N.T.S. 35, https://www.congress.gov/105/plaws/publ330/PLAW-105publ330.pdf [https://perma.cc/DEC6-D6Y2].

<sup>233</sup> Id. at art. 14.

<sup>234</sup> Id. at art. 17-20.

changes to the Treaty and to issue new accompanying regulations or to modify those already in place.<sup>235</sup> Even though scholars have opined that the Treaty may have fallen short of its objectives towards a greater harmonization on the law of non-traditional trademarks, it may be worthwhile for India to accede.<sup>236</sup> However, any such decision should be backed by a systematic empirical study, which has not yet been undertaken.

## 2. Inadequate Trade Secret Protection

Since 2014, the USTR has expressed concerns over India's ineffective trade secret protection regime.<sup>237</sup> The primary reason for these concerns is that India is one of the few countries in the world that does not provide for specific statutory protection for trade secrets.<sup>238</sup> There is no statutory definition whatsoever of "trade secrets" in India. However, it has been defined by the Bombay and the Delhi High Court. In Bombay Dyeing and Manufacturing Co. Ltd. v. Mehar Karan Singh, the Bombay High Court cited the definition of trade secret from Black Law's Dictionary which defines is it as a formula, process, device or other business information that is kept confidential to maintain an advantage over the competitors.<sup>239</sup> On the other hand, the Delhi High Court in American Express Bank Ltd. v. Priya Puri has laid down its own definition of trade secret. It has defined trade secret as a formula, technical know-how or a method of business adopted by an employer which is unknown to others and that has reasonable impact on organizational expansion and economic interests.<sup>240</sup> Therefore, at present trade secret law is a judiciary-made law which relies upon its British common law tradition of tort and contract

<sup>235</sup> *Id.* at art. 23.

<sup>236</sup> Samay Gheewala, Singapore Sling: WIPO Passes the Buck on Meaningful Reform of International Trademark Law, 17 DEPAUL-LCA J. ART. & ENT. L. 305, 329 (2007).

OFF. OF THE U.S. TRADE REPRESENTATIVE, 2014 SPECIAL 301 REPORT 42 (2014), https://ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to %20Congress%20FINAL.pdf [https://perma.cc/D452-YWQP] (stating that the U.S. was increasingly concerned about trade secret protection in India especially the reported difficulty in obtaining remedies and damages).

<sup>238</sup> Brandon Kinnard, Keep It Secret; Keep It Safe: A Practitioner's Guide to the "BRIC" Trade Secret Regimes, 3 Am. U. Bus. L. Rev. 503, 509 (2014).

<sup>239</sup> Trade Secret, BLACK'S LAW DICTIONARY (10th ed. 2014).

<sup>&</sup>lt;sup>240</sup> American Express Bank Ltd. v. Priya Puri, 2006 Indian Dec. 362 (Del.).

law.<sup>241</sup> For example, an employee is obligated towards his or her employer with respect to confidential information accessed during the course of employment. This is reflected in a GATT discussion paper presented by India on trade secret protection where it expounds its rationale for granting contractual rather than IP protection to trade secrets. The paper states trade secrets are not IP because the fundamental basis of IP rests upon its disclosure, publication, and registration while trade secrets are premised upon secrecy and confidentiality.<sup>242</sup> Therefore, contractual obligations and other appropriate civil law should govern its protection and enforcement. However, it has been found that enforcement of contractual terms has separate limitations in practice. An employee accused of breach of contract can question whether the divulged information or the data was even confidential in the first place, and if the confidentiality of the information is not established, then no breach can be proved. All this makes the enforcement of trade secrets cumbersome. It is because of this that the USTR and certain other countries have expressed concerns over India's trade secret protection regime. The Indian Government has perhaps realized that the absence of trade secret legislation is hampering foreign investment into India. Therefore, in 2008, for the first time, the Department of Science and Technology proposed a draft trade secret legislation known as the National Innovation Act, 2008, which contains many provisions on trade secret protection. To date, this draft legislation has not been enacted into law by the Indian parliament. With the release of the National IPR Policy, it is hoped that India will undertake more robust efforts to enact trade secret protection legislation on a priority basis.<sup>243</sup>

#### V. India and 2019 Special 301 Report

The National IPR Policy was meant to end the long-standing discord between India and the U.S. on the issue of intellectual

<sup>241</sup> Id.

<sup>&</sup>lt;sup>242</sup> Written Submission of India, *Standards and Principles Concerning the Availability, Scope, and use of Trade-Related Intellectual Property Rights*, 18 MTN.GNG/NG11/W/37 (July 10, 1989),

https://www.wto.org/gatt\_docs/English/SULPDF/92070115.pdf [https://perma.cc/5NRJ-JZS2].

<sup>243</sup> See Gov't of India, National Intell. Prop. Rts. Pol'y 10 (2016), http://dipp.nic.in/sites/default/files/National\_IPR\_Policy\_English.pdf [https://perma.cc/82DR-YA7T].

property rights. The 2018 Special Report indicates the prevailing sentiment in Washington D.C. with respect to India's IP regime is still cautionary pessimism as the USTR continues to consider India to be one of the most challenging economies as far as IP is concerned.<sup>244</sup> One of the reasons for this sentiment is the National IPR Policy's failure to outline specific reforms required to be undertaken for harnessing India's innovative and creative potential.<sup>245</sup> For example, the National IPR Policy states that India will consider acceding to some international IP treaties which are beneficial to it but does not propose any concrete metrics to gauge which treaties are actually beneficial for India.<sup>246</sup> Similarly, the National IPR Policy speaks about expedited examination of patent applications but is absolutely silent about its implementation.<sup>247</sup> Whether a mere legislative attempt in the form of the Patent (Amendment) Rules 2016 will actually expedite the patent examination process is yet to be seen. Regardless, the National IPR Policy is a laudable initiative and a stepping stone towards assuaging U.S. concerns over India's IP regime.

In early 1999, USTR removed Hong Kong as a watch list country when it undertook substantial efforts to improve its IP regime.<sup>248</sup> USTR first placed Hong Kong as a watch list country in April 1997 because of rampant copyright piracy in the SAR region which "had worsened over the past year, despite requests from the US Government for action." Even in the 1997 Special 301 Report, USTR requested the Government of Hong Kong to act

<sup>&</sup>lt;sup>244</sup> 2018 Special 301 Report, *supra* note 7.

<sup>245</sup> See Prabha Raghavan & Divya Rajagopal, IPR Policy Lacks Specifics, Won't be Enough to Foster Innovation: Lobby Groups, ECON. TIMES (May 16, 2016), https://economictimes.indiatimes.com/news/economy/policy/ipr-policy-lacks-specifics-wont-be-enough-to-foster-innovation-lobby-groups/articleshow/52285393.cms [https://perma.cc/U87D-V22J]

<sup>246</sup> See National Intellectual Property Rights Policy, supra note 243, at 9.

 $_{247}$  For more on expedited examination of patent applications, see *supra* Part IV(A)(5).

OFF. OF THE UNITED STATES TRADE REPRESENTATIVE, 1999 SPECIAL 301 REPORT, (1999), https://ustr.gov/sites/default/files/1999%20Special%20301%20Report.pdf [https://perma.cc/3Z3U-G6GX] (stating that as a result of the decisive steps taken by Hong Kong in 1998, USTR removed Hong Kong from the Watch List during a February 1999 out-of-cycle review).

OFF. OF THE UNITED STATES TRADE REPRESENTATIVE, 1997 SPECIAL 301 REPORT, 13 (1997), https://ustr.gov/sites/default/files/1997%20Special%20301%20Report.pdf [https://perma.cc/9VTC-62SA].

decisively against copyright piracy, which it ultimately did by enacting an anti-piracy legislation in late 1997. The new anti-piracy legislation required licensing and inspection of CD production sites and licensing of import and export of machinery and equipment used for production of compact discs, video compact discs, or CD-ROMs. It is because of these decisive steps that USTR removed Hong Kong from the watch list during a February 1999 out-of-cycle review even though Hong Kong had not fully addressed the situation.<sup>250</sup> Hong Kong's case study is important as it serves as precedent for USTR to reconsider India's designation as a priority watch list country in the next cycle of the Special 301 Report. If USTR could altogether remove Hong Kong from the Special 301 Report despite Hong Kong's IP regime being far from perfect, it can certainly consider upgrading India from a priority watch list to a watch list country since India has made significant improvements to its IP regime with the release of the National IPR Policy. Perhaps, USTR can designate India as a watch list country in the next Special 301 report with periodic monitoring of its IP regime in the form of an out-of-cycle review. Of course, this is not to say that India's IP regime is perfect. There is much room for improvement in areas such as administrative issues related to processing of patent and trademark applications, trade secret protection regime, acceding to the Singapore Treaty, curbing copyright piracy, and enactment of camcording legislation. India should strive to improve its IP regime specifically in these areas, steps which would go a long way in causing its status to be upgraded from a priority watch list to a watch list country.

#### **VI. Conclusion**

The U.S.-India relationship is not a relationship between two governments, but a relationship between two economies and societies, based on common values of diversity, human rights, equality, the rule of law, and the peaceful resolution of disputes.<sup>251</sup> In the wider scheme of bilateral relations between the two countries, intellectual property is a minor issue, and should not come in the

<sup>250 1999</sup> SPECIAL 301 REPORT, supra note 248, at 2.

<sup>251</sup> Stephen P. Cohen, *More Than Just the 123 Agreement: The Future of U.S.-India Relations*, BROOKINGS (June 25, 2008), https://www.brookings.edu/testimonies/more-than-just-the-123-agreement-the-future-of-u-s-india-relations/ [https://perma.cc/FDX2-VZGQ].

way of an otherwise amicable relationship. As enduring partners of the 21st century, India and the United States should strive to look past short-term differences such as intellectual property in order to build long-term partnership based on peace, prosperity, and democracy in the world. Upgrading India from a priority watch list to a watch list country in the 2019 Special 301 Report would give India a sense of relief, which in turn would pave the way for a solid long-term partnership between the two countries.

## VII. Annexure A

TABLE 2: LIST OF PhRMA's ACCUSATIONS BY YEAR

Year	PhRMA's accusations	Special 301 Report
2018	Intellectual Property Protection	Intellectual
	Restrictive patentability criteria	Property Protection
	under Section 3(d) of the Indian Patent Act,	Restrictive
	1970	patentability criteria under
	Absence of regulatory data	Section 3(d) of the Indian
	protection	Patent Act, 1970
	Weak patent enforcement.	Absence of
	Unpredictable compulsory	regulatory data protection
	licensing regime	Weak IP
	Unpredictable IP environment	enforcement
	that posed procedural and substantive	Potential threat
	barriers at every step of the patent process	of compulsory licensing
	Administrative burdens such as	
	patent examination backlogs and	
	burdensome application procedures	
	Market Access Barriers	
	High tariffs and taxes on	
	medicines ranging from 10-20%	
	Discriminatory and non-	
	transparent market access policies which	
	hindered further investment	
	Unpredictable environment for	
	clinical research which undermined the	
	availability of new treatments and vaccines	
	for Indian patients	
	General lack of access to	
	healthcare	
	Discriminatory and non-	
	transparent pharmaceutical pricing policies	
	Unpredictable environment for	
	clinical research and drug approval	

2017	Intellectual Property Protection	Intellectual
	Unpredictable IP environment	Property Protection
	that posed procedural and substantive	Unpredictable IP
	barriers at every step of the patent process	environment having an
	Restrictive patentability criteria	effect on innovative
	under Section 3(d) of the Indian Patent Act,	industries
	1970	Restrictive
	Regulatory data protection	patentability criteria under Section 3(d) of the Indian
	failures leading to unfair commercial use and hindering development of new	Patent Act, 1970
	and hindering development of new medicines that could meet unmet medical	Lack of
	needs	regulatory data protection
	Weak patent enforcement	Overall weak
	Unpredictable compulsory	levels of IP enforcement
	licensing regime	Threat of
	Administrative burdens such as	compulsory licenses
	patent examination backlogs and	Administrative
	burdensome application procedures	burdens such as costly and
	Market Access Barriers	time-consuming patent
	High tariffs and taxes on	opposition hurdles, long timelines for receiving
	medicines ranging from 10-20%.	patents, and excessive
	Discriminatory and non-	reporting requirements
	transparent market access policies which hindered further investment.	Absence of
		protection against unfair
	Unpredictable environment for clinical research which undermined the	commercial use
	availability of new treatments and vaccines	Unauthorized
	for Indian patients.	disclosure, of undisclosed
	Tor metali pations.	test or other data generated
		to obtain marketing
		approval for such products
		Lack of effective
		system for notifying
		interested parties for
		marketing approvals
		Onerous
		localization requirements
		Market Access
		Barriers
		None

2016	Intellectual Property Protection	Intellectual
	Generally weak IP environment	Property Protection
	Regulatory data protection	Generally weak
	failures leading to unfair commercial use	IP environment
	and hindering development of new	Regulatory data
	medicines that could meet unmet medical	protection failures
	needs	Unpredictable
	Restrictive patentability criteria	patentability standards
	under Section 3(d) of the Indian Patent Act,	under Section 3(d) of the
	1970	Indian Patent Act, 1970
	Weak patent enforcement	Weak patent
	Unpredictable compulsory	enforcement in the form of
	licensing regime	difficulty in securing
	Administrative burdens such as	injunctions and marketing
	unduly burdensome patent application	approval for
	procedures	pharmaceutical drugs
	Market Access Barriers	Unpredictable
	High tariffs and taxes on	compulsory licensing
	medicines ranging from 10-20%	regime
	Discriminatory and non-	Administrative
	transparent market access policies	burdens such as patent
	Burdensome environment for	application backlog
	clinical research.	Ineffective
		system for protecting
		against unfair commercial
		use
		Onerous
		localization requirements
		Lack of
		transparency in Computer
		Related Inventions (CRI)
		guidelines
		Market Access
		Barriers
		None
2015	Intellectual Property Protection	Intellectual
2013	Lack of patent protection and	Property Protection
	enforcement	Lack of patent
	Lack of regulatory data protection	protection and
	Restrictive patentability criteria	enforcement
	under Section 3(d) of the Indian Patent Act,	Lack of
	1970.	regulatory data protection
	Unpredictable compulsory	Restrictive
	licensing regime	patentability criteria under
	Administrative burdens such as	Section 3(d) of the Indian
	unduly burdensome patent application	Patent Act, 1970
	procedures	Unpredictable
	Market Access Barriers	compulsory licensing
		regime
	Government price controls which fail to maintain transparency and	Administrative
	1 3	burdens such as inefficient
	predictability	caraciis sacii as incincient

	Uncertainty in the regulatory process for clinical trials	patent opposition procedures and patent application backlog
2014	Intellectual Property Protection	Intellectual
	Lack of regulatory data protection Abusive pre-grant and post-grant opposition proceedings Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Administrative burdens such as unduly burdensome patent application procedures Need for patent enforcement and regulatory approval Poor civil and criminal enforcement leading to rampant counterfeiting of medicines  Market Access Barriers Government price controls in the form of price discrimination High import duties for active ingredients and finished products Uncertainty in the regulatory process for clinical trials Unpredictable environment for foreign direct investment (FDI) in pharmaceutical sector	Property Protection Lack of regulatory data protection Ineffective patent opposition procedures Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Problematic patent enforcement such as coordination between state and central patent offices Forced localization requirements Unauthorized disclosure of undisclosed test or other data generated for seeking marketing approval for pharmaceutical products Market Access Barriers None
2013	Intellectual Property Protection Unpredictable compulsory licensing regime	Intellectual Property Protection Unpredictable compulsory licensing
	Lack of regulatory data protection.  Ineffective patent enforcement	regime  Lack of

	and regulatory approval process  Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970  Market Access Barriers  Government price controls in the form of price discrimination  Unpredictable environment for foreign direct investment (FDI) in pharmaceutical sector  High import duties for active ingredients and finished products  Poor civil and criminal enforcement leading to rampant counterfeiting of medicines	regulatory data protection Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Onerous localization requirement Administrative burdens such as inefficient patent opposition procedures and patent application backlog Market Access Barriers None
2012	Intellectual Property Protection Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Unpredictable compulsory licensing regime Lack of regulatory data protection Ineffective patent enforcement and regulatory approval process Administrative burdens such as backlog of unexamined patent applications Market Access Barriers Government price controls in the form of price discrimination Unpredictable environment for foreign direct investment (FDI) in pharmaceutical sector High import duties for active ingredients and finished products Poor civil and criminal enforcement leading to rampant counterfeiting of medicines	Intellectual Property Protection Administrative burdens such as patent opposition proceedings Ineffective patent enforcement in the form of coordination between state and central patent offices Ineffective system for protection against unfair commercial use or unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural products Judicial inefficiencies and weak criminal enforcement Market Access Barriers None
2011	Intellectual Property Protection Overall IP environment Lack of regulatory data protection Narrow patentability standards Ineffective patent enforcement and regulatory approval process Administrative burdens such as backlog of unexamined patent applications	Intellectual Property Protection Overall IP environment Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Administrative

	Unpredictable compulsory licensing regime  Market Access Barriers  Government price controls in the form of price discrimination  High import duties for active ingredients and finished products.  Poor civil and criminal enforcement leading to rampant counterfeiting of medicines	burdens such as patent application backlog and ineffective patent opposition proceedings Ineffective system for protection against unfair commercial use or unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural products Inefficient judicial proceedings Market Access Barriers None
2010	Intellectual Property Protection  Lack of regulatory data protection  Inadequate intellectual property protection in the form of narrow patentability criteria  Lack of patent linkage and growing backlog of patent applications at the Indian Patent Office.  Poor patent enforcement by courts.  Unpredictable compulsory licensing regime  Market Access Barriers  Government price controls in the form of price discrimination  High import duties for active ingredients and finished products  Poor civil and criminal enforcement leading to rampant counterfeiting of medicines	Intellectual Property Protection Narrow patentability standards Rampant piracy and counterfeiting of medicines Administrative burdens such as patent application backlog Ineffective system for protection against unfair commercial use or unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural products Inadequate legal framework and ineffective enforcement Market Access Barriers None
2009	Intellectual Property Protection  Lack of regulatory data protection  Absence of patent linkage with marketing approval  Administrative burdens such as backlog of unexamined patent applications	Intellectual Property Protection Weak patent enforcement Effective protection against unfair

and ineffective nature apposition	a commonaid use of
and ineffective patent oppositio	
proceedings	undisclosed test and other
Narrow patentability standards	data generated to obtain
Unpredictable compulsor	marketing approval for
licensing regime	pharmaceutical and
Rampant piracy an	agrochemical products
counterfeiting of pharmaceuticals	Rampant piracy
Market Access Barriers	and counterfeiting of
Government Price Controls in th	pharmaceuticals
form of price discrimination	Market Access
High import duties for activ	Barriers
ingredients and finished products	None

TABLE 3: LIST OF IIPA'S ACCUSATIONS BY YEAR

Year	IIPA's accusations	Special 301 Report
2018	Intellectual Property	Intellectual Property
	Lack of effective enforcement.	Lack of effective
	Absence of anti-camcording legislation	enforcement
	Non-accession to the WIPO	Absence of anti-
	Internet Treaties	camcording legislation
	Absence of statutory provisions	Non-accession to
	on circumvention of technological	the WIPO Internet Treaties
	protection measures	Absence of
	Signal theft and widespread use	statutory provisions on
	of illicit streaming devices	circumvention of
	Unauthorized book copying	technological protection
	Rampant retail piracy	measures
	Localization requirements and	
	per-channel fees	
	Market Access	
	Burdensome "must-provide"	
	rules in the pay-TV sector	
	Onerous regulations on uplink	
	and downlink of satellite signals beaming	
	into India	
	High tariffs on entertainment	
	software and hardware products	
	Impractical and outdated cinema	
	regulations	
2017	Intellectual Property	Intellectual Property
	Absence of anti-camcording	Absence of anti-
	legislation	camcording legislation
	Non-accession to the WIPO	Non-accession to
	Internet Treaties	WIPO Internet Treaties
	Rampant retail piracy	Rampant online
	Signal theft and widespread use	copyright piracy
	of illicit streaming devices	Widespread use
	Absence of statutory provisions	of illicit streaming devices
	on circumvention of technological	Absence of

protection measures statutory provisions on circumvention Unauthorized book copying of technological protection Poor enforcement measures Market Access Non-existence of Burdensome "must-provide" copyright royalty board and rules in the pay-TV sector Intellectual Property Harmful compulsory and Appellate Board statutory remuneration schemes Underreporting High tariffs on video game of cable subscriptions software and hardware Problematic Non-implementation of new copyright royalty regime Goods and Services Tax (GST) rules Non-existence of copyright royalty board and Intellectual Property Appellate Board 2016 **Intellectual Property Intellectual Property** Non-accession to the WIPO Non-accession to Internet Treaties the WIPO Internet Treaties Unauthorized Unauthorized camcording Rampant retail piracy including camcording mobile device piracy Rampant online copyright piracy Absence of statutory provisions circumvention of technological Inadequate statutory damages protection measures Lack of standard operating procedures among states hampering the rights of copyright owners Dismissal of civil claims by courts which deterred copyright owners from initiating cases Complex, time-consuming, and expensive court procedures and other court grievances such as overburdened courts and clogged dockets Unauthorized use of books which continued to plague publishers Signal theft by cable operators which violated the interest of the audiovisual industry Market Access Burdensome "must-provide" rules in the pay-TV sector Harmful compulsory and statutory remuneration schemes High tariffs on video game software and hardware

Non-implementation of new

Goods and Services Tax (GST) rules

2015	Intellectual Property	Intellectual Property
	Absence of anti-camcording legislation  Rampant signal theft by cable operators which violated the interest of the audiovisual industry  Rampant retail piracy including mobile device piracy  Lack of standard operating procedures among states which hampered the rights of copyright owners  Complex, time-consuming, and expensive court procedures and other court grievances such as overburdened courts and clogged dockets  Unauthorized use of books which continued to plague publishers	Absence of anti- camcording legislation Signal theft Rampant online copyright piracy Absence of statutory provisions on circumvention of technological protection measures Inadequate statutory damages
2014	Intellectual Property  Absence of anti-camcording legislation  Signal theft by cable operators which violated the interest of the audiovisual industry  Rampant retail piracy  Absence of statutory provisions on circumvention of technological protection measures  Unauthorized book copying  Lack of standard operating procedures among states which hampered the rights of copyright owners  Complex, time-consuming, and expensive court procedures and other court grievances such as overburdened courts and clogged dockets	Intellectual Property Absence of anti- camcording legislation Rampant signal theft Rampant online copyright piracy Absence of statutory provisions on circumvention of technological protection measures
2013	Intellectual Property Absence of anti-camcording legislation Retail piracy such as book, internet, and mobile device piracy Signal theft by cable operators which violated the interest of the audiovisual industry Absence of statutory provisions on circumvention of technological protection measures Poor enforcement Inadequate protection for online infringement and ISP responsibility under	Intellectual Property Absence of anti- camcording legislation Rampant online copyright piracy Rampant signal theft Absence of statutory provisions on circumvention of technological protection measures

	the Indian Copyright Act, 1957	
	Market access barriers for the	
	motion picture industry in the form of high	
	services and discriminatory entertainment	
	taxes	
	High tariffs on entertainment	
	software products	
	Double taxation of business	
	software	
	Technology mandates or tech	
	transfer mandates	
2012	Intellectual Property	Intellectual Property
	Internet and mobile device piracy	Rampant online
	Retail piracy and circumvention	copyright piracy
	of TPMs	
	2	
	performance piracy	
	Unauthorized Camcording	
	Pirate printing and photocopying	
	of books and journals	
	Inadequate protection for online	
	infringement and ISP responsibility under	
	the Indian Copyright Act, 1957	
	Extension to foreign works of,	
	and addition of new, compulsory licenses	
	Overly Broad Exceptions	
	Market access barriers for the	
	motion picture industry in the form of high	
	services and discriminatory entertainment	
	taxes	
2011	Intellectual Property	Intellectual Property
2011	Non-accession to WIPO Internet	Non-accession to
	Treaties.	WIPO Internet Treaties
		· · · · · · ·
	Rampant retail piracy	Rampant online
	Corporate end-user piracy of	copyright piracy
	business software	Widespread
	Unauthorized camcording	optical disc piracy
	Pirate printing and photocopying	
	of books and journals	
	Internet and mobile device piracy	
	Signal theft and public	
	performance piracy	
	Ineffective enforcement by	
	courts to curtail piracy	
	Lax enforcement at border	
	Inadequate protection for online	
	infringement and ISP responsibility under	
	the Indian Copyright Act, 1957	
2010	7 ( 11 ) 17	T . 11 . 15
2010	Intellectual Property	Intellectual Property

	Non-accession to WIPO Internet	Non-accession to
	Treaties	WIPO Internet Treaties
	Piracy of various types such as	Rampant optical
	optical disc piracy, retail piracy, corporate	disc piracy
	end-user piracy of business software,	Inadequate legal
	internet, and mobile device piracy	framework and ineffective
	Signal theft and public	enforcement
	performance piracy	
2009	Piracy of various types such as	Rampant optical
	optical disc piracy, retail piracy, corporate	disc piracy
	end-user piracy of business software,	Non-accession to
	internet, and mobile device piracy	WIPO Internet Treaties

TABLE 4: LIST OF GIPC's ACCUSATIONS BY YEAR

Year	GIPC's Accusations	Special 301 Report
2018	Patent-Related Concerns	Patent-Related
	Restrictive patentability criteria	Concerns
	under Section 3(d) of Indian Patent Act,	Restrictive
	1970	patentability criteria under
	Unpredictable compulsory	Section 3 (d) of Indian
	licensing regime	Patent Act, 1970
	Lengthy patent opposition	Potential threat
	proceedings	of compulsory licensing
	Absence of regulatory data	Lengthy patent
	protection	opposition proceedings
	Ambiguous Computer Related	Absence of
	Inventions (CRI) guidelines	regulatory data protection
	Absence of patent term	Copyright-Related
	restoration	Concerns
	Copyright-Related Concerns	Absence of
	Absence of statutory provisions	statutory provisions on
	on circumvention of technological	circumvention of
	protection measures	technological protection
	Absence of anti-camcording	measures
	legislation	Absence of anti-
	Non-accession to the WIPO	camcording legislation
	Internet Treaties	Non-accession to
	Lack of clarity on notice and	the WIPO Internet Treaties
	takedown provisions to combat online	Trademark-Related Concerns
	piracy	
	Broad limitations and exceptions	Non-accession to
	for personal use and for personal	the Singapore Treaty on the Law of Trademarks
	reproduction	Trade Secret-
	Inclusion of internet music	Related Concerns
	streaming services within the scope of	Ineffective trade
	broadcasting	secret protection regime
	Trademark-Related Concerns	secret protection regime
	Non-accession to the Singapore	
	Treaty on the Law of Trademarks	

	Lack of clarity on Trademark	
	Rules issued in May 2017	
	Trade Secret-Related Concerns	
	Ineffective trade secret protection	
	regime	
	Other Concerns	
	Non-compliance of security	
	testing requirements for ICT equipment	
	with global practices	
	Lack of effective enforcement	
	Market Access Concerns	
	Ineffective "must provide" rules	
	in the pay-TV sector and price caps for pay- TV channels	
	1 V Chamiers	
2017	Patent-Related Concerns	Patent-Related
2017	_	Concerns
	Restrictive patentability criteria under Section 3(d) of Indian Patent Act,	Restrictive
	1970	patentability criteria under
	Ineligibility of computer	Section 3(d) of Indian
	software to seek patents	Patent Act, 1970
	Unpredictable compulsory	Unpredictable
	licensing regime	Computer-Related
	Lengthy patent-opposition	Inventions (CRI)
	procedures	guidelines
	Absence of regulatory data	Unpredictable
	protection	compulsory licensing
	Onerous updates of counterpart	regime
	prosecution	Administrative
	Absence of patent term	burdens such as costly and time-consuming patent
	restoration for pharmaceutical products	time-consuming patent opposition hurdles, lengthy
	Lack of state-level patent	timeline for receiving
	enforcement	patents, and excessive
	Copyright-Related concerns	reporting requirements
	Unauthorized camcording	Lack of adequate
	Non-accession to the WIPO	and effective protection for
	Internet Treaties	regulatory test or other data
	Rampant online copyright piracy	submitted by
	Absence of statutory provisions on circumvention of technological	pharmaceutical and
	on circumvention of technological protection measures	agricultural chemical
	Absence of predictable copyright	producers
	royalty regime	Copyright-Related
	Broad limitations and exceptions	Absonos of onti
	to copyright	Absence of anti- camcording legislation
	Unpredictable notice and	Non-accession to
	takedown provisions	WIPO Internet Treaties
	Inadequate DRM provisions	Rampant online
	Non-compliance of statutory	copyright piracy
	licenses with Berne Convention and TRIPS	Absence of
	Trademark-Related Concerns	statutory provisions on

**Trademark-Related Concerns** 

statutory provisions

	Non-accession to Singapore Treaty on the Law of Trademarks Trade Secret-Related Concerns Ineffective trade secret protection regime Other Concerns Weak enforcement of IP rights at border by customs authorities Unpredictable regime for security testing requirements for ICT equipment Ineffective "must provide" rules in the pay-TV sector and price caps for pay-TV channels	circumvention technological protection measures  Problematic copyright royalty regime Overly broad limitations and exceptions Non-existence of copyright royalty board and Intellectual Property Appellate Board Underreporting of cable subscriptions Widespread use of illicit streaming devices Trademark-Related Concerns Non-accession to Singapore Treaty on the Law of Trademarks High levels of trademark counterfeiting Administrative burdens such as delay in obtaining trademarks and lengthy opposition and cancellation proceedings Trade Secret-Related Concerns Ineffective trade secret protection regime Other Concerns Overall level of weak IP enforcement Onerous localization requirements
2016	Patent-Related Concerns Restrictive patentability criteria under Section 3(d) of Indian Patent Act,	Patent-Related Concerns Restrictive
	Lack of predictability and	patentability criteria under Section 3(d) of Indian
	transparency related to Computer Related Inventions (CRI) guidelines	Patent Act, 1970 Unpredictable
	Absence of regulatory data protection	Computer-Related Inventions (CRI)
	Unpredictable compulsory	guidelines
	licensing regime Onerous updates of counterpart	Absence of regulatory data protection
	prosecution counterpart	Unpredictable
	Absence of patent term restoration for pharmaceutical products	compulsory licensing regime

	Onerous patent working	Copyright-Related
	requirement	Concerns
	Copyright-Related Concerns	Non-accession to
	Non-accession to the WIPO	WIPO Internet Treaties
	Internet Treaties	Lack of effective
	Unpredictable notice and	notice and takedown
	takedown provisions	provisions
	Inadequate DRM provisions  Trade Secret-Related Concerns	Trade Secret- Related Concerns
	Inadequate trade secret	Inadequate trade
	protection trade secret	secret protection
	Trademark-Related Concerns	Trademark-Related
	_	Concerns
	Non-accession to Singapore	Non-accession to
	Treaty on the Law of Trademarks	Singapore Treaty on the
		Law of Trademark
		Other Concerns
		Onerous
		localization requirements
		Ineffective
		protection against unfair
		commercial use
2015	N/A	Patent-Related
2013	IVA	Concerns
		Restrictive
		patentability criteria under
		Section 3(d) of Indian
		Patent Act, 1970
		Administrative
		burdens such as lengthy
		patent opposition
		procedures
		Unpredictable
		compulsory licensing
		regime
		Ineffective
		protection against unfair
		commercial use
		Trademark-Related
		Concerns
		Administrative
		burdens such as lengthy
		cancellation and opposition
		proceedings
		Trade Secrets-
		Related Concerns
		Inadequate trade
		secret protection
		Copyright-Related
		Concerns
		Absence of anti-
		camcording legislation

		Signal theft Absence of statutory provisions on circumvention of
		technological protection measures Rampant online
		copyright piracy Inadequate statutory damages
		Other Concerns Onerous localization requirements
2014	Patent-Related Concerns	Patent-Related
	Restrictive patentability criteria	Concerns
	under Section 3(d) of the Indian Patent Act,	Restrictive
	1970 Unpredictable compulsory licensing regime	patentability criteria under Section 3 (d) of the Indian Patent Act, 1970
	Absence of regulatory data	Unpredictable
	protection regulatory data	compulsory licensing
	Onerous local working	regime
	requirement	Absence of
	Copyright-Related Concerns	regulatory data protection
	Rampant online piracy	Onerous local
	Absence of anti-camcording legislation	working requirement Administrative
	Rampant piracy of movies in theatres and optical disc piracy	burdens such as lengthy patent opposition
	Broad limitations and exceptions to copyright	procedures and patent application backlog  Copyright-Related
	Weak enforcement Onerous tax burden for captive	Concerns  Rampant online
	development centers  Trade Secrets-Related Concerns	piracy  Absence of anti-
	Inadequate trade secret	camcording legislation
	protection regime	Rampant signal
	Other Concerns	theft
	Outlier position aimed at weakening IP protection at multilateral	Absence of
	forums such as UNFCCC, WTO and WIPO	statutory provisions on circumvention of
		technological protection
		measures
		Trade Secrets-
		Related Concerns
		Inadequate trade secret protection regime
		Other Concerns
		Outlier position
		aimed at weakening IP

		protection at multilateral forums such as UNFCCC, WTO and WIPO Onerous localization requirements
2013	Patent-Related Concerns	Patent-Related Concerns  Unpredictable compulsory licensing regime  Restrictive patentability criteria  Administrative burdens such as patent application backlog and lengthy patent opposition proceedings  Absence of regulatory data protection  Copyright-Related concerns  Absence of anti- camcording legislation  Rampant online copyright piracy  Rampant signal theft  Absence of statutory provisions on circumvention of technological protection measures  Other Concerns  Ineffective IP enforcement Onerous localization requirements
2012	Patent-Related Concerns Restrictive patentability criteria Unpredictable compulsory licensing regime Absence of regulatory data protection Lack of patent linkage Copyright-Related Concerns Non-accession to the WIPO Internet Treaties	Patent-Related Concerns Restrictive patentability criteria Unpredictable compulsory licensing regime Lack of effective protection for unfair commercial use of
	Broad limitations and exceptions to copyright	unauthorized disclosure, of test or other data generated to obtain marketing

	Unauthorized camcording  Trade Secret-Related Concerns  Inadequate trade secret protection regime	approval for pharmaceutical and agricultural chemical products  Administrative burdens such as lengthy patent opposition proceedings  Copyright-Related Concerns  Non-accession to the WIPO Internet Treaties  Other Concerns  Ineffective IP enforcement
2011	N/A	Patent-Related Concerns  Weak patent protection  Restrictive patentability criteria  Administrative burdens such as patent application backlog and lengthy patent opposition proceedings  Copyright-Related Concerns  Non-accession to WIPO Internet Treaties Rampant online copyright piracy Widespread optical disc piracy Trademark-Related concerns  Rampant trademark counterfeiting Other Concerns Inadequate protection for unfair commercial use

TABLE 5: LIST OF BIO's ACCUSATIONS BY YEAR

Year	BIO's Accusations	Special 301 Report
2018	Restrictive patentability criteria	Restrictive
	under Section 3(d) of the Indian Patent Act,	patentability criteria under
	1970	Section 3(d) of the Indian
	Onerous patent disclosure	Patent Act, 1970

		**
2017	requirement  Absence of regulatory data protection  Unpredictable compulsory licensing regime  Administrative burden and delays such as patent examination backlogs and lengthy patent opposition proceedings  Ineffective patent enforcement  Restrictive patentability criteria under Section 3(d) of the Indian Patent Act	Unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for such products
	under Section 3(d) of the Indian Patent Act, 1970  Onerous patent disclosure requirement  Unpredictable compulsory licensing provisions  Administrative burden and delays such as patent examination backlogs and lengthy patent opposition proceedings  Exclusion of patent protection for plants  Inadequate regulatory data protection  Ineffective patent enforcement	patentability criteria under Section 3(d) of the Indian Patent Act, 1970  Onerous patent disclosure requirement  Unpredictable compulsory licensing regime  Administrative burdens such as costly and time-consuming patent opposition hurdles, delay in processing patent applications and excessive reporting requirements  Onerous localization requirement
2016	Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970  Unpredictable compulsory licensing regime  Administrative burdens such as delay in processing applications, lengthy opposition procedures and administrative burdens related to first filing in India for inventions made by Indian residents  Exclusion of patent protection for plants  Curtailment of the rights of patent holders to conclude licensing agreements on their terms  Revocation of patents on outlier grounds	Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970  Unpredictable compulsory licensing regime  Administrative burdens such as long application backlog Onerous localization requirement Unpredictable guidelines on computer related inventions Ineffective protection against unfair

	Lack of consistent adherence to patent rules and procedures between the	commercial use
	regional patent offices	
	Onerous patent working	
	requirement  Failure to recognize or enforce	
	patents	
	Inadequate regulatory data	
	protection	
2015	Absence of patent linkage system  Restrictive patentability criteria	Restrictive
2013	under Section 3(d) of the Indian Patent Act,	patentability criteria under
	1970	Section 3(d) of the Indian
	Unpredictable compulsory	Patent Act, 1970
	licensing regime  Administrative burdens such as	Unpredictable compulsory licensing
	delay in processing applications and	regime
	lengthy opposition procedures	Administrative
	Onerous patent disclosure	burdens such as lengthy patent opposition
	requirement Onerous patent working	patent opposition procedures
	requirement patent working	Unauthorized
	Unreasonable disclosure of	disclosure of test or other
	source and geographic material requirement	data generated to obtain marketing approval
	Exclusion of patent protection for plants in generic terms	Onerous
	Failure to extend protection to	localization requirement
	crops under its plant variety protection law	Ineffective
	Revocation of patents on outlier	unfair commercial use
	grounds  Lack of consistency between	
	regional patent offices	
	Failure to recognize or enforce	
	patents	
	Absence of patent linkage system	
2014	Unpredictable compulsory	Unpredictable
	licensing regime	compulsory licensing
	Restrictive patentability criteria	regime
	under Section 3(d) of the Indian Patent Act, 1970	Restrictive patentability criteria under
	Administrative burdens such as	Section 3(d) of the Indian
	delay in processing applications, lengthy	Patent Act, 1970
	opposition procedures and administrative burden related to first filing in India for	Administrative
	inventions made by Indian residents	burdens such as lengthy patent opposition
	Lack of consistency between	procedures
	regional patent offices	Ineffective
	Outlier approach for granting	protection against unfair commercial use
	patents Onerous patent working	Unauthorized
L	Onerous patent working	

	requirement  Unreasonable disclosure of source and geographic material requirement  Failure to extend protection to crops under its plant variety protection law  Outlier approach adopted by Indian courts  Ineffective patent enforcement  Absence of patent linkage system	disclosure of undisclosed test or other data generated for seeking marketing approval for pharmaceutical products
2013	Administrative burdens such as delay in processing applications, lengthy opposition procedures and administrative burden related to first filing in India for inventions made by Indian residents  Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970  Unpredictable compulsory licensing regime  Revocation of patents on outlier grounds  Lack of consistency between regional patent offices  Absence of patent term extensions  Onerous patent working requirement  Unreasonable disclosure of source and geographic material requirement  Outlier approach adopted by Indian courts  Failure to recognize or enforce patents	Administrative burdens such as patent application backlog and lengthy opposition proceedings Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Unpredictable compulsory licensing regime Ineffective protection against unfair commercial use Onerous localization requirements
2012	Administrative burdens such as delay in processing applications, lengthy opposition procedures, and burden related to first filing in India for inventions made by Indian residents  Unpredictable compulsory licensing regime  Lack of consistency between regional patent offices  Absence of patent term extensions  Onerous patent working requirement  Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970	Administrative burdens such as patent application backlog and lengthy patent opposition proceedings

	Unreasonable disclosure of source and geographic material requirement Outlier approach adopted by Indian courts Failure to recognize or enforce patents Inadequate drug regulatory data protection	
2011	Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970  Administrative burdens such as delay in processing applications and lengthy opposition procedures  Lack of consistency between regional patent offices  Onerous patent working requirement  Outlier approach adopted by Indian courts  Failure to recognize or enforce patents  Unpredictable compulsory licensing regime	Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Administrative burdens such as patent application backlog and lengthy patent opposition proceedings Ineffective protection against unfair commercial use Unauthorized disclosure of undisclosed test and other data
2010	Administrative burdens such as delay in processing applications, lengthy opposition procedures, and limited capacity of Indian Patent Office to review and grant patent applications  Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970  Unreasonable restriction on the use of patent rights  Inadequate drug regulatory data protection	Administrative burdens such as patent application backlogs and lengthy patent opposition proceedings Ineffective protection against unfair commercial use Unauthorized disclosure of undisclosed test or other data
2009	Inadequate drug regulatory data protection  Exclusion of living organisms, such as transgenic plants and animals from patentable subject matter  Unreasonable restriction on the use of patent rights  Limited capacity of Indian Patent Office to review and grant patent applications  Inexperienced judiciary to tackle patent litigation cases	Unauthorized disclosure of undisclosed test or other data

implementing data exclusivity was identified	 No	transition	period	for	
	implementing identified	data exc	clusivity	was	

TABLE 6: LIST OF BSA's ACCUSATIONS BY YEAR

Year	BSA's Accusations	Special 301 Report
2018	Intellectual Property Onerous proposed data localization requirements Lack of statutory damages and inadequate damage awards Market Access Preference for local content and technology Proposed overly regulated approach to regulate cloud computing Need for new draft encryption policy Other Issues Procedural delays in court process	Intellectual Property Onerous data localization requirements
2017	Intellectual Property Inconsistent patentability guidelines for Computer Related Inventions (CRI) with international practices Lack of statutory damages and inadequate damages in civil suits Market Access Domestic preferences and technology mandates in public procurement limiting cross-border data flows Heterogeneous application of data and server localization requirements Lack of effective and uniform encryption policy Proposed overly regulated approach to regulate cloud computing Other Issues Ineffective enforcement against enterprises using unlicensed software	Intellectual Property Problematic patentability guidelines for Computer Related Inventions (CRI) Market Access Onerous data and server localization requirements Other Issues Inefficient IP enforcement
2016	Intellectual Property Onerous patent working requirement as enshrined under Form 27 of Patent Guidelines Absence of viable patentability guidelines for computer related inventions	Intellectual Property Onerous local working requirement Lack of transparency leading

	Market Access  Domestic preferences and technology mandates in public procurement Confusing regulatory environment regarding security and privacy Onerous data and server localization requirements Lack of a uniform and effective encryption policy Need for data privacy policy Outmoded and inefficient government procurement policies High rates of software piracy Inconsistent implementation of policies affecting the IT Sector  Other Issues Long pendency of infringement cases	to the guidelines on patentability of computer-related inventions  Other Issues  Long pendency of infringement cases
2015	Intellectual Property  Lack of statutory damages and inadequate damages in civil suits  Other Issues  Procedural delays in court process  Market Access  Domestic preferences in public procurement  Outmoded and inefficient government procurement policies  Confusing regulatory environment regarding security and privacy  Heterogeneous application of data-and server-localization requirements  Lacks a uniform and effective encryption policy  Inadequate data protection and information privacy law  Onerous data and server localization requirements  Inconsistent implementation of policies affecting the IT Sector	Intellectual Property Onerous local working requirement Other Issues Procedural delays in court process

TABLE 7: LIST OF AFTI'S ACCUSATIONS BY YEAR

Year	AFTI Accusations	Special 301 Report
2018	Patent-Related Concerns	Patent-Related
	Restrictive patentability criteria	Concerns
	under Section 3(d) of Indian Patent Act,	Restrictive
	1970	patentability criteria

Administrative

under Section 3(d) of Lack of regulatory data protection Indian Patent Act, 1970 Lengthy patent opposition Lack procedures regulatory data protection Unpredictable compulsory licensing regime Lengthy patent opposition procedures Onerous localization Potential threat requirements of compulsory licensing Lack of clarity on guidelines on Copyright-Related patentability of computer related inventions Concerns **Copyright-Related Concerns** Rampant Rampant copyright piracy copyright piracy Absence of anti-camcording Absence of legislation anti-camcording Illegal copying of books and legislation written publications **Trade Secrets-Related Concerns** Trade Secrets-Lack of trade secret protection **Related Concerns** Other Concerns Lack of trade Lack transparency, secret protection predictability, and trust in medical devices **Other Concerns** price controls Lack of Negative impact of price controls transparency, on agricultural biotechnology industry predictability, and trust in medical devices price controls 2017 **Patent-Related Concerns** Patent-Related Concerns Restrictive patentability criteria under Section 3(d) of Indian Patent Act, Restrictive 1970 patentability criteria Unpredictable compulsory under Section 3(d) of Indian Patent Act, 1970 licensing regime Ineffective system for protection Unpredictable compulsory licensing against unfair commercial use regime Forced localization requirement Ineffective Unauthorized disclosure protection system undisclosed test or other data generated for against unfair seeking marketing approval commercial use pharmaceutical products Onerous Lack of clarity of standards for localization requirements compulsory licenses under Sections 85 and Unauthorized 92 and revocation under Section 66 of the disclosure of undisclosed Indian Patent Act, 1970 test or other data Absence of patentability Unpredictable guidelines for computer related inventions compulsory licensing Lack of an effective system for regime notifying interested parties of marketing Problematic approvals for generic pharmaceuticals guidelines Lack of regulatory data protection patentability of computer **Copyright-Related Concerns** related inventions Unauthorized camcording

High levels of piracy and	burdens such as
unpredictability in the market	expensive and lengthy
Non-accession to the WIPO	patent opposition
Internet Treaties	procedures, long
Unauthorized book copying	timelines for receiving
Trademark-Related Concerns	patents, and excessive
Rampant rates of trademark	reporting requirements
counterfeiting	Ambiguous
Non-accession to Singapore	patent disclosure
Treaty on the Law of Trademarks	requirement
Trade Secrets-Related Concerns	Copyright-Related
Lack of trade secret protection	Concerns
Lack of trade secret protection	Absence of
	anti-camcording
	legislation
	Rampant
	physical and online
	copyright piracy
	Non-accession
	to WIPO Internet Treaties
	Non-existence
	of copyright royalty
	board and Intellectual
	Property Appellate Board
	Underreporting
	of cable subscriptions
	Widespread
	use of illicit streaming
	devices
	Absence of
	statutory provisions on
	circumvention of
	technological protection
	measures
	Problematic
	copyright royalty regime
	Trademark-
	Related Concerns
	Rampant rates
	of trademark
	counterfeiting
	Non-accession
	to Singapore Treaty on
	the Law of Trademarks
	Trade Secrets-
	Related Concerns
	Inadequate
	trade secret protection
2016 Patent-Related Concerns	Patent-Related
Restrictive patentability criteria under Section 3(d) of Indian Patent Act,	Concerns  Restrictive

1970

Forced localization requirements
Lack of regulatory data protection
Ineffective protection against
unfair commercial use

Unpredictable compulsory licensing regime

Administrative burdens such as patent application backlog and lengthy patent opposition procedures

#### **Copyright-Related Concerns**

High levels of online copyright piracy and unpredictability in the market

Absence of anti-camcording legislation

Rampant illegal downloading and streaming

Illegal copying of books and written publications

#### **Trade Secrets-Related Concerns**

Inadequate trade secret protection

patentability criteria under Section 3(d) of Indian Patent Act, 1970

Onerous

localization requirements

Unauthorized disclosure of test and other regulatory data protection

Ineffective protection against unfair commercial use

Unpredictable compulsory licensing regime

Administrative burdens such as patent application backlog and lengthy patent opposition procedures

Lack of transparency leading to the guidelines on patentability of computer related inventions

# Copyright-Related Concerns

Rampant physical and online copyright piracy

Absence of anti-camcording legislation

Widespread use of illicit streaming devices

Non-accession to WIPO Internet Treaties Underreporting of cable subscriptions

Absence of statutory provisions on circumvention of technological protection measures

Problematic copyright royalty regime

## Trade Secrets-

#### **Related Concerns**

Inadequate trade secret protection

Trademark-

		Related Concerns
		Burdensome
		procedures for acquiring
		a trademark and
		significant delays
		associated with
		cancellation and
		opposition proceedings at
		the administrative level
		High levels of
		trademark counterfeiting
		Non-accession
		to Singapore Treaty on
		the Law of Trademarks
		the Law of Tradelliarks
2015	Patent-Related Concerns	Patent-Related
2013		Concerns
	Restrictive patentability criteria	
	under Section 3(d) of Indian Patent Act,	Restrictive
	1970	patentability criteria
	Onerous, time-consuming, and	under Section 3(d) of
	costly facility inspection rules	Indian Patent Act, 1970
	Unpredictable compulsory	Administrative
	licensing regime	burdens such as lengthy
	Ineffective protection against	patent opposition
	unfair commercial use	procedures
	Lack of regulatory data protection	Unpredictable
	Onerous patent working	compulsory licensing
	requirement	regime
	Revocation of patent of key	Ineffective
	pharmaceutical drugs such as Bonviva,	protection against unfair
	Humira and Sovaldi	commercial use
		Unauthorized
	Copyright-Related Concerns	disclosure of undisclosed
	Absence of anti-camcording	test or other data
	legislation	
	Rampant copyright infringement	Copyright-Related Concerns
	Trade Secrets-Related Concerns	Absence of
	Lack of trade secret protection	
	_	anti-camcording
		legislation
		Rampant
		online copyright piracy
		Signal theft
		Absence of
		statutory provisions on
		circumvention of
		technological protection
		measures
		Inadequate
		statutory damages
		Trade Secrets-
		Related Concerns
		Inadequate
	l	

		trade secret protection
2014	Patent-Related Concerns	Patent-Related
	Restrictive patentability criteria	Concerns
	under Section 3(d) of Indian Patent Act,	Restrictive
	1970	patentability criteria
	Unpredictable compulsory	under Section 3(d) of the
	licensing regime	Indian Patent Act, 1970
	Onerous local working	Unpredictable
	requirement	compulsory licensing
	Ineffective protection against	regime
	unfair commercial use of undisclosed test	Onerous local
	and other data generated to obtain	working requirement
	marketing approval for pharmaceutical and	Ineffective
	agrochemical products	protection against unfair
	No data exclusivity	commercial use of
	Copyright-Related Concerns	undisclosed test and other
	Rampant online copyright piracy	data generated to obtain
	and illegal downloading	marketing approval for
	Absence of anti-camcording	pharmaceutical and
	legislation	agrochemical products
	Illegal copying of books and	Administrative
	written publications	burdens such as patent
	Non-accession to the WIPO	application backlog and lengthy patent opposition
	Internet Treaties	procedures
	Trademark-Related Concerns	Copyright-Related
	Rampant trademark	Concerns
	counterfeiting	Rampant
	Trade Secrets-Related Concerns	online copyright piracy
	Inadequate trade secret protection	Absence of
		anti-camcording
		legislation
		Lack of
		effective protection
		against signal theft
		Absence of
		statutory provisions on
		circumvention of
		technological protection
		measures
		Trademark-
		Related Concerns
		Rampant
		trademark counterfeiting
		Administrative
		burdens such as
		trademark application
		backlog and lengthy
		opposition proceedings
		Trade Secret-
		Related Concerns
		Inadequate

	1 1 1 1 1
	trade secret protection

TABLE 8: LIST OF USIBC's SUBMISSIONS BY YEAR

Year	USIBC's submissions	Special 301 Report
2018	N/A	Patent-Related
		Concerns
		Restrictive
		patentability criteria under
		Section 3(d) of Indian
		Patent Act, 1970
		Potential threat
		of compulsory licensing
		Lengthy patent
		opposition proceedings
		Absence of
		regulatory data protection
		Copyright-Related
		Concerns
		Absence of
		statutory provisions on
		circumvention of
		technological protection
		measures
		Absence of anti-
		camcording legislation
		Non-accession
		to the WIPO Internet
		Treaties
		Trademark-Related
		Concerns
		Non-accession
		to the Singapore Treaty on
		the Law of Trademarks
		Trade Secret-
		related Concerns
		Ineffective trade
		secret protection regime
2017	Patent-Related Concerns	Patent-Related
	Restrictive patentability criteria	Concerns
	under Section 3(d) of Indian Patent Act,	Restrictive
	1970	patentability criteria under
	Absence of guidelines for	Section 3(d) of Indian
	computer related inventions	Patent Act, 1970
	Non-compliance of compulsory	Unpredictable
	licensing provisions with the Berne	Computer-Related
	Convention and TRIPS	Inventions (CRI)

	Rampant willful patent	guidelines
	infringement	Unpredictable
	Copyright-Related concerns	compulsory licensing
	Absence of anti-camcording	regime
	legislation	Copyright-Related
	Insufficiency of Section 69A of IT	Concerns
	Act to combat copyright infringement	Absence of anti-
	Lack of explicit safe harbor	camcording legislation
	framework for online intermediaries	Rampant online
	Trade Secrets-Related Concerns	copyright piracy
	Inadequate trade secret protection	Absence of
	regime	statutory provisions on
	Trademark-Related Concerns	circumvention of
	Lack of training and skills to	technological protection
	combat trademark infringement by Indian	measures
	customs authorities	Non-accession
	Other Concerns	to WIPO Internet Treaties
		Non-existence
	Lack of skilled and trained Indian	of copyright royalty board
	custom officials to combat IP infringement	and Intellectual Property
	at the border effectively	Appellate Board
		Underreporting
		of cable subscriptions
		Widespread use
		of illicit streaming devices
		Problematic
		copyright royalty regime
		Trade Secrets-
		Related Concerns
		Inadequate
		trade secret protection
		regime
		Trademark-Related
		Concerns
		High levels of
		trademark counterfeiting
		Administrative
		burdens such as delay in
		obtaining trademarks and
		lengthy opposition and
		cancellation proceedings
		Other Concerns
		Onerous localization requirements
2016	Detent Deleted Concerns	Patent-Related
2016	Patent-Related Concerns Restrictive patentability criteria	Concerns
	under Section 3(d) of Indian Patent Act,	-
	1970	Restrictive
		patentability criteria under Section 3(d) of Indian
	Unpredictable compulsory	Patent Act, 1970
	licensing regime  Absence of patentability	Unpredictable
	Absence of patentability guidelines for CRIs	compulsory licensing
	guidennes for CKIS	compuisory neclisting

Absence of patent linkage or lack of protection for regulatory data protection
Onerous patent disclosure requirement

#### **Copyright-Related Concerns**

Non-accession to the WIPO Internet Treaties

Underreporting of cable subscriptions

Rampant piracy of premium programming content

Distribution of sports content on unencrypted basis

Confusion over inclusion of broadcasting services within the ambit of TRAI

#### **Trademark-Related Concerns**

Non-accession to the Singapore Treaty on the Law of Trademarks

Unpredictable regime on lawful enforcement of trademarks

#### **Trade Secrets-Related Concerns**

Lack of trade secret protection

regime

Lack of transparency leading to the guidelines on patentability of computer related-inventions

Unauthorized disclosure of test and other regulatory data protection

Administrative burdens such as patent application backlog and lengthy patent opposition procedures

Ineffective protection against unfair commercial use

Onerous localization requirements

# Copyright-Related Concerns

Non-accession to WIPO Internet Treaties

Absence of anticamcording legislation

Rampant online copyright piracy

Absence of statutory provisions on circumvention of technological protection measures

Non-existence of copyright royalty board and Intellectual Property Appellate Board

Underreporting of cable subscriptions

Widespread use of illicit streaming devices
Problematic

copyright royalty regime

# Trademark-Related

#### Concerns

Non-accession to the Singapore Treaty on the Law of Trademarks

Unlawful

enforcement of trademarks

Trade Secrets-Related Concerns

	Inadequate
	trade secret protection

TABLE 9: LIST OF NAM's ACCUSATIONS BY YEAR

Year	NAM's accusations	Special 301 Report
2018	Patent-Related Concerns	Patent-Related
	Restrictive patentability criteria	Concerns
	under Section 3(d) of the Indian Patent Act,	Restrictive
	1970 and patent review processes	patentability criteria under
	Unpredictable compulsory	Section 3 (d) of Indian
	licensing regime	Patent Act, 1970
	Lengthy patent opposition	Potential threat of
	proceedings	compulsory licensing
	Outlier position aimed at	Lengthy patent
	weakening IP protection at multilateral	opposition proceedings
	forums such as UNFCCC, WTO and WIPO	Absence of
	Ineffective protection against	regulatory data protection
	unfair commercial use	Copyright-Related
	Onerous localization	Concerns
	requirements	Rampant
	Copyright-Related Concerns	copyright piracy
	Rampant copyright piracy	Absence of
	Trademark-Related Concerns	statutory provisions on
	High levels of trademark	circumvention of
	counterfeiting	technological protection
	Trade Secret-Related Concerns	measures
	Absence of trade secret	Absence of anti-
	protection	camcording legislation
		Non-accession to
		the WIPO Internet Treaties
		Trademark-Related
		Concerns
		Non-accession to
		the Singapore Treaty on the
		Law of Trademarks
		Trade Secret-
		Related Concerns
		Ineffective trade secret protection regime
2017	Patent-Related Concerns	Patent-Related
2017		Concerns
	licensing regime  Restrictive patentability criteria	Unpredictable compulsory licensing
	and lengthy patent review processes	regime
	Long backlog of patent	Narrow
	applications under review	patentability criteria
	Copyright-Related Concerns	Administrative
	Rampant online copyright piracy	issues such as costly and
	Trademark-Related Concerns	time-consuming patent
	i rademark-keiated Concerns	patent

	Domnant trademark	opposition proceedings,
	Rampant trademark counterfeiting	long timelines for receiving
	Long backlog of trademark	patents, and excessive
	applications under review	reporting requirements
	Trade Secret-Related Concerns	Problematic CRI
	Inadequate trade secret	guidelines
	protection trade secret	Absence of
	-	regulatory data protection
	Insufficient protection of business confidential information and	Onerous
	regulatory data	localization requirement
	Other Concerns	Copyright-Related
		Concerns
	Outlier position aimed at weakening IP protection at multilateral	Rampant online
	forums	copyright piracy
	Torums	Absence of anti-
		camcording legislation
		Underreporting
		of cable subscriptions
		Widespread use
		of illicit streaming devices
		Absence of
		statutory provisions on
		circumvention of
		technological protection
		measures
		Non-accession to
		the WIPO Internet Treaties
		Trademark-Related
		Concerns
		High levels of
		trademark counterfeiting
		Challenges and
		delays in obtaining
		trademarks
		Non-accession to
		the Singapore Treaty on the
		Law of Trademarks
		Trade Secrets related
		concerns
		Inadequate trade
		secret protection
		Other concerns
		Inadequate IP
		enforcement
2016	Patent-Related Concerns	Patent-Related
	Restrictive patentability criteria	Concerns
	under Section 3(d) of the Indian Patent Act,	Restrictive
	1970 and patent review processes	patentability criteria under
	Unpredictable compulsory	Section 3(d) of the Indian
	licensing regime	Patent Act, 1970 and patent
		review processes

### **Copyright-Related Concerns**

Rampant physical and online copyright piracy

Signal theft

Absence of statutory provisions on circumvention of technological protection measures

#### **Trade Secret-Related Concerns**

Inadequate trade secret protection

Insufficient protection of business confidential information and regulatory data

## **Other Concerns**

Outlier position aimed at weakening IP protection at multilateral forums

Unpredictable compulsory licensing regime

Unpredictable

CRI guidelines

# Copyright-Related Concerns

Rampant copyright piracy

High incidence of camcording

## Trade Secret-Related Concerns

Inadequate trade secret protection

## **Other Concerns**

Non-accession to important international treaties such as the WIPO Internet Treaties and the Singapore Treaty on the Law of Trademarks

Onerous localization requirement

# Trademark-Related

#### Concerns

Delay in obtaining trademarks

Rampant

trademark counterfeiting

# 2015 Patent-Related Concerns

Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 and patent review processes

Unpredictable compulsory licensing regime

#### **Copyright-Related Concerns**

Rampant copyright piracy

## **Trade Secret-Related Concerns**

Inadequate trade secret protection

Insufficient protection of business confidential information and regulatory data

# Patent-Related Concerns

Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 and patent review processes

Unpredictable compulsory licensing regime

Ineffective patent enforcement

Ineffective protection against unfair commercial use

Unauthorized disclosure of test and other regulatory data protection

# Copyright-Related Concerns

Rampant online

		copyright piracy Absence of anti- camcording legislation Inadequate copyright enforcement Trade Secret- Related Concerns Inadequate trade secret protection Trademarks Rampant trademark counterfeiting Other Issues Onerous localization requirement
2014	Patent-Related Concerns Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 and patent review processes Unpredictable compulsory licensing regime Inadequate regulatory data protection Copyright-Related Concerns Rampant copyright piracy Trade Secrets-Related Concerns Inadequate trade secret protection	Patent-Related Concerns  Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970  Unpredictable compulsory licensing regime  Patent application backlog Copyright-Related Concerns  Rampant copyright piracy  Absence of anticamcording legislation  Trade Secrets- Related concerns  Inadequate trade secret protection  Trademark-Related Concerns  Administrative burdens such as lengthy cancellation and opposition proceedings at the Trademark Registry, backlog of trademark applications,  Other Issues  Ineffective protection against unfair commercial use Onerous

		localization requirements
2013	Patent-Related Concerns    Unpredictable compulsory licensing regime    Other Concerns    Outlier position aimed at weakening IP protection at multilateral forums	Patent-Related Concerns
2012	Patent-Related Concerns	Patent-Related Concerns Unpredictable compulsory licensing regime Administrative burdens such as patent application backlog and lengthy opposition proceedings Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Copyright-Related Concerns Rampant online

		copyright piracy Other Concerns Ineffective protection against unfair commercial use
2011	Restrictive patentability criteria Rampant pharmaceutical counterfeiting Unpredictable compulsory licensing regime Trade Secret-Related Concerns Inadequate trade secret protection Other Concerns Outlier position aimed at weakening IP protection at multilateral forums Ineffective enforcement through judicial delays and extremely low rates of conviction Burdensome bureaucracy	Patent-Related Concerns  Restrictive patentability criteria Administrative burdens such as patent application backlog and lengthy opposition proceedings Ineffective protection against unfair commercial use Unauthorized disclosure of undisclosed test and other regulatory data Copyright-Related Concerns Non-accession to WIPO Internet Treaties Rampant optical disc piracy Other Concerns Ineffective protection against unfair commercial use Ineffective judicial proceedings and criminal enforcement regime
2010	Copyright-Related Concerns Rampant copyright piracy Trademark-Related Concerns Rampant trademark counterfeiting	Patent-Related Concerns Restrictive patentability criteria under Section 3(d) of the Indian Patent Act, 1970 Administrative burdens such as patent application backlog and lengthy patent opposition

	proceedings
	Ineffective
	protection against unfair
	commercial use
	Unauthorized
	disclosure of undisclosed
	test or other data
	Copyright-Related
	Concerns
	Inadequate legal
	framework and ineffective
	enforcement
	Rampant optical
	disc piracy
	Non-accession to
	WIPO Internet Treaties
	Other Concerns
	Ineffective
	protection against unfair
	commercial use
	Ineffective IPR
	enforcement