



United States
International Trade Commission

Trade and Investment Policies in India, 2014–2015

September 2015
Publication Number: 4566
Investigation Number: 332-550

United States International Trade Commission

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Abstract

This report by the U.S. International Trade Commission (the Commission), *Trade and Investment Policies in India, 2014–2015*, reviews significant changes made to India’s trade and investment policies by the government of Narendra Modi since he took office in May 2014. It also describes changes to policies identified in *Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy* (hereafter *India 2014*), a December 2014 report by the Commission. Both reports were requested by the U.S. House Committee on Ways and Means and the U.S. Senate Committee on Finance.

The Modi government made significant changes to certain barriers to trade and investment described in *India 2014*. The Modi government also announced several new trade and investment-related policies between May 2014 and July 2015. The Commission found significant changes or new policies in four areas: foreign direct investment; tariffs and customs procedures; local-content requirements, particularly concerning information and communications technology goods; and standards and technical regulations. U.S. industry representatives and other observers viewed some of the policy changes described in this report as promising from the standpoint of U.S. trade and investment opportunities in India; other policies, as less so. The Modi government enacted no new laws to address intellectual property rights (IPR)-related barriers. However, U.S. industry representatives report that the Modi government has shown more interest in improving IPR policy transparency and more willingness to engage with the United States in this area than Indian governments in the past.

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Acronyms and Abbreviations

Terms	Definitions
BEA	Bureau of Economic Analysis (USDOC)
BIS	Bureau of Indian Standards
BIT	bilateral investment treaty
BJP	Bharatiya Janata Party
BRICS	Brazil, Russia, India, China, and South Africa
CBEC	Central Board of Excise and Customs
CCEA	Cabinet Committee on Economic Affairs
CCS	Cabinet Committee on Security
CII	Confederation of Indian Industry
CLNDA	Civil Liability for Nuclear Damage Act
CMN	Coal Mines Nationalization (Act)
CRO	Compulsory Registration Order
CSC	Convention on Supplementary Compensation (for Nuclear Damage)
DAHDF	Department of Animal Husbandry, Dairying, and Fisheries
DIPP	Department of Industrial Policy and Promotion
DPCO	Drug Pricing Control Order
DTTI	Defense Trade and Technology Initiative
EDI	electronic data interchange
FAS	Foreign Agriculture Service (United States Department of Agriculture)
FDI	foreign direct investment
FICCI	Federation of Indian Chambers of Commerce and Industry
FIPB	Foreign Investment Promotion Board
FSSAI	Food Safety and Standards Authority of India
FTP	Foreign Trade Policy (Government of India)
GDP	gross domestic product
GIPC	Global Intellectual Property Center
GST	goods and services tax
ICT	information and communications technology
IIPA	International Intellectual Property Alliance
IMF	International Monetary Fund
IPA	Indian Pharmaceutical Alliance
IPR	intellectual property rights
IT	information technology
ITA	Information Technology Agreement (WTO Agreement)
LARR	Land Acquisition, Rehabilitation and Resettlement (Act)
LCD	liquid-crystal display
LCR	local-content requirement
LED	light-emitting diode

Contents

Terms	Definitions
MAP	mutual agreement procedure
MAT	minimum alternative tax
MEIS	Merchandise Exports from India Scheme
MMDR	Mines and Minerals Development and Regulation (Amendment)
MOCI	Ministry of Commerce and Industry
MSD	Merck, Sharp, and Dohme
MSF	Doctors Without Borders/Médecins Sans Frontières
MSG	monosodium glutamate
MSP	minimum support price
NAM	National Association of Manufacturers
NFSA	National Food Security Act
NGO	non-governmental organization
NHP	National Health Policy
NIST	National Institute of Standards and Technology
NITI	National Institution for Transforming India
NMDA	National Medical Device Authority
NPCIL	Nuclear Power Corporation of India Limited
NPPA	National Pharmaceutical Pricing Authority
NTP	National Telecom Policy
OECD	Organisation for Economic Co-operation and Development
OEM	original equipment manufacturer
OIE	World Organization for Animal Health
PA	product approval
PhRMA	Pharmaceutical Research and Manufacturers of America
PMA	preferential market access
PPP	public-private partnership
PQIS	Department of Plant Protection, Quarantine, and Storage
R&D	research and development
RBI	Reserve Bank of India
Rs	generally accepted symbol for Indian rupees (currency unit) ¹
SDoC	Suppliers Declaration of Conformity
SEIS	Services Exports from India Scheme
SEZ	special economic zone
SIA	Semiconductor Industry Association
SPS	sanitary and phytosanitary
TBT	Technical Barriers to Trade (WTO Agreement)
TPF	Trade Policy Forum

¹ For this report, all rupee amounts are converted to U.S. dollars at the rate of 61.95 rupees per dollar—the exchange rate on December 10, 2014. Dollar amounts above \$1 million are rounded to the nearest hundred thousand dollars; other dollar amounts are rounded to the nearest hundred dollars. IMF, “Exchange Rate Archives by Month,” https://www.imf.org/external/np/fin/data/param_rms_mth.aspx (accessed September 10, 2015).

Terms	Definitions
TRIPS	Trade-Related Aspects of Intellectual Property Rights (WTO Agreement)
USDA	United States Department of Agriculture
USDOC	United States Department of Commerce
USIBC	United States-India Business Council
USITC	United States International Trade Commission
USTR, the	United States Trade Representative
WTO	World Trade Organization

Contents

Executive Summary

On May 26, 2014, Narendra Modi of the Bharatiya Janata Party became Prime Minister of India. Soon after taking office, Prime Minister Modi stated his intention to introduce a broad range of trade and investment policy reforms to promote India's economic growth and development. Given this change in India's political leadership and the new leaders' promises of policy reforms, the U.S. House Committee on Ways and Means and the U.S. Senate Committee on Finance (the Committees) requested on September 25, 2014, that the U.S. International Trade Commission (USITC or Commission) provide up-to-date information on India's trade and investment policies.

In response to an earlier request from the Committees, in December 2014 the Commission published a report, *Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy* (hereafter *India 2014*). *India 2014* identified and described India's industrial policies that discriminate against U.S. trade and investment. As requested by the Committees, the present report describes significant changes that have been made under the Modi government, from May 2014 to July 2015, to policies identified as problematic in *India 2014*. Also as requested, the new report identifies other relevant trade and investment policies and practices adopted by the Modi government during May 2014–July 2015.

Main Findings

Information obtained for this report indicates that the Modi government made significant changes to some of the barriers to trade and investment identified in *India 2014*. The Modi government also implemented several new trade and investment-related policies between May 2014 and July 2015.

The Commission found significant policy changes or new policies in four areas:

- foreign direct investment (FDI);
- tariffs and customs procedures;
- local-content and localization requirements, particularly concerning information and communications technology (ICT) goods; and
- standards and technical regulations.

The Modi government faced legislative challenges in passing other key policy reforms—notably changes in India's land acquisition laws, taxation policies, and other measures affecting the overall business climate—and, as a result, many of India's policies and practices that were

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identified in *India 2014* as discouraging U.S. trade and investment did not change during May 2014–July 2015. Moreover, during this period, the Modi government enacted no new laws to address intellectual property rights (IPR)-related barriers—an area of particular concern for U.S. companies.

U.S. industry representatives nonetheless report that the Modi government has shown greater interest in improving IPR policy transparency and a greater willingness to engage with the United States in this area than Indian governments in the past. Similarly, U.S. industry representatives and other observers saw some of India’s policy changes described in this report as promising from the standpoint of U.S. trade and investment opportunities in India; they viewed other policy changes as less so.

Information in this report draws on publicly available information. Sources included testimony from a Commission public hearing in Washington, DC; written submissions to the Commission; and Commission staff interviews with U.S. industry and government officials in the United States as well as with U.S. and Indian industry and government officials in several important Indian commercial centers—Bangalore, Hyderabad, Mumbai, New Delhi, and Jaipur. This report also draws on Indian and U.S. government documents, academic and private sector publications, and press reports.

Analysis of the economic effects of India’s laws, policies, and practices during May 2014–July 2015 on U.S. trade and investment was beyond the scope of the request for this report. Moreover, it would not have been feasible to conduct a quantitative analysis of India’s trade and investment policy changes during May 2014–July 2015, such as was done for *India 2014*, due to the lack of necessary economic data.²

Table ES.1 summarizes the trade and investment barriers identified in *India 2014*, and shows changes and new policies and practices introduced in India during May 2014–July 2015. In view of the short period of time the Modi government has been in office, some of the policies and practices shown include draft policies and policy proposals, in addition to laws and policies already implemented. Appendix E offers a timeline of India’s key trade and investment-related laws, policies, and practices during May 2014–July 2015.

² For *India 2014*, the Commission conducted quantitative analysis through economic modeling and a survey of U.S. businesses of trade and investment policy reforms in India during 2003–13. For this report, however, the lack of comparable economic data for the 14-month period May 2014 through July 2015 precluded a similar quantitative analysis. Data on trade and investment in the short term can be too variable to be meaningful, and the effects of policy changes may take some time to be reflected in economic data.

Table ES.1: Indian barriers to U.S. trade and investment identified in the Commission’s *India 2014* report by industry, product, or policy, and changes, and new policies/practices introduced by the Modi government during May 2014–July 2015

Industry, product, or policy type	Barriers to U.S. trade and investment identified in the Commission’s <i>India 2014</i> report	Changes and new policies/practices made by the Modi government (chapter where discussed in this report)
Agricultural products	High tariffs; customs delays; and certain sanitary and phytosanitary restrictions that reportedly are not scientifically warranted and inconsistent with international standards.	Indian government undertook efforts in late 2014 to reduce customs delays and speed up customs clearance for agricultural products. (Chapter 4) Certain new standards introduced in 2015 could create new barriers to U.S. meat and poultry exports. (Chapter 6)
Alcoholic beverages	High tariffs; high excise taxes on inputs; price controls; and India-unique mandatory standards and labeling requirements.	New labeling requirements could create challenges for certain U.S. exports. (Chapter 6)
Civil nuclear energy	A lack of clear regulations, uncertain legal liabilities, and a burdensome operating environment that reportedly deter foreign firms from participating in this sector. ^a	In early 2015 India effectively limited the legal liability of foreign suppliers, potentially boosting FDI in this sector. (Chapter 3)
Clinical trials for new drugs	Lack of clear regulations, uncertain legal liabilities, and a burdensome operating environment.	December 2014 provision gives more clarity on compensation for clinical trial participants; June 2015 rule clarifies the definition of a study-related injury. (Chapter 6)
Construction	Open to FDI only for projects that exceed a certain size.	New policies in late 2014 allow FDI in smaller projects. (Chapter 3)
Cosmetics and personal care products	Presence of counterfeit goods and uncertainties in product registration process.	Imports of animal-tested cosmetics were banned in late 2014. In 2015, the government introduced new test rules to detect trace heavy metals; proposed new in-country testing requirements; and made changes to product approval procedures. (Chapter 6)
Customs procedures	Customs clearance delays; complicated procedures; and agriculture-specific procedures.	In late 2014, customs officials were made available 24/7 at major seaports and air ports, and customs clearance facilitation committees were established at major seaports and airports. (Chapter 4)
Defense and civil aerospace	26 percent FDI equity limit. Offset provisions requiring foreign firms to use locally sourced equipment or agree to other similar arrangements in order to be awarded contracts by the Indian government further discourage foreign participation in this sector.	In August 2014 the FDI equity limit was raised to 49 percent, and could be higher on a case-by-case basis. (Chapter 3) U.S. companies report that India’s 2015 draft new procedures for offsets reflect the Indian government’s efforts to build in more transparency and accessibility for foreign partners. (Chapter 5)

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Industry, product, or policy type	Barriers to U.S. trade and investment identified in the Commission's <i>India 2014</i> report	Changes and new policies/practices made by the Modi government (chapter where discussed in this report)
FDI approval process	An approval process that can cause delays and lead some time-sensitive deals to fall through.	<p>In May 2015, the government announced that approval is no longer required in cases of mergers and acquisitions for new operations and facilities in certain industries. (Chapter 3)</p> <p>In June 2015, the government raised the threshold for investment projects requiring cabinet approval. (Chapter 3)</p>
Food products	High tariffs; India-unique mandatory standards and technical regulations (particularly on packaging, labeling, and product approval) that create uncertainty, delays, and additional costs.	New testing and labeling requirements were introduced in 2015 that could hinder certain U.S. exports. But new measures in late 2014 and 2015 that aim to streamline product approval processes and harmonize standards with international ones could facilitate some U.S. exports. (Chapter 6)
ICT and electronic products	<p>Variable and opaque tariffs and taxation; local-content policies that encourage indigenous manufacturing and establish preferences for certain domestically manufactured products.</p> <p>Rules under Preferential Market Access (PMA) policy and Compulsory Registration Order (CRO) policy that require foreign firms to purchase Indian inputs, perform a share of business in India, perform certain activities in India, or submit to India-specific testing or registration.</p> <p>Amendments to telecommunications rules proposed under the previous Indian government. These would require testing of imported equipment in Indian laboratories; require vendors to allow inspection of manufacturing facilities; and impose liability when vendor has taken "inadequate" precautionary security measures.</p>	<p>In 2015, duty reductions were announced for 22 ICT-related products. (Chapter 4)</p> <p>Additional products were made subject to PMA and CRO in late 2014, which could restrict some U.S. ICT exports. (Chapter 5)</p> <p>In December 2014 Indian government directed all ministries to give preference to domestically manufactured electronic products in government procurement as part of the Make in India initiative (August 2014). The Digital India initiative (also August 2014) sets a goal of net zero ICT imports by 2020. (Chapter 5)</p> <p>May 2015 National Telecom Roadmap proposes new policy guidelines that could restrict some U.S. ICT exports and services, including preference for servers and data centers to be located in India; restrictions on the use of foreign SIM cards; plans to make Internet-connected devices subject to the PMA policy; and mandatory certification and registration policies. (Chapter 5)</p> <p>In April 2015 the Modi government delayed implementation of telecommunications amendments, reportedly due to the lack of adequate testing facilities in India. (Chapter 5)</p>
Insurance	26 percent FDI equity limit.	March 2015 legislation increased the FDI equity limit to 49 percent. (Chapter 3)

Industry, product, or policy type	Barriers to U.S. trade and investment identified in the Commission's <i>India 2014</i> report	Changes and new policies/practices made by the Modi government (chapter where discussed in this report)
IPR	Barriers in the areas of trade secrets and regulatory test data, patents, trademarks, and copyrights.	No new IPR laws have been enacted. The December 2014 Draft IPR policy acknowledges that some new laws and other improvements may be needed. (Chapter 7)
Medical devices	High tariffs on inputs/components; additional duties on base tariff rates; and price controls. FDI subject to prior approval. An unclear regulatory environment, in which medical devices and pharmaceuticals are regulated under the same standards, further discourages foreign participation in this sector.	In 2015, duties were reduced on some medical device components and some finished products. (Chapter 6) In February 2015, the government approved 100 percent foreign equity in medical device firms without prior authorization. (Chapter 6) The December 2014 draft National Health Policy and January 2015 draft Drugs and Cosmetics Bill proposed treating medical devices as distinct from pharmaceuticals. But the June 2015 draft National Medical Device Policy and other government measures placed additional products within scope of price controls. (Chapter 6)
Mining—coal (merchant mining, i.e., for-profit sales in open market)	Government monopoly—all private investment prohibited. ^a	March 2015 legislation allows private investment including FDI up to 100 percent equity. (Chapter 3)
Mining—other	Lack of regulatory transparency, making FDI difficult. ^a	New measures beginning in 2015 give more transparency to investors. (Chapter 3)
Pharmaceuticals	Price controls on various pharmaceuticals (and medical devices) make it difficult for exports to penetrate Indian market.	New measures in 2014 may place additional products under price controls. (Chapter 6)
Railway infrastructure	Government monopoly—all private investment prohibited.	Certain rail infrastructure segments were opened to private investment, including FDI, in late 2014. (Chapter 3)
Solar energy products	Local-content requirements require foreign firms bidding on certain solar energy-related projects to purchase Indian inputs.	No significant policy changes were identified; local-content policies continue to be applied in 2015. (Chapter 5)

Source: Compiled by the Commission.

^a Barrier in place but sector not covered in India 2014.

Investment

Investment policy changes during May 2014–July 2015 helped improve India's overall investment regime.

The Modi government made two industry-wide FDI changes during May 2014–July 2015. For selected industries it eliminated the need for prior government approval of FDI in cases of mergers and acquisitions involving new operations and facilities. It also raised the threshold for

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other investment projects requiring cabinet approval from Rs 20 billion (\$322.8 million) to Rs 30 billion (\$484.3 million).³

The Modi government also made a number of industry-specific FDI changes during May 2014–July 2015. Key changes included raising FDI equity limits in the insurance and defense and civil aerospace industries; removing the requirements for pre-investment authorization in several cases; removing requirements for prior government approval of FDI in medical devices; and permitting FDI in certain segments of the railways industry, in which FDI had previously been wholly prohibited. The Commission did not identify any FDI changes that have increased restrictions on U.S. firms seeking to do business in India.

India’s remaining investment restrictions continue to present challenges for U.S. companies in India.

Although they welcomed the steps the Modi government took during May 2014–July 2015 to liberalize India’s FDI policy, many U.S. industry representatives voiced concerns that India still maintains substantial barriers to FDI in some industries. They said that U.S. economic engagement in India remained constrained by FDI equity limits in other industries (notably multibrand retail and e-commerce) and that India’s local-content policies, such as mandates for local production and local sourcing, continue to limit U.S. investment opportunities in India.

Tariffs and Customs Procedures

India made a small number of changes to its tariffs during May 2014–July 2015.

India announced a small number of tariff reductions and tariff increases across various manufacturing sectors in February 2015. Goods on which tariffs were lowered included 22 ICT-related products, such as high-definition television panels; clean energy goods, such as solar water heaters; textiles and footwear; and medical devices. Tariffs were raised on several telecommunications-related products, including cellphones, tablet computers, and digital video cameras.

India took steps to reduce customs clearance delays during May 2014–July 2015.

In late 2014 India began deploying additional workers to provide 24/7 customs clearance at major seaports and airports. In April 2015 India announced further measures to expedite

³ Rs is a generally accepted symbol for Indian rupees. For this report, all rupee amounts are converted to U.S. dollars at the rate of 61.95 rupees per dollar—the exchange rate on December 10, 2014. IMF, “Exchange Rate Archives by Month,” https://www.imf.org/external/np/fin/data/param_rms_mth.aspx (accessed September 10, 2015).

customs clearance. These included establishing a special Customs Clearance Committee to facilitate customs at major seaports and airports, and setting up a “single window” to handle regulatory matters for agricultural imports.

Local-content and Localization Requirements

During May 2014–July 2015, India expanded the scope of several local-content and localization policies—rules that require foreign firms to purchase Indian inputs, conduct a share of business in India, conduct certain business activities in India, or submit to India-specific testing or registration. The policies affected certain ICT, electronics, and defense and civil aerospace products.

These measures include:

- **Changes to the Preferential Market Access (PMA) policy.** The PMA policy, in place prior to the Modi administration, requires certain ICT products purchased from foreign firms to include a specified share of Indian content when procured by Indian government entities. India added three new products to the PMA list in November 2014, and implemented an online system to monitor enforcement of the PMA policy in December 2014. In December 2014 the Indian government directed all ministries to give preference to domestically manufactured electronic products in government procurement as part of the Make in India initiative.
- **Changes to the Compulsory Registration Order (CRO) policy.** The CRO policy, also in place prior to the Modi administration, requires the registration and testing in India of certain electronic products, whether imported or made in India—even when the products have already been tested and certified by internationally accredited labs. The stated purpose of the CRO is to ensure consumer safety. India expanded CRO coverage and added new products to the CRO list in November 2014 to include many major ICT products.
- **Rules governing telecommunications licenses.** These rules, which evolved under the previous Indian government, would require testing of imported equipment in Indian laboratories; require vendors to allow inspection of manufacturing facilities; and impose liability when a vendor has taken “inadequate” precautionary security measures. In April 2015, the Modi government postponed implementation of requirements, reportedly due to the absence of adequate testing facilities in India.

- **National Telecom Roadmap (the Roadmap).**⁴ The Modi government issued the Roadmap in May 2015 to provide a policy framework for India’s deployment of certain Internet technologies determined to be an integral part of the country’s future economic growth and development. It builds on policies set out in 2012, prior to the Modi administration. The 2015 Roadmap underscores the importance to India of indigenous Internet-based innovation, local research and development, and local manufacturing of telecommunication products. U.S. industries expressed concerns about certain proposals in the Roadmap, including mandatory data localization (i.e., that data be located on servers in India), restrictions on the use of foreign SIM cards,⁵ and making certain Internet-connected devices subject to the PMA policy.
- **Proposed changes to the offset program.** India’s offset program, implemented prior to the Modi administration, requires foreign defense sector companies to offset a minimum of 30 percent of the value of their contracts with the Indian government with purchases of Indian goods. The goal of this program is to promote industrial activity in India. While the Commission found no changes in the offset program during May 2014–July 2015, a draft national offset policy reportedly under consideration by the Modi government would, among other things, extend India’s offset program to other sectors (possibly including telecommunications, medicines, civil aerospace, power generation, fertilizer, railways, ports and shipyards, and mining).

Standards and Technical Regulations

The Modi government has expressed a commitment to harmonize India’s standards with international standards and to increase engagement with the United States on standards.

- **Harmonizing with international standards.** In April 2015, India announced plans to promote greater harmonization of Indian standards with international standards. The harmonization plan, which was announced in the 2015–20 Foreign Trade Policy statement, is something U.S. exporters have long sought. India also set out a roadmap to achieve this goal through proposed legislative and institutional reforms and a proposal to make conformity assessment for low-risk imports less burdensome.

⁴ The Indian government’s official name for this plan is the “National Telecom Machine-to-Machine (M2M) Roadmap.” M2M communications involves a network of Internet-connected devices that communicate among themselves and without human intervention. It is also referred to as the “Internet of Things.”

⁵ A SIM (“subscriber identity module”) card is a component of mobile devices, such as cellphones and tablets. The main use of the SIM card is to securely store information used to identify and authenticate subscribers on mobile networks.

- **Increasing engagement with the United States.** Since May 2014, the United States and India have held multiple working-level and senior-level meetings on bilateral standards and technical requirement issues. After a long hiatus, the United States-India Trade Policy Forum resumed meetings in November 2014; the two countries have held discussions in that forum on key standards-related issues, including animal health, plant health, and food safety.

U.S. industry representatives also expressed concerns about certain standards-related policies implemented by the Modi government in late 2014 and 2015. These concerns are addressed in case studies described below.

Case Studies

Six case studies examine developments in a variety of policy areas reported in *India 2014 as barriers to U.S. trade and investment in India*.

U.S. industry observers state that certain new India-unique mandatory standards and technical requirements implemented in late 2014 and 2015 increase costs, delay time to market, and exclude certain U.S. products from the Indian market. Four case studies examine the impact of India-unique standards and technical requirements:

- **Agricultural products.** This case study describes developments in three areas: (1) changes introduced in late 2014 to India's restrictive import requirements for bovine genetics, and ongoing concerns by U.S. exporters about India's trade barriers in this area; (2) India's new 2015 meat, pork, and poultry requirements, and the potential impacts for U.S. exporters; and (3) a June 2015 WTO ruling upholding an earlier ruling that India's 2007 ban on various U.S. agricultural products, including poultry, eggs, and swine, violates certain Indian trade obligations.
- **Food products.** This case study reviews regulatory changes to India's food labeling and packaging requirements and its food product approval system since May 2014. It describes (1) more restrictive regulatory changes in 2015 concerning food safety; (2) changes to some of India's labeling and packaging requirements in 2015, and ways India's labeling and packaging policies continue to adversely affect U.S. exporters; and (3) some of the Modi government's efforts to change India's food product approval system in late 2014 and 2015 to address some longstanding concerns of exporters.
- **Alcoholic beverages.** This case study summarizes the Modi government's revised labeling requirement guidelines issued in late 2014 and 2015 requiring an ingredients list on wine and spirits, which could adversely impact U.S. alcoholic beverage exports.

- **Cosmetics and personal care products.** This case study describes (1) India's late 2014 ban on animal-tested cosmetics, a potential hurdle for U.S. exports to India; (2) U.S. industry concerns about India's application of testing requirements for cosmetics beginning in 2015, and the requirements' potential adverse impact on U.S. exports to India; (3) a 2015 draft bill that would mandate new India-unique standards and clinical trials for imports of these products; and (4) specific instances of the Modi government's improved cooperation with exporters since May 2014 in ways that improve transparency and make it easier for foreign firms to do business in India.

Two case studies examine developments in the medical devices and clinical trials sectors in late 2014 and 2015. The case studies follow up on regulatory issues identified in *India 2014* as impeding U.S. economic engagement in India.

- **Medical devices.** This case study summarizes several developments in India's medical devices concerning barriers described in *India 2014*. It examines (1) India's February 2015 decision to open the medical devices sector to FDI without prior government approval; (2) the February 2015 announcement of reduced duties on inputs and components used to make medical devices; and (3) a bill introduced in January 2015 that would harmonize India's medical device regulations with international best practices by reversing India's practice of regulating medical devices in the same way as it regulates pharmaceuticals.
- **Clinical trials.** This case study describes several changes India made since May 2014 to improve transparency, predictability, and accountability in India's clinical trial environment. U.S. industry representatives generally reported more opportunities to engage with the Indian government as a result of these changes.

Intellectual Property Rights

The Modi government introduced no new IPR laws during May 2014–July 2015 to address barriers to the protection of trade secrets, regulatory test data, patents, trademarks, and copyrights. Nevertheless, U.S. industry and government representatives noted the willingness of Modi government officials to engage in discussions with the United States on IPR issues, particularly in the context of the December 2014 Draft National IPR Policy.

India 2014 noted that industry representatives in the United States and India had expressed cautious optimism that the Modi government would improve the IPR regime. Furthermore, witnesses at the Commission's May 2015 hearing, and industry representatives interviewed by Commission staff in 2015 in India and the United States, commented positively on the Modi government's apparent willingness to consider and discuss IPR issues with stakeholders. Many

U.S. government and industry representatives in 2015 remain concerned, however, that this increased engagement by the Indian government has not yet led to concrete action. They state that India's persistent IPR barriers continue to undermine the value of intellectual property and make U.S. companies less likely to partner with Indian firms and to exchange the knowledge that will help India to achieve its goal of becoming an innovation leader.

Cross-Cutting Policy Initiatives under the Modi Government

The Modi government pursued several broad policy initiatives to enhance India's business climate during May 2014–July 2015. Four such efforts that may positively affect India's trade and investment climate are:

Improving economic infrastructure. The Modi government launched several initiatives to address the problems created by India's poor physical infrastructure, unreliable electricity supply, and weak communications infrastructure. The Digital India initiative seeks to improve India's telecommunications infrastructure through increased FDI and, along with the Make in India initiative, to indigenously produce ICT products. The Modi government's Smart Cities initiative seeks to improve India's urban physical infrastructure using ICT to manage resources and deliver services.

Improving the ease of doing business and bureaucratic accountability. To address bureaucratic and regulatory delays that create trade and investment challenges (as described in *India 2014*), the Modi government has taken a number of steps to reduce the number of documents required for trade, move government clearances online, and speed up certain approvals. The Modi government has also worked to improve bureaucratic transparency and accountability by increasing bureaucratic responsiveness, reducing corruption, and consulting more with the business community.

Reforming taxation policy. *India 2014* reported that U.S. businesses have had longstanding concerns about India's tax policies. The Modi government has promised to provide fair tax treatment to foreign investors. In 2015, U.S. industry representatives report that the government has taken positive steps to reduce retroactive taxation claims. The Modi government is also seeking to simplify India's complicated tax structure by creating a single national tax, the Goods and Services Tax.

Encouraging state-level initiatives. Beyond central government efforts, the Modi government has pressed Indian states toward "competitive federalism," wherein the states compete to

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create good governance and to promote investment. The Modi government has asked states to improve their business climates, including through changes in their labor laws.

Chapter 1

Introduction

Since taking office on May 26, 2014, Prime Minister Narendra Modi of India has stated his intention to introduce a broad range of trade and investment policy changes to promote India's economic growth and development. In his first speech to Parliament as prime minister, Prime Minister Modi cited among the goals of his administration the following: to create a predictable, transparent, and fair policy environment; to build a non-adversarial tax regime; to simplify trade procedures; to reduce trade transaction time and costs; to create world-class investment and industrial regions in India; to liberalize foreign investment; and to bring renewed vigor to India's bilateral engagement with the United States in all areas, including trade and investment.⁶

At a January 2015 meeting in New Delhi of U.S. and Indian business executives, Prime Minister Modi stated that the U.S. business community would find an open and welcoming environment in India that works to “make it easy to do business,” “encourages investment and rewards enterprise,” works to “nurture innovation and protect . . . intellectual property,” and offers “a tax regime that is predictable and competitive.”⁷ The Indian government again confirmed at a June 2015 World Trade Organization (WTO) meeting that it “is committed to pursue greater reforms with an objective to liberalize trade and attract investments.”⁸

Information obtained for this report indicates that the Modi government made significant policy changes or implemented new policies in four areas concerning U.S. trade and investment during May 2014–July 2015: foreign direct investment (FDI); tariffs and customs procedures; local-content and localization requirements, particularly concerning information and communications technology (ICT) goods; and standards and technical regulations. The Modi government faced legislative challenges in passing other key policy changes and, as a result, many of India's policies and practices that were identified in *India 2014* as discouraging U.S. trade and investment did not change during May 2014–July 2015. In addition, while U.S. industry representatives and other observers saw some of the policy changes described in this

⁶ Modi, “Full Text of Hon’ble President’s Address,” June 9, 2014.

⁷ Modi, “Text of Remarks by Prime Minister,” January 26, 2015.

⁸ WTO, *Trade Policy Review: India, Minutes*, 2015, 51.

report as promising from the standpoint of U.S. trade and investment opportunities in India, they viewed other policy changes as less so.⁹

Objective

This report provides information documenting changes in India’s trade and investment policies and practices that have occurred since a recent report by the U.S. International Trade Commission (Commission or USITC). The earlier report, which appeared in December 2014, was titled *Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy* (hereafter *India 2014*).¹⁰ The U.S. House Committee on Ways and Means and the U.S. Senate Committee on Finance (the Committees) requested this follow-up report on September 25, 2014.¹¹ In their request letter, the Committees asked that the Commission conduct an investigation to include (1) information on “significant changes” made by the Modi government in policies and practices since *India 2014*, and (2) “any new relevant trade and investment policies and practices” since mid-2014.

Scope and Approach

As requested by the Committees, much of this report updates information on India’s policies and practices described in *India 2014*. That report, summarized in box 1.1, focused on India’s industrial policies that discriminate against U.S. trade and investment, looking at policies in effect during the period 2003–14. The present report examines India’s trade and investment policies and practices in effect or introduced since late May 2014 that either were not described in *India 2014* or reflect new, relevant modifications made by the Modi government through July 2015.

This report also presents the views of U.S. industry representatives and other interested parties on India’s laws, policies, and practices and their likely effects. As requested by the Committees, and as with *India 2014*, this report does not make findings regarding the legal merits of any Indian laws or policies.

⁹ WTO members at their June 2015 meeting made similar assessments. While noting India’s recent efforts to liberalize its trade and investment policies, the WTO members reported that India’s tariffs, customs procedures, and regulatory environment continue to present concerns, and encouraged India to continue efforts to align its policies more closely with international standards. WTO, *Trade Policy Review: India, Minutes*, 2015, 53–54.

¹⁰ USITC, *India 2014*, 2014.

¹¹ See appendixes A and B, respectively, for the request letter from the Committees and the *Federal Register* notices associated with this report.

Box 1.1: Key Findings in *India 2014*

In *India 2014* the Commission examined trade, investment, and industrial policies in India that restrict U.S. exports and investment, and estimated the effects these policies have on U.S. companies, U.S. workers, and the U.S. economy. The report focused on India's policies during 2007–13, and used three complementary approaches to study these issues: a quantitative analysis of the effects on the U.S. economy; a survey of U.S. companies doing business in India; and qualitative research, including a hearing and fieldwork, to produce case studies and examples that help illustrate effects of the policies on particular companies or industries.

India's main policy barriers were found to include tariffs and customs procedures, FDI restrictions, local-content restrictions, treatment of intellectual property (IP), taxes and financial regulations, regulatory uncertainty, and other nontariff measures. The effects of these policies were found to vary widely by sector. But eliminating some of them, particularly IP barriers, potentially could have small but positive macroeconomic effects on the U.S. economy.

Based on model results, if India's tariff and investment restrictions were fully eliminated and India's standards of IP protection were made comparable to U.S. and Western European levels, U.S. exports to India would rise by two-thirds (66.4 percent), and U.S. investment in India would roughly double (96.4 percent). Effects on U.S. employment would be very small, but positive. Improving India's IP protection alone would have a much larger impact than eliminating tariff and investment restrictions—U.S. exports to India would increase by 55.5 percent due to improved IP protection alone. Improving IP protection would also increase U.S. investment in India by 68.1 percent, starting from small current baseline levels.^a Model results further estimated that eliminating India's trade and investment restrictions would have favorable macroeconomic effects for the United States. However, those effects would, again, be small, given the large size of the U.S. economy and the small baseline levels of current U.S. trade and investment in India.

Survey results estimated that the share of U.S. companies engaged in India substantially adversely affected by restrictive Indian policies rose from 18.8 to 26.1 percent between 2007 and 2013. Shares for individual sectors in 2013 ranged from 7.7 to 44.1 percent. India's tariffs, taxes, and financial regulations were estimated to have the heaviest negative effects on U.S. companies. Other issues, including India's FDI and IP policies, were also estimated to have large negative effects on specific U.S. industries.^b

Source: Compiled by the Commission.

^a USITC, *India 2014*, 2014, table 3.19, 93; table 3.25, 99.

^b *Ibid.*, 65, 81, table 3.10.

Analysis of the economic effects of these laws, policies, and practices on U.S. trade and investment was beyond the scope of the request by the Committees. Moreover, a quantitative analysis of India's trade and investment policy changes during May 2014–July 2015, such as was

done for *India 2014*, would not have been feasible due to the lack of necessary economic data.¹²

The Commission's research and data collection for this report concluded in July 2015.¹³ Thus, this report covers a period of just 14 months. The shortness of the period covered by this report presented several challenges to assessing policy changes under the Modi government:

- **Limited time to pass new laws and implement regulations.** Enacting new laws on trade and investment policy takes time. The Modi government has introduced several bills into Parliament that impact, or could impact, India's trade and investment policies. As further explained in chapter 2, India's Parliament has enacted a few of these bills, including one that liberalizes foreign investment in the insurance sector and others providing investment-friendly changes in the mining sector.¹⁴ To date, two other noteworthy bills have been introduced into Parliament but have not yet been passed. One concerns changes in land acquisition procedures, while the other mandates a major tax system overhaul by replacing a system of national and state taxes with a comprehensive national tax.¹⁵
- **Limited time to see the results of policies that have been implemented.** Both U.S. and Indian sources have stressed that trade and investment policy changes need to evolve over time to become fully realized and sustainable. Moreover, businesses also need time to develop and carry out responses to the new measures by making new investments and increasing exports.¹⁶ U.S. industry representatives in the United States and in India reported that not enough time has passed for them to be able to measure the impact of the Modi government's policy changes to date.¹⁷

¹² For *India 2014*, the Commission conducted quantitative analysis through economic modeling and a survey of U.S. businesses of trade and investment policy changes in India during 2003–13. For this report, however, the lack of necessary comparable economic data for the brief period May 2014 through July 2015 precluded a similar quantitative analysis. Moreover, data on trade and investment in the short term can be too variable to be meaningful, and the effects of policy changes may take some time to be reflected in economic data. As an Organisation for Economic Co-operation and Development (OECD) report notes "economic statistics are produced with some lag and the full effect of the measures on the economy will take time to become apparent." OECD, *Trade and the Economic Effects of Responses to the Economic Crisis*, 2010, 65.

¹³ Information in this report is current through July 2015. Commission staff updated a few key developments in this report before its September 2015 delivery to the Committees, as indicated in selected footnotes in the report.

¹⁴ These bills are described later in this report. See appendix E for a timeline of legislation related to trade and investment in India under the Modi government.

¹⁵ The land acquisition legislation and taxation issues are described in chapter 2. See appendix E for a timeline of legislation related to trade and investment in India under the Modi government.

¹⁶ Confederation of Indian Industry, written submission to the USITC, April 24, 2015, 11–12; industry representatives, interviews by USITC staff, New Delhi, May 14, 2015.

¹⁷ *Ibid.*

- **To become fully effective, trade and investment policy changes need support from other policy and institutional changes.** Representatives of a variety of U.S. businesses doing or planning to do business in India indicated that, in addition to investment laws, other policies also impede U.S. economic engagement in India. Examples include India’s land acquisition laws, taxation policies, and overall business climate, especially problems with bureaucratic transparency and accountability.¹⁸ These topics, and developments during 2015, are addressed in more detail in chapter 2.

Information Sources

As requested by the Committees, this report is based on publicly available information. Primary sources of information on Indian laws and regulations included Indian government websites and websites that document such legal matters. Appendix E presents a chronological list of key trade and investment-related laws, policies, and practices introduced in India during the period May 2014–July 2015.

The Commission held a public hearing in Washington, DC, on May 5, 2015. Witnesses included representatives of nongovernmental organizations and U.S. industry and trade associations. Written submissions were provided by a diverse group of U.S. industry and trade associations, as well as associations representing the international business community engaged in India.

The Commission also conducted over 90 interviews with industry representatives and government officials in the United States and in India for this report. As part of this outreach, USITC staff traveled to India in April and May 2015 to conduct about 50 interviews total in Bangalore, Hyderabad, Mumbai, New Delhi, and Jaipur. Staff spoke with a wide range of industry representatives, representatives of industry associations, individuals from academic and non-private-sector institutions, and certain Indian government officials.¹⁹ Industry representatives interviewed included those of Indian companies as well as of U.S. and other foreign companies and affiliates operating in India.

¹⁸ USITC, *India 2014*, 2014, 208, 270–71; USITC, hearing transcript, May 5, 2015, 20 (testimony of Richard Rossow, Center for Strategic and International Studies); USITC, hearing transcript, May 5, 2015, 195 (testimony of Mukesh Agha, U.S.-India Business Council); U.S. industry representatives, interviews by USITC staff, Bangalore, April 21, 2015; U.S. industry representatives, interviews by USITC staff, Mumbai, April 22, 2015; academic and U.S. industry representatives, interviews by USITC staff, New Delhi, May 12 and 14, 2015. A report by the OECD also describes the way that trade and investment policy changes in India are linked with the need for institutional changes in India’s labor regulations, education and workforce training systems, infrastructure bottlenecks, land acquisition regulations, and complex tax system. OECD, *OECD Economic Surveys: India 2014*, 2014, 71–91.

¹⁹ The Commission conducted extensive outreach to obtain meetings with a wide range of Indian government officials. Staff met with officials in the Ministry of Agriculture, the Ministry of Railways, the Reserve Bank of India, and officials in the state of Rajasthan.

Organization of the Report

The remainder of this chapter provides background information on U.S. economic engagement with India under the Modi government and summarizes findings of other sources on the Modi government's trade and investment-related policy changes through July 2015.

Chapter 2 describes cross-cutting trade and investment-related economic initiatives, policies, and practices under the Modi government, including initiatives designed to improve India's economic infrastructure; improve the ease of doing business; strengthen regulatory transparency and bureaucratic accountability; facilitate land acquisition; promote new investment-friendly state-level initiatives; and improve taxation policies.

Chapter 3 examines India's policy changes with respect to FDI. In *India 2014* the Commission identified several types of FDI policy barriers in India, including FDI equity limits, the foreign investment authorization process, prohibition of FDI in certain industries, and restrictions on the form of business establishment that FDI could be used for. This chapter provides an overview of FDI policies, including a number of new developments since December 2014, in the insurance, defense and civil aerospace, railway infrastructure, construction, mining, and civil nuclear energy sectors.

Chapter 4 examines changes in India's tariff and customs policies since December 2014. The Commission reported in *India 2014* that India's high and variable tariff structure and unreliable administration of customs regulations limited U.S. exports and discouraged wider investment in India.

Chapter 5 describes changes in India's trade and investment policies with respect to local-content and localization requirements—broadly defined in this report as policies that require foreign firms to purchase Indian inputs, conduct a share of business in India, conduct certain business activities in India, or submit to India-specific testing or registration. *India 2014* identified several local-content and localization requirements as barriers to U.S. trade, particularly those regarding information and communication technology products and solar power generation products.

Chapter 6 has two parts. The first part describes changes in India's trade and investment policies with respect to standards and technical regulations. *India 2014* reported that certain Indian standards, technical regulations, conformity assessments, and labeling requirements restrict U.S. exports of a number of products. The second part presents six case studies that examine developments in late 2014 and 2015 in a variety of policy areas, most of which were reported in *India 2014* as barriers to U.S. trade and investment in India. The case studies involve

agricultural products; food products; alcoholic beverages; cosmetics and personal care products; medical devices; and clinical trials.

Chapter 7 describes developments in India’s trade and investment policies and practices with respect to intellectual property rights (IPR). IPR policies remain a key area of focus for U.S. companies across many economic sectors. *India 2014* described the IPR-related barriers in the areas of trade secrets and regulatory test data, patents, trademarks, and copyrights. Model results in that report found that improvements in India’s IPR policies could have substantial positive effects on FDI and U.S. exports to India, although from small current baseline levels, as discussed above in box 1.1.

U.S. Economic Engagement with India

As described in *India 2014*, U.S. economic engagement in India has grown substantially in the past decade, albeit from a very small base. Given the fact that this investigation only covers a 14-month period—May 2014 to July 2015—it is not surprising that there is little evidence of significant change in the level of economic engagement during that time.²⁰ India ranked as the 18th-largest single-country market for U.S. total exports of goods in 2014, unchanged from 2013.²¹ U.S. exports of goods and services to India did rise by 5.6 percent; they totaled \$37.7 billion in 2014, up from \$35.7 billion in 2013.²² At yearend 2014, however, India still accounted for less than 2 percent of total U.S. exports of goods and services and for less than 1 percent of the stock of U.S. overseas investment.²³

²⁰ Data on long-term investment trends as of mid-2015 indicate that foreign investors have shown greater interest and willingness to commit in India since Prime Minister Modi assumed office in mid-May 2014. Overall FDI inflows into India increased from \$36.0 billion in the previous fiscal year (FY) to \$44.9 billion during India’s FY 2014–15 (April 1–March 31). This FY 2014–15 total represented an increase of 24.0 percent and was almost equal to the recorded high of \$46.6 billion in FY 2011–12. FDI from the United States into India was 93.5 percent higher in India’s FY 2014–15 than the annual average for 2000–2015, though the latter, as noted above, represents a very small base. Government of India, DIPP, “Fact Sheet on Foreign Direct Investment (FDI),” 2015.

²¹ USITC DataWeb/USDOC (accessed July 31, 2015).

²² Leading U.S. exports to India in 2014 included nonindustrial diamonds, aircraft and parts, nonmonetary gold, and coal. USITC, *The Year in Trade*, 2014, 200.

²³ *India 2014* provides data on U.S. economic engagement in India during 2001–13. USDOC, BEA, International Economic Accounts: U.S. Trade in Goods and Services by Selected Countries and Areas, tables 1, 4, and 7 (accessed July 13, 2015); USDOC, BEA, U.S. Direct Investment Abroad: Balance of Payments and Direct Investment Position Data; Position on a Historical-Cost Basis, Country Detail by Selected Industry (accessed July 13, 2015).

Other Assessments of the Modi Government's Policy Changes in 2015

Six international nongovernment organizations that monitor country policy developments have reported so far in 2015 that the Modi government has taken important steps to implement trade and investment policy changes during its first year, from May 2014 to mid-2015.

Highlights of their observations follow:

- In February 2015, the president of the Asian Development Bank “lauded India’s brighter growth prospects in the light of the government’s bid to improve the business environment and accelerate infrastructure investment.”²⁴
- In March 2015, the International Monetary Fund (IMF) said it “welcomed the [Indian] authorities’ comprehensive policy initiatives. . . . Among these initiatives are recent policy measures to revive investment . . . and improve the ease of doing business.”²⁵
- The WTO reported in April 2015 that the Modi government had “continued its efforts to liberalize and facilitate trade” and had relaxed FDI restrictions in some sectors.²⁶
- Also in April 2015, the World Bank reported that the Modi government “has started implementing reforms spanning a number of areas,” including “efforts to improve the business environment; liberalization of FDI; enhancing investment in infrastructure; speedier resolution of corporate disputes; and simplified and lower corporate taxation.”²⁷
- The Organisation for Economic Co-operation and Development (OECD) observed in June 2015 that India’s “policies are becoming more favorable to investment,” and that the Modi government’s “structural reforms to improve the ease of doing business and the Make in India initiative should boost corporate investment.”²⁸
- A June 2015 United Nations report stated that “[India’s] FDI inflows are likely to maintain an upward trend in 2015. . . . Manufacturing is gaining strength, as policy

²⁴ ADB, “ADB President Lauds India’s Efforts at Accelerating Growth,” February 5, 2015.

²⁵ IMF, “IMF Executive Board Concludes 2015 Article IV Consultation,” March 11, 2015.

²⁶ The WTO particularly noted India’s efforts to streamline customs procedures and to implement trade-facilitation measures, as well as measures intended to attract foreign investment by opening more sectors to FDI and reducing investment restrictions in certain sectors. WTO, *Trade Policy Review: India*, 2015, 8–9. See also Confederation of Indian Industry, written submission to the USITC, April 24, 2015, 1.

²⁷ World Bank, *India Development Update*, 2015, i.

²⁸ While not a member of the OECD, India is an OECD partner country. OECD, *OECD Economic Outlook*, 2015, 130. The Make in India initiative works to encourage companies doing business in India to manufacture their products in India, focusing on innovation and job creation in 25 target sectors. It is described in more detail in chapter 2.

efforts to revitalize the sector are sustained, including for instance the launch of the ‘Make in India’ Initiative.”²⁹

However, despite the Modi government’s commitments and the implementation of these first-year policy changes, some of these same sources expressed concerns that India so far in 2015 continues to fall short of addressing the full range of its policies and practices that hinder trade and investment by the United States and some of India’s other trading partners. Some of their concerns include:³⁰

- The IMF observed that for India, “boosting potential growth would require addressing long-standing supply bottlenecks . . . as well as bolstering the business climate.”³¹
- The OECD found that India’s “economy could grow by more than 8 percent if ambitious structural reforms, in particular the GST [a proposed goods and services tax], land acquisition, and labor laws were to be approved by the Parliament.”³²
- The WTO reported that “India continues to use trade policy as a means to regulate domestic supply and to address short-term objectives,” that “frequent changes to policy are disruptive and reduce predictability of India’s trade policy,”³³ that “India’s import regime remains complex,”³⁴ and that India has made “no significant changes” to its technical regulations and industry standards affecting international trade.³⁵
- Moreover, the World Bank stated that “the pace of these [policy reform] efforts would need to be maintained or even stepped up to unleash the productivity and scale enhancement needed for the Indian firms to become globally competitive.”³⁶

²⁹ UNCTAD, *World Investment Report, 2015*, 2015, 48.

³⁰ As discussed in the subsequent chapters of this report, three sets of sources—witnesses at the Commission’s hearing, individuals interviewed by USITC staff, and written submissions received for this report—noted successful trade and investment policy changes undertaken by the Modi government during its first year in office. They also described some recent positive assessments from U.S. businesses operating in India. In addition, however, these sources commented on many Indian policy shortcomings that continue to hinder U.S. trade and investment.

³¹ IMF, “IMF Executive Board Concludes 2015 Article IV Consultation,” March 11, 2015.

³² OECD, *OECD Economic Outlook*, 2015, 131.

³³ WTO, *Trade Policy Review: India*, 2015, 26–27.

³⁴ *Ibid.*, 9.

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Chapter 2

Cross-Cutting Initiatives, Policies, and Practices

In India's general election of May 2014, the Bharatiya Janata Party (BJP) won a majority in India's lower house, and Narendra Modi became the prime minister of India. Since taking power the Modi government has gradually presented key policies and initiatives designed to achieve its goals for trade and investment policy.

This chapter examines major themes in the Modi government's trade and investment policy approach, focusing on cross-cutting initiatives, policies, and practices that impact a variety of goods and services sectors. Some of the themes covered involve non-policy (or "doing business") issues that shape India's overall business climate, which in turn influence the effectiveness of specific policies on trade and investment. In *India 2014*, the Commission's survey results indicated that these non-policy issues substantially affected 15.2 percent of U.S. companies engaged in India.³⁷ In addition, such issues provide an important context for the Modi government's approach to trade and investment policies.

The chapter begins by describing the Modi government's general approach to trade and investment policy. It then describes three new Modi government initiatives designed to promote economic growth and development—Make in India, Digital India, and the Smart Cities Mission—that have implications for trade and investment policies. The chapter then reviews policy changes and goals in several different areas: improving the ease of doing business in India, creating greater bureaucratic transparency and accountability, and encouraging state-level initiatives. The chapter concludes by describing four categories of taxation policies and practices that affect foreign companies under the Modi government. Table 2.1 summarizes the issues identified in this chapter, along with the cross-cutting changes that the Modi government has made between May 2014 and July 2015.

³⁷ USITC, *India 2014*, 2014, 76–78.

Table 2.1: Cross-cutting initiatives, policies, and practices, May 2014–July 2015

Policy or practice	Description of barrier pre-May 2014	Changes found under Modi government
Infrastructure	Poor roads and other physical infrastructure; unreliable electricity supply; weak communications infrastructure.	Launched initiatives with goals of improving infrastructure: Digital India (communications infrastructure) and Smart Cities Mission (physical infrastructure and electricity).
Ease of doing business	Bureaucratic and regulatory delays that create challenges in trading and in starting or expanding a business.	Reduced number of documents required for trade; moved more government clearances online; seeks to speed up certain clearances.
Transparency and bureaucratic accountability	Implementation of regulations by government officials subject to discretion. Corruption problematic for some firms.	Seeks to reduce bureaucratic absenteeism and increase responsiveness; seeks to reduce corruption; consults more with business community.
Land acquisition	Difficulty in acquiring land for business operations.	Issued ordinances to temporarily facilitate land acquisition beginning in December 2014. A bill to change land acquisition rules was introduced into Parliament in February 2015 and passed by the lower house in March 2015. No land acquisition bill was passed during the monsoon session (July 21–August 13, 2015) of Parliament.
State-level regulations	Regulations that restrain business activity in some states.	Provided guidance to states on adopting good practices to improve business environment; started to measure state-level business climates and publish results to encourage policy changes that would improve climates.
Taxation	High tax rates; retroactive taxation (new tax claims against previously concluded transactions); disputes over transfer pricing for tax purposes. Complex tax system that creates uncertainty and added costs.	Made statements about avoiding retroactive taxation and paring back minimum alternative tax (MAT) assessments; exempted foreign institutional investors from MAT; proposed a bill to simplify tax system using a unified goods and services tax (GST). A constitutional amendment to implement the GST was introduced into Parliament in December 2014 and passed by the lower house in May 2015, but no further legislative action on the GST was taken during the monsoon session (July 21–August 13, 2015) of Parliament.

Source: Compiled by the Commission.

The Modi Government’s Approach to Trade and Investment Policy

This section provides an overview of the Modi government’s vision for trade and investment policy. It describes expectations for policy changes from industry representatives and media commentators. The section then summarizes the Modi government’s policy framework as articulated in the 2015–16 Union Budget and the 2015–20 Foreign Trade Policy statement.³⁸ This section also outlines some of the legislative challenges the Modi government has faced in passing bills, and describes how the government has responded to those challenges using executive branch ordinances.

Public Expectations of Policy Changes

The BJP’s 2014 election manifesto³⁹ promised to increase economic growth and job creation through “consistent, long-term” policies. These policies included opening up certain sectors to foreign direct investment (FDI), providing predictable taxation policies, simplifying doing business, encouraging manufacturing in India, and improving infrastructure.⁴⁰ After the election, U.S. industry representatives and media commentators expressed optimism that the Modi government had a mandate for—and an interest in—making policy changes that promote greater trade and investment.⁴¹ Some press reports voiced the expectation that the government would quickly pursue major policy changes in key areas, such as coal mining, agriculture, and labor.⁴² Other press reports cautioned that the Modi government’s lack of a majority in the upper house of Parliament could hinder significant progress.⁴³

Government Statements on Policy Changes

In its 2015 *Economic Survey*, an annual summary of the Indian economy and related policies, India’s Ministry of Finance stated that “Big Bang reforms” were not the right benchmarks by

³⁸ India’s Foreign Trade Policy is issued every five years, and is annually reviewed and adjusted. Government of India, Ministry of Commerce and Industry (MOCI), Department of Commerce, “Handbook of Procedures,” April 1, 2015.

³⁹ The Election Commission of India has stated that election manifestos typically showcase a political party’s “declared ideology . . . and its policies and programmes for the Country/State and people at large” and thus can be considered “a reference document or benchmark for the public at large for what a political party stands for.” Election Commission of India, “Letter to Recognized Political Parties,” August 2, 2013.

⁴⁰ BJP, *Election Manifesto 2014*, April 7, 2014, 26–30.

⁴¹ USITC, *India 2014*, 2014, 54.

⁴² Fensom, “Will Investors’ Gamble on Modi Pay Off?” May 20, 2014; CNBC-TV18, “Expect Major Agri Reforms,” June 16, 2014; *Daily Mail* (UK), “Down with Corruption and Red Tape!” May 21, 2014.

⁴³ Domínguez, “‘Quick Economic Turnaround’ Expected of Modi,” May 16, 2014; Thomas, “First Budget Will Be Key Test,” May 30, 2014; Bagri, “Analysts Have High Hopes,” May 19, 2014.

which to measure the Modi government’s policy successes. Instead, the survey stated that India’s policy approach should embrace “a persistent, encompassing, and creative incrementalism.” The survey called, however, for bold steps in a few areas that would signal a decisive departure from the past. These steps would be aimed at addressing key imperatives, such as ramping up investment; rationalizing subsidies; creating a competitive, predictable, and clean tax policy environment; and accelerating privatization.⁴⁴ The Modi government’s overall economic policy—as set forth in the 2015–16 Union Budget and the 2015–20 Foreign Trade Policy—seeks to address a number of key trade and investment issues (box 2.1).

Legislative Challenges Slow New Policy Changes

The BJP’s victory in the May 2014 elections marked the first time since 1984 that any party has won an absolute majority of seats in the lower house (Lok Sabha) of India’s Parliament. Following the election, Prime Minister Modi’s BJP-led government⁴⁵ took control of the lower house, but not the upper house (Rajya Sabha).⁴⁶ As reported in *India 2014*, the Modi government soon approved amendments to India’s FDI regulations allowing domestic and foreign investment in certain segments of the railways sector for the first time, and increasing the FDI equity cap in the defense sector from 26 percent to 49 percent.⁴⁷ However, the Modi government has faced legislative challenges in passing other key policy changes because it does not control the upper house of Parliament. To hasten the introduction of a few key initiatives, the Modi government has issued ordinances, time-limited legislation issued by the president under specific circumstances when both houses of Parliament are not in session (box 2.2).⁴⁸

⁴⁴ Government of India, Ministry of Finance, *Economic Survey 2014–15*, February 2015, 2.

⁴⁵ The BJP is the lead party in India’s National Democratic Alliance (NDA) coalition government. India’s head of state is the president, Pranab Mukherjee, who appoints the prime minister. The prime minister acts as an advisor to the president and leader of the Council of Ministers. Kronstadt, “India’s New Government and Implications,” 2014. For information on the BJP and the NDA, see BJP, “Statement of BJP National President,” April 4, 2015.

⁴⁶ Under India’s legislative process, bills introduced into either house of Parliament must be passed by both houses and then approved by the president (special procedures apply to joint sittings of both houses). Government of India, *An Introduction to Parliament of India*, 2007, 6; Government of India, “Government and Administration,” updated May 21, 2015. See also WTO, *Trade Policy Review: India*, 2015, 24.

⁴⁷ USITC, *India 2014*, 2014, 54. FDI is discussed in more detail in chapter 3.

⁴⁸ For more information on ordinances and the legislative powers of the Indian president, see Government of India, “Constitution of India,” chapter III, article 123, <http://indiacode.nic.in/coiweb/welcome.html> (accessed July 31, 2015).

Box 2.1: Trade and Investment Objectives in the Union Budget and Foreign Trade Policy

2015–16 Union Budget: When Finance Minister Arun Jaitley presented the Modi government’s 2015–16 budget to Parliament in February 2015, he described the budget as a chance “to indicate the direction and the pace of India’s economic policy.” He stressed the government’s desire to attract foreign investment and to make India “the manufacturing hub of the world.” Among measures included in the budget speech were efforts to:

- simplify India’s tax structure by introducing a bill to replace India’s system of federal and state taxes with a unified goods and services tax (GST);
- “provide a hassle free structure to the taxpayers” by committing to avoid retroactive taxation of foreign companies and by clarifying capital gains taxes on foreign portfolio fund investors;
- promote the growth of Indian defense equipment and aircraft manufacturers;
- continue reducing red tape by changing a large number of procedures, rules, and regulations; and
- increase the basic customs duty on certain articles and reduce duties on others.

2015–20 Foreign Trade Policy: Minister of Commerce and Industry Nirmala Sitharaman introduced the Modi government’s 2015–20 Foreign Trade Policy on April 1, 2015.^a It covers four core areas: simplification and merger of export and import incentive schemes; measures to increase domestic manufacturing, especially of products with high domestic content and value addition; measures to facilitate trade and improve the ease of doing business in India; and other trade incentives. The minister’s statement described the Foreign Trade Policy’s objectives as:

- Raising India’s share of world exports from the current 2 percent to 3.5 percent by 2020.
- Developing policies to provide “a stable and sustainable policy environment for foreign trade.”
- Enhancing trade and investment linkages with the U.S. economy and using the Make in India initiative as a tool to simplify and further open India’s investment policies to attract U.S. investment.
- Addressing constraints such as infrastructure bottlenecks, high transaction costs, complex procedures, and constraints in manufacturing.
- Helping the Indian economy to gain global competitiveness.

Sources: Government of India, MOCI, “Foreign Trade Policy 2015–2020 Unveiled,” April 1, 2015; Government of India, MOCI, Department of Commerce, “Highlights of the Foreign Trade Policy 2015–2020,” n.d. (accessed July 2, 2015); Ministry of Finance, “Budget 2015–16 Marks the Beginning of Co-operative Federalism,” February 28, 2015; Government of India, Ministry of Finance, “Union Budget 2015–16: Union Budget of India,” n.d. (accessed July 2, 2014); Government of India, Indian Parliament, “Budget in Parliament,” 2014; Jaitley, “Budget Speech,” February 28, 2015; PRS Legislative Research, “Parliament Session Alert Budget Session: February 23–May 08, 2015,” February 23, 2015, 1.

^a The government published several minor amendments to the Foreign Trade Policy in June, July, and August 2015.

Box 2.2: Ordinances Impact Trade and Investment Policies

The Modi government has used presidential ordinances in several key areas that have significant bearing on India's trade and investment policies. An ordinance is a time-limited law issued when Parliament is out of session—typically when a similar bill is pending in Parliament. An ordinance must be approved by Parliament within six weeks of Parliament's reassembling or it lapses, although the president can reissue it.

The Modi government has instituted ordinances on opening FDI in the insurance sector, opening coal mining to domestic and foreign investment, and liberalizing the mining and minerals sector (FDI in these sectors is discussed in more detail in chapter 3), as well as facilitating land acquisition. As of mid-August 2015, three of these ordinances (all except the one on land acquisition) had been passed by Parliament and enacted into law.

- An ordinance liberalizing FDI in the insurance sector was issued by the Modi government on December 27, 2014. Among other things, that ordinance increased the cap for foreign equity in Indian insurance companies from 26 percent to 49 percent. A bill to make this ordinance permanent was passed by Parliament on March 12, 2015.
- An ordinance opening certain government-controlled coal mining blocks to private domestic and foreign investors, allowing them to mine coal for sale on the open market, was issued by the Modi government on October 21, 2014 (and reissued on December 31, 2014). A bill to make the ordinance permanent was introduced into Parliament on December 10, 2014, and passed by Parliament on March 20, 2015.
- An ordinance introducing provisions to increase transparency in India's mining and minerals sector by providing for auctions via competitive bidding was issued by the Modi government on January 12, 2015. A bill to make the ordinance permanent was introduced into Parliament on February 24, 2015, and was passed by Parliament on March 20, 2015.
- An ordinance making it easier to acquire certain land in India was issued by the Modi government on December 31, 2014. A bill to replace the ordinance was introduced into Parliament on February 24, 2015; however, as further described in box 2.3, no land acquisition bill was passed during the monsoon session (July 21–August 13, 2015) of Parliament.^a

Sources: PRS Legislative Research, "Monthly Policy Review, March 2015," April 1, 2015; PRS Legislative Research, "Monthly Parliament Review, December 2014," January 2, 2015; PRS Legislative Research, "Parliament as a Law Making Body," December 2, 2014; WTO, *Trade Policy Review: India*, 2015, 25.

Notes: See appendix E for a timeline of legislation related to trade and investment in India under the Modi government. Land acquisition issues are discussed in more detail in box 2.3 and appendix H.

^a Prime Minister Modi announced that the government would not reissue the ordinance on land acquisition in August 2015. Government of India, "English Rendering of PM's 'Mann Ki Baat,'" August 30, 2015.

New Economic Initiatives

The Modi government has introduced several economic initiatives to restructure India’s economy, all of which seek to impact India’s trade and investment policies. These initiatives link long-term economic goals with near-term changes to policies and practices, and will sometimes rely on the participation and cooperation of foreign companies to succeed. This section briefly discusses Make in India, which includes investment liberalization and other policy changes to incentivize domestic manufacturing. The section also describes two initiatives designed to improve India’s infrastructure: Digital India, which seeks to enhance communications infrastructure, and the Smart Cities Mission, which aims to upgrade India’s physical infrastructure. The financial inclusion initiative,⁴⁹ which seeks to increase the availability and affordability of formal financial services in rural India, is discussed in appendix F.

Make in India

Before the April 2014 election, the BJP’s manifesto set out the party’s goal of turning India into “a hub for cost competitive labour-intensive mass manufacturing.”⁵⁰ Make in India, which was launched by Prime Minister Modi on September 25, 2014, is a cross-cutting initiative that seeks to realize this objective by encouraging foreign investors and domestic companies to manufacture in India.

Make in India seeks to open up new sectors to FDI, create new “Smart Cities” and industrial clusters, simplify regulatory approvals for opening manufacturing facilities, improve the business climate, and provide tax relief and other incentives for manufacturing in India. Make in India reemphasizes and expands upon the goals of the 2011 National Manufacturing Policy (created under the previous government). The new initiative’s targets include creating 100 million new manufacturing jobs and growing the share of manufacturing in India’s gross domestic product (GDP) from 16 percent to 25 percent by 2022.⁵¹

The initiative includes certain economic priorities and policies for Indian manufacturing, such as promoting employment-intensive industries; creating national investment and manufacturing zones to promote world-class manufacturing in India; simplifying the manufacturing regulatory environment; and offering economic incentives for environmentally friendly industries and for small and medium-sized enterprises.⁵² As part of the initiative, the Indian government

⁴⁹ The Indian government’s official name for this plan is the Pradhan Mantri Jan-Dhan Yojana.

⁵⁰ BJP, *Election Manifesto 2014*, April 7, 2014, 29.

⁵¹ Make in India, “National Manufacturing” (accessed June 8, 2015); *Christian Science Monitor*, “Survey: Modi Has an Answer for India,” November 20, 2014, 5.

⁵² Government of India, MOCI, DIPP, “Make in India: Policies,” n.d. (accessed July 10, 2015).

identified 25 priority growth sectors for the Indian economy.⁵³ Modi approved an action plan for Make in India in December 2014, but the details have not been made public.⁵⁴

U.S. and Indian industry representatives interviewed in India generally welcomed the Make in India initiative, but expressed concern that the government had not yet published a detailed map for policy changes.⁵⁵ U.S. industry representatives also expressed concerns that Make in India could lead the Modi government to restrict foreign trade and investment through local-content requirements and other policies.⁵⁶ In December 2014, for example, the Modi government cited Make in India in issuing guidelines to favor locally manufactured electronic goods in government procurement.⁵⁷ In addition, U.S. and Indian industry representatives and researchers stated that India's limitations in several areas—weak physical infrastructure, poor reliability of power and water supplies, and challenges of land acquisition—raise the costs of manufacturing in India; they felt the Modi government would struggle to achieve the goals of Make in India without policy changes to address these limitations.⁵⁸

Digital India and Smart Cities Mission Seek to Improve India's Infrastructure

In *India 2014*, the Commission's survey results indicated that infrastructure challenges substantially affected 7.6 percent of U.S. companies engaged in India. Companies reported that weaknesses in India's physical infrastructure (e.g., poor road conditions) were bigger obstacles to progress than problems in India's communications structure and electricity supply.⁵⁹ The BJP election manifesto promised to seek improvements in the country's physical infrastructure,

⁵³ These sectors are automotive, automotive components, aviation, biotechnology, chemicals, construction, defense manufacturing, electrical machinery, electronic systems, food processing, information technology (IT) and business process management, leather, media and entertainment, mining, oil and gas, pharmaceuticals, ports, railways, renewable energy, roads and highways, space, textiles and garments, thermal power, tourism and hospitality, and wellness. Government of India, MOCI, DIPP, "Make in India: Sectors," n.d. (accessed July 10, 2015).

⁵⁴ *Economic Times*, "Make in India: PM Narendra Modi Approves," December 30, 2014.

⁵⁵ U.S. and Indian industry representatives, interviews by USITC staff, Hyderabad, April 16–17, 2015; U.S. industry representative, interview by USITC staff, Bangalore, April 20, 2015; Intellectual Property Owners Association, written submission to the USITC, June 2, 2015, 1. Local-content requirements are described in chapter 5.

⁵⁶ ITIF, written submission to the USITC, June 2, 2015, 2; U.S. industry representative, interview by USITC staff, Washington, DC, April 30, 2015; U.S. government official, interview by USITC staff, March 19, 2015. Local-content requirements are described in chapter 5.

⁵⁷ The Make in India initiative's links to the Preferential Market Access policy for electronics are discussed in chapter 5.

⁵⁸ Research official, interview by USITC staff, Washington, DC, March 9, 2015; U.S. industry representative, interview by USITC staff, Hyderabad, April 16, 2015; industry representative, interview by USITC staff, Hyderabad, April 17, 2015; U.S. industry representative, interview by USITC staff, Bangalore, April 20, 2015; Indian industry representative, interview by USITC staff, Mumbai, April 22, 2015; U.S. industry representative, interview by USITC staff, Mumbai, April 23, 2015.

⁵⁹ USITC, *Trade, Investment, and Industrial Policies in India*, 2014, 76–78, 189, 286.

electricity supply, and telecommunications infrastructure; this theme was reiterated in the Foreign Trade Policy.⁶⁰ The Modi government has introduced two major initiatives to upgrade India’s infrastructure: Digital India and the Smart Cities Mission.

Digital India

Prime Minister Modi introduced the Digital India initiative in his August 15, 2014, Independence Day speech.⁶¹ Digital India brings together many existing Indian government programs (some created by the previous government) that seek to increase the availability to Indian citizens of high-speed Internet access, electronic financial services, online government services (“e-governance”), and information technology training. The program also sets the goal of increasing domestic manufacturing of electronics so that India will no longer be a net importer of these goods by 2020. The program envisions connecting India’s rural population by bringing broadband access to 250,000 rural villages and facilitating universal access to mobile phone networks. The program seeks to increase e-governance by building electronic databases, creating digital workflows for ministries, and enabling government to field more forms and complaints online.⁶² The National Telecom Roadmap, which is linked to Digital India’s goals of domestic manufacturing, includes certain local-content requirements.⁶³

In a joint statement issued during a bilateral summit meeting of the two heads of states in September 2014, the United States and India “committed to partner on the Digital India initiative, with the goal of enhancing digital infrastructure, deploying e-governance and e-services, promoting industry collaboration, and digitally empowering India’s citizens.”⁶⁴ In January 2015, the United States and India agreed to take additional steps to further U.S. partnership in advancing the implementation of Digital India and to strengthen bilateral cooperation on information and communications technology.⁶⁵

⁶⁰ BJP, *Election Manifesto 2014*, April 7, 2014, 29–33. The Foreign Trade Policy is discussed in more detail in box 2.1.

⁶¹ Government of India, Office of the Prime Minister, “Text of PM’s Speech at Red Fort,” August 15, 2014. The Cabinet approved Digital India on August 7, 2015. Government of India, “Digital India: A Program to Transform India,” August 20, 2014.

⁶² Government of India, “Digital India: A Programme to Transform India,” n.d. (accessed July 1, 2015).

⁶³ The National Telecom Roadmap is discussed in Chapter 5.

⁶⁴ White House, “U.S.-India Joint Statement,” September 30, 2014.

⁶⁵ White House, “Shared Effort: Progress for All,” January 25, 2015.

Smart Cities Mission

India launched its Smart Cities⁶⁶ initiative, led by the Ministry of Urban Development, in 2014.⁶⁷ The Cabinet formally approved the two parts of the program—the Smart Cities Mission and the Atal Mission for Rejuvenation and Urban Transformation of 500 Cities (AMRUT)—in April 2015.⁶⁸ The Smart Cities Mission seeks to develop 100 Indian cities into Smart Cities, which would feature upgraded infrastructure and a variety of other amenities. The AMRUT Mission plans to deliver infrastructure improvements through public-private partnerships with Indian and foreign companies.⁶⁹

Since late 2014, the U.S. private sector has increased its participation in the development of smart cities in India. The U.S.-India Business Council conducted a weeklong mission in India in November 2014 to explore opportunities for U.S. partnership in the smart cities effort.⁷⁰ In January 2015 the U.S. Trade and Development Agency (USTDA) signed three memorandums of understanding (MOUs) to support the development of smart cities in three Indian states—Visakhapatnam (Vizag), in Andhra Pradesh; Ajmer, in Rajasthan; and Allahabad, in Uttar Pradesh—with the respective Indian state governments. Under the MOUs, USTDA is to contribute funding for feasibility studies, study tours, training, and other projects to be mutually determined.⁷¹

Improving the Ease of Doing Business

Poor Rankings Inspire Modi Government to Improve India's Business Climate

As another means of pursuing economic growth and job creation, the Modi government is seeking to increase the ease of doing business in India. India has been assessed as a difficult country in which to do business: it was ranked 165th out of 184 countries in the Business

⁶⁶ Smart cities are cities in which information and communications technology (ICT) replaces traditional ways of communication and service delivery to reduce costs, energy use, and consumption of other resources. The concept of smart cities also envisions much more widespread social and economic benefits, including ultimately providing more efficient urban transportation; providing safer public spaces; effectively meeting the needs of an aging population; and allowing more a more interactive and responsive city administration. European Union, "Smart Cities," June 22, 2015.

⁶⁷ Much of the vision for the Smart Cities project is laid out in a draft concept note released in March 2014. See Government of India, Ministry of Urban Development, "Draft Concept Note on Smart City Scheme," December 3, 2014.

⁶⁸ Government of India, Cabinet, "Union Cabinet Approves Atal Mission," April 29, 2015.

⁶⁹ Smart Cities India, "Smarter Solutions for a Better Tomorrow," n.d. (accessed July 24, 2015).

⁷⁰ USIBC, "USIBC Takes U.S.-India Smart Cities Initiative Forward," November 22, 2014.

⁷¹ PRS Legislative Research, "Cabinet Approves Mission for Urban Rejuvenation and Smart Cities," April 2015, 4–5.

Freedom component of the Heritage Foundation’s Index of Economic Freedom in 2015.⁷² In *India 2014*, USITC survey results indicated that 22.4 percent of U.S. companies with foreign affiliate sales in India faced difficulty getting required permits, approvals, or licenses for investment. In addition, judicial and administrative efficiency issues substantially affected 11.8 percent of U.S. companies engaged in India.⁷³

Moreover, India was ranked 140th out of 189 economies in the World Bank’s Doing Business rankings in 2014,⁷⁴ and the ranking declined to 142nd in 2015. Among the five BRICS countries (Brazil, Russia, India, China, and South Africa), India is the lowest ranked (table 2.2). Compared to countries with similar purchasing power parity (PPP) GDP⁷⁵ per capita (table 2.3), India ranked ahead of Bolivia (157th in 2015), Laos (148th), and Nigeria (170th), but behind countries like Moldova (63rd), Vietnam (78th), the Philippines (95th), and Pakistan (128th).

Table 2.2: Rankings of India and other BRICS economies in the World Bank’s Doing Business reports

Country	2012	2013	2014 ^a	2015
South Africa	35	39	37	43
Russia	120	112	64	62
China	91	91	93	90
Brazil	126	130	123	120
India	132	132	140	142

Source: Compiled by the Commission, “Doing Business Data” (accessed June 8, 2015); World Bank and IFC, *Doing Business 2013*, October 23, 2012; World Bank and IFC, *Doing Business 2012*, October 20, 2011.

^a Rankings for 2014 are adjusted rankings, which have been provided by the World Bank and IFC to reflect data corrections.

⁷² Calculated by USITC staff from Heritage Foundation, “2015 Index of Economic Freedom: Explore the Data” (accessed June 23, 2015).

⁷³ USITC, *India 2014*, 2014, 76, 229.

⁷⁴ The World Bank Group’s Doing Business project seeks to measure business-related regulations and their enforcement across economies from the perspective of domestic small and medium-sized enterprises. The annual Doing Business reports rank economies according to their ease of doing business, with a ranking of 1 going to the economy with the most business-friendly regulatory environment. In the 2015 report, the ranking was based on each economy’s “distance to frontier”—the disparity between that economy’s performance and the best observed performance—in 10 categories, including starting a business, paying taxes, and trading across borders. World Bank Group, “About the World Bank Group Doing Business,” n.d. (accessed July 1, 2015).

⁷⁵ Purchasing power parity (PPP) GDP is GDP that has been converted to “international dollars” for each country, which have the same purchasing power in that country as U.S. dollars do in the United States. The PPP GDP is in current international dollars, based on the International Comparison Program’s 2011 results. World Bank, World DataBank (accessed July 22, 2015).

Table 2.3: Rankings of selected lower-middle-income countries in the World Bank’s Doing Business reports

Country	PPP GDP per capita, 2013 (international \$) ^a	2013 ranking	2014 ranking ^b	2015 ranking
Moldova	4,692	83	82	63
Ghana	4,001	64	69	70
Vietnam	5,294	99	72	78
Philippines	6,536	138	86	95
Honduras	4,292	125	100	104
Nicaragua	4,579	119	126	119
Pakistan	4,602	107	127	128
Uzbekistan	5,168	154	149	141
India	5,418	132	140	142
Laos	4,822	163	155	148
Bolivia	6,131	155	151	157
Nigeria	5,602	131	175	170

Source: Compiled by the Commission, “Doing Business Data” (accessed July 22, 2015); World Bank and IFC, *Doing Business 2013*, October 23, 2012; World Bank, World DataBank (accessed July 22, 2015).

^a Purchasing power parity (PPP) GDP is GDP that has been converted to “international dollars,” which have the same purchasing power in that country as U.S. dollars do in the United States. The PPP GDP is in current international dollars, based on the International Comparison Program’s 2011 results.

^b Rankings for 2014 are adjusted rankings, which have been provided by the World Bank and IFC to reflect data corrections.

The BJP’s election manifesto promised to make it easier to do business in India by simplifying regulations, improving turnaround time on environmental permits, and attempting to create a single window⁷⁶ for clearances.⁷⁷ Citing India’s low ranking in the World Bank’s Doing Business reports, the Department of Industrial Policy and Promotion of the Ministry of Commerce and Industry has asserted that India is in “urgent need of reforms.”⁷⁸

In September 2014, Modi stated that transparency and simplification in government decisions and rules could bring India into the top 50 of the World Bank’s Doing Business rankings; in January 2015 he announced that this was the government’s goal.⁷⁹ Government officials stated in April and May 2015 that the government has been developing an action plan on regulatory

⁷⁶ The UN Centre for Trade Facilitation and Electronic Business defines a single window as “a facility that allows parties involved in trade and transport to lodge standardized information and documents with a single entry point to fulfil all import, export, and transit-related regulatory requirements.” Although the term is typically used to describe import/export-related facilities, some countries use it to refer to a single entry point for starting a new business. UN, Economic Commission for Europe, “Recommendation and Guidelines on Establishing a Single Window,” 2005, 7.

⁷⁷ BJP, *Election Manifesto 2014*, April 7, 2014, 29.

⁷⁸ Government of India, *Assessment Framework for State Level Reforms*, June 2015, 2.

⁷⁹ Government of India, Ministry of External Affairs, “English Rendering of Prime Minister Shri Narendra Modi’s Address,” September 26, 2014; Government of India, Ministry of External Affairs, “Remarks by Prime Minister at the India-U.S. Business Summit,” January 26, 2015.

and doing-business issues, but the plan had not yet been released as of mid-July 2015.⁸⁰ The government is also seeking to simplify the process of acquiring land (box 2.3).

Box 2.3: Land Acquisition Legislation under the Modi Government

The Modi government has sought to reshape India’s laws on land acquisition in order to improve the ease of doing business.^a Since January 2014, land acquisition in India has generally been governed by the Right to Fair Compensation in Land Acquisition, Rehabilitation and Resettlement Bill, 2013. The bill requires consent of at least 80 percent of affected landowners before acquiring land for private-sector projects, and consent of at least 70 percent of affected landowners for land acquired for public-private partnerships. It also mandates a Social Impact Assessment to determine if the proposed acquisition serves a public purpose, and requires the buyer to provide resettlement and rehabilitation packages to affected families.^b

In *India 2014*, some foreign investors reported that difficulty in acquiring land for business operations had kept them from setting up their facilities in their preferred locations. Of surveyed companies with foreign affiliate sales of goods in India, 5.4 percent were substantially affected by land acquisition restrictions. In the agriculture and food sector, 29.4 percent of companies had faced challenges in buying or using land.^c According to witnesses at the Commission’s hearing, individuals interviewed in India by Commission staff, and written submissions received for this report, land acquisition in India remains a hindrance to FDI in 2015.^d

The Modi government issued an ordinance in December 2014 that not only eliminated the consent requirements and the Social Impact Assessment but also sought to facilitate land acquisition for industrial corridors and other priority projects.^e Despite widespread opposition from farmers’ unions, civil society groups, and opposition lawmakers, the lower house of Parliament passed a proposed bill to make the ordinance permanent on March 10, 2015. The bill, however, encountered strong opposition in the upper house of Parliament and was sent to joint Parliamentary committees for revision. The Modi government reissued the ordinance in April and May 2015.^f No land acquisition bill was passed during the monsoon session (July 21–August 13, 2015) of Parliament.

Source: Compiled by the Commission.

^a Jaitley, “Tax Reforms in India,” April 16, 2015.

^b *Gazette of India*, The Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement, Act, 2013, September 27, 2013.

^c USITC, *India 2014*, 2014, 208–10, 226–28, 271.

^d USITC, hearing transcript, May 5, 2015, 163, 195–96 (testimony of Mukesh Aghi, U.S.-India Business Council); industry representatives, interviews by USITC staff, Bangalore, April 15, 2015; Mumbai, April 23, 2015; New Delhi, May 12–15, 2015.

^e Jaitley, “Tax Reforms in India,” April 16, 2015.

^f Prime Minister Modi announced that the government would not reissue the ordinance on land acquisition in August 2015. Government of India, “English Rendering of PM’s ‘Mann Ki Baat,’” August 30, 2015.

⁸⁰ *Economic Times*, “Make in India: Government Taking Steps,” May 5, 2015; *Livemint*, “No Proposals Under Consideration to Review FDI Policy,” April 29, 2015.

Policy Changes to Improve the Ease of Doing Business

To simplify starting or expanding a business, the Modi government has made several notable changes aimed at digitizing and streamlining the process. The Modi government has enlarged India's online eBiz portal—launched by the previous government as a pilot project in January 2013—to include more central and state government services.⁸¹ In the portal, upon answering a set of questions related to location, industry, size, and other characteristics, companies can view a list of required licenses and permits, some of which they can apply for through the portal. The government plans to continue adding more central-government services and including more state-level services in the portal.⁸² The Modi government has also created online processes for companies to get required environmental and forest clearances.⁸³ Several states have their own online portals for certain permits and clearances.

The government has also implemented a series of changes to reduce the number of clearances required and to speed up the processing time for certain authorizations. For example, the government reduced the number of documents required to import or export to three, where previously it had required seven documents to export and 10 documents to import.⁸⁴ The government has also extended the validity period of industrial licenses⁸⁵ from two to three years and has stated that the Ministry of Home Affairs will provide security clearance on industrial licenses within 12 weeks of application.⁸⁶

Industry Views on Doing Business Changes

U.S. and Indian industry representatives interviewed for this report were generally enthusiastic about the government's intent to improve the business environment.⁸⁷ Several industry

⁸¹ The eBiz portal, which is available at <https://www.ebiz.gov.in/>, was originally launched in January 2013 and re-launched in January 2014. As of mid-July 2015, the portal included 14 central government services. Mehdudia, "eBiz Portal Launched," January 29, 2013; Government of India, "Anand Sharma Launches eBiz Portal," January 20, 2014; Government of India, "Major Initiatives on Improving 'Ease of Doing Business,'" May 31, 2015.

⁸² *Economic Times*, "Government Plans to Integrate 36 Services," June 3, 2015.

⁸³ Government of India, "Major Initiatives on Improving 'Ease of Doing Business,'" May 31, 2015, 3.

⁸⁴ Government of India, "Mandatory Documents Required for Export and Import," March 12, 2015. Other measures to reduce customs clearance delays are described in chapter 4.

⁸⁵ The industrial license is required to operate a business in certain industries, including alcoholic beverage production and aerospace and defense equipment manufacturing. Government of India, "Issue of Industrial License," <https://www.ebiz.gov.in/industriallicense> (accessed August 18, 2015).

⁸⁶ Government of India, "Major Initiatives on Improving 'Ease of Doing Business,'" May 31, 2015, 2.

⁸⁷ U.S. industry representative, interview by USITC staff, Mumbai, April 23, 2015; U.S. industry representative, interview by USITC staff, New Delhi, May 15, 2015; U.S. industry representative, telephone interview by USITC staff, May 6, 2015; USITC, hearing transcript, May 5, 2015, 119; U.S.-India Business Council, written submission to the USITC, June 2, 2015.

representatives reported that the Modi government has made the process faster, easier, and more predictable for environmental clearances for new projects, import licenses for pharmaceuticals, and other authorizations.⁸⁸ Other industry representatives, however, reported that they had not yet experienced concrete improvements, and instead had encountered delays in obtaining permits similar to those they experienced before May 2014.⁸⁹

Bureaucratic Transparency and Accountability

The Modi government has sought to create a more responsive, accountable bureaucracy. In *India 2014*, the Commission reported that some U.S. and foreign companies engaged in India had complained that the discretionary implementation of regulations, lack of regulatory transparency, corruption, and other forms of regulatory uncertainty substantially hindered their ability to do business in India.⁹⁰ The BJP's election manifesto expressed the goal of making government decision-making processes more transparent and accountable in order to reduce corruption.⁹¹

Once in office, the Modi government instituted programs to encourage greater responsiveness and public accountability of civil servants.⁹² The government also announced that auctions for coal-mining licenses and telecommunications spectrum bandwidth would take place online to avoid the corruption that it said had affected such auctions under the previous government.⁹³ Furthermore, the Modi government has released several notable draft policies for public consultation and comment, including the December 2014 draft National Intellectual Property Rights Policy (discussed in more detail in chapter 7) and the April 2015 model bilateral investment treaty (described in more detail in chapter 3). In addition, the government has set goals in Digital India to make more government services available online.⁹⁴

Industry and government representatives interviewed in India generally agreed that higher-level central government officials under the Modi government are more open to dialogue with industry than under the previous government. They often reported that government ministers,

⁸⁸ Industry representatives, interviews by USITC staff, Hyderabad, April 16–17, 2015; industry representatives, interviews by USITC staff, Mumbai, May 12–14, 2015.

⁸⁹ Industry representatives, interviews by USITC staff, Hyderabad, April 16–17, 2015; industry representative, interview by USITC staff, Mumbai, April 22, 2015; industry representative, telephone interview by USITC staff, May 6, 2015; industry representative, interview by USITC staff, New Delhi, May 12–13, 2015.

⁹⁰ USITC, *Trade, Investment, and Industrial Policies in India*, 2014, 76–78, 209, 241, 246–249.

⁹¹ BJP, *Election Manifesto 2014*, April 7, 2014, 10–11.

⁹² Gowen, “No Golf, Long Days Are New Norm,” July 11, 2014; AFP, “India’s Work-shy Bureaucrats Face Attendance Tracking,” August 30, 2014.

⁹³ Bellman, “The Top 10 Successes,” May 26, 2015; *Economist*, “Uncurl the Body,” May 23, 2015.

⁹⁴ Government of India, “Digital India,” August 20, 2014.

junior ministers, or joint secretaries had reached out to foreign businesses about the current policy environment or pending policy changes.⁹⁵ Furthermore, some companies expressed the view that the government was open to hearing about their concerns and acting on them.⁹⁶ Media reports about industry opinions also generally state that the Modi government has been seeking greater input from foreign industry and has reduced high-level corruption.⁹⁷

However, U.S. and Indian industry representatives interviewed report that at the lower levels of bureaucracy, government officials have not changed their approach to reflect the Modi government's goals.⁹⁸ Several representatives interviewed in India report that lower-level officials are slow or reluctant to make ordinary regulatory decisions to approve licenses or permits for fear that doing so might leave them liable to charges of corruption.⁹⁹

State-level Initiatives and Competitive Federalism

To facilitate further improvement in India's trade and investment climate, the Modi government has sought to create a larger role for individual Indian states in policies that affect state-level trade and investment. The motivation for spurring sub-federal policy changes is clear: World Bank Group President Jim Yong Kim stated that India's Doing Business ranking would be 50 places higher if all Indian states had the business climate of the state of Gujarat.¹⁰⁰

⁹⁵ Industry representative, interview by USITC staff, Mumbai, April 23, 2015; government official, interview by USITC staff, New Delhi, May 11, 2015; industry representatives, interviews by USITC staff, New Delhi, May 12 and May 14, 2015; government official, interview by USITC staff, Washington, DC, June 17, 2015.

⁹⁶ Industry representative, Hyderabad, April 17, 2015; industry representatives, interviews by USITC staff, New Delhi, May 12 and May 14, 2015; U.S.-India Business Council, written submission to the USITC, June 2, 2012, 2.

⁹⁷ Tremblay, "India: Under New Management," May 4, 2015, 10; Gupta and Gupta, "Top-level Corruption's Down," February 22, 2015; Guha, "Corruption at Highest Levels in India Has Disappeared," June 4, 2015.

⁹⁸ Industry representative, interview by USITC staff, Hyderabad, April 16, 2015; industry representative, interview by USITC staff, Mumbai, April 23, 2015; industry representatives, interviews by USITC staff, New Delhi, May 12 and May 14, 2015; research official, interview by USITC staff, Jaipur, May 18, 2015; USITC, hearing transcript, May 5, 2015, 198.

⁹⁹ Under India's Prevention of Corruption Act, 1988, a public servant who "obtains . . . any valuable thing or pecuniary advantage without any public interest" is committing criminal misconduct. The Act does not define what constitutes "public interest," which industry representatives and press articles believe creates a chilling effect on bureaucratic actions—even when officials receive no advantage. Finance Minister Arun Jaitley has emphasized the need to clarify "public interest" and other terms to separate genuine corruption from honest mistakes. In April 2015, the Modi government proposed amendments to the act, which had stalled in Parliament under the Singh government; the amendments seek to eliminate the "public interest" language. Industry representative, interview by USITC staff, Hyderabad, April 16, 2015; government official, interview by USITC staff, New Delhi, April 11, 2015; research official, interview by USITC staff, Jaipur, May 18, 2015; Madhu, "Why the Prevention of Corruption Act Needs to Be Amended," March 15, 2015; Government of India, "Proposal to Move Official Amendments," April 29, 2015; PRS Legislative Research, "Legislative Brief," July 23, 2014.

¹⁰⁰ World Bank Group, "Transcript of Press Conference," July 23, 2014.

India's states vary considerably in their business environments,¹⁰¹ which can affect foreign companies' investment and trading decisions.¹⁰² In *India 2014*, the Commission's survey results indicated that 22.6 percent of U.S. companies engaged in India perceived at least one state-level policy to have a greater effect on their operations than national policies did.¹⁰³ The BJP election manifesto set goals of including states in promoting trade and attracting investment, and of providing greater fiscal independence to states.¹⁰⁴ In pursuit of these goals, the 2015–16 Union Budget increased the share of tax revenues given to the states from 32 to 42 percent of total revenues.¹⁰⁵

Improving Sub-federal Business Climates

In early 2014, under the previous government, the Department of Industrial Policy and Promotion commissioned a study by Accenture, *Best Practices to Improve the Business Environment across India*. The study highlighted six areas—taxation, labor law, infrastructure and utilities, land, environmental clearances, and general clearances—in which state-level measures could be effective in improving the business climate.¹⁰⁶ The Modi government has guided states to adopt good practices in these areas.¹⁰⁷ The government reports that several states and territories have achieved successful changes in expediting electric connections, enabling online applications for construction permits, and simplifying tax registration.¹⁰⁸

To encourage state-level initiatives, the Modi government plans to rank each of the states on their business climates. The Department of Industrial Policy and Promotion has released a framework to assess states' business climates, which included a 285-question survey for state

¹⁰¹ A report by the World Bank Group that ranked 17 Indian cities cited "large variations in the way local government regulations enhance or restrain business activity." World Bank Group, "Doing Business in India 2009," 2009, 10.

¹⁰² Industry representatives, interviews by USITC staff, Hyderabad, April 16, 2015; Bangalore, April 20–21, 2015; New Delhi, May 12–13, 2015.

¹⁰³ USITC, *Trade, Investment, and Industrial Policies in India*, 2014, 74–75.

¹⁰⁴ BJP, *Election Manifesto 2014*, April 7, 2014, 7.

¹⁰⁵ The average percentage of tax revenues given to states over the previous three years was 32 percent, whereas the new budget committed to raise that to 42 percent for the coming five years. Government of India, Ministry of Finance, Office of the Chief Economic Adviser, "The Economic Survey of India, 2014–15," March 9, 2015; *Economic Times*, "Modi Government Cuts Social Sector Allocations to States," June 1, 2015.

¹⁰⁶ The study, which was released in early May 2014, is available at http://dipp.nic.in/English/publications/Reports/improve_BusinessEnvironment_06May2014.pdf.

¹⁰⁷ *Economic Times*, "Congress Rushes to Disown DIPP Report," May 8, 2014; Government of India, *Assessment Framework for State Level Reforms*, June 2015, 2.

¹⁰⁸ Government of India, "Major Initiatives on Improving 'Ease of Doing Business,'" May 20, 2015, 4.

governments.¹⁰⁹ The government plans to “name and shame” states that are not making positive changes.¹¹⁰

Competitive Federalism

To complement efforts to improve state business climates, the government has emphasized “competitive federalism,” which involves Indian states competing to create good governance and to promote investment. The Modi government has also stated that it will allow states to take the initiative to improve their doing-business climates, particularly on labor issues (box 2.4).

Industry Views on State-level Changes

Industry and government representatives interviewed have mixed views on the effect of “competitive federalism” and efforts to improve state-level business climates. Some stated that they have not yet felt the effects of competitive federalism, while others reported increased competition among the states for attracting investment and improving the doing-business climate.¹¹¹ Several industry representatives and analysts expressed concern that implementation of state-level projects and initiatives would remain a problem in less business-friendly states; they pointed out that states already control a number of policies that impact trade and investment and that only a few states had delivered positive changes.¹¹²

¹⁰⁹ The framework is available at http://dipp.nic.in/English/Investor/Ease_Doing_Business_08June2015.pdf.

¹¹⁰ Zeenews.com, “Ease of Doing Business: DIPP,” June 15, 2015; Government of India, *From Planning to NITI*, February 8, 2015, 11; *Economic Times*, “DIPP Releases Framework to Rank States,” June 8, 2015; *Business Standard*, “Ease of Doing Business: Centre,” March 19, 2015; *Business Standard*, “DIPP to Release State Rankings,” July 25, 2015. The government released a report on September 14, 2015, that assesses each state on business climate reforms implemented during January 1, 2015, to June 30, 2015. Government of India, *Assessment of State Implementation of Business Reforms*, September 2015, 6.

¹¹¹ Industry representative, interview by USITC staff, Mumbai, April 23, 2015; industry representative, telephone interview by USITC staff, May 6, 2015; government official, interview by USITC staff, New Delhi, May 11, 2015; industry representatives, interviews by USITC staff, New Delhi, May 12 and May 14, 2015.

¹¹² Industry representative, interview by USITC staff; USITC, hearing transcript, May 5, 2015, 73–74 (testimony of Richard Rossow, Center for Strategic and International Studies).

Box 2.4: Labor Initiatives under the Modi Government

India has been cited as having a labor market that creates challenges for businesses: a recent World Bank report stated that India has “one of the most rigid labor markets in the world.”^a The World Economic Forum ranked India 112th out of 144 economies reviewed for labor market efficiency in 2014.^b To aid efforts to boost Indian manufacturing, the BJP election manifesto promised to “undertake labour reforms” by working with industry and unions to review India’s “outdated, complicated and even contradictory” laws.^c One such law is the Industrial Disputes Act, 1947, which requires companies with more than 100 employees to apply for government permission before firing any workers or shutting down.^d

Soon after the Modi government formed, the Ministry of Labour sought public comments in June 2014 on proposals to amend certain labor provisions, including the Factories Act, which covers work conditions in factories. In 2015, the government published proposals to consolidate and update many Indian labor regulations through the draft Labour Code on Industrial Relations Bill 2015. Indian unions have objected to the bill because it would allow firms with 300 employees or less to fire workers without government permission and would place new restrictions on union registration.^e The Modi government has implemented an online labor compliance and inspection portal designed to eliminate arbitrary inspections,^f but none of the proposals had been passed by Parliament as of mid-August 2015.

Given the challenges in achieving national labor law changes, the Modi government has sought to encourage Indian states—particularly those under BJP control—to amend their labor laws. Under Article 254(2) of the Constitution of India, the President of India can choose to approve state-level laws that contravene the national Parliament’s laws on certain matters, including labor. The state of Rajasthan passed several labor law amendments, including one allowing easier firing of workers, in August 2014; the President of India approved the amendments in November 2014. Later in November 2014, Madhya Pradesh adopted an ordinance to amend labor laws; the Modi government approved some of these in April 2015.^g Governments of several other states, including Maharashtra, are considering similar policy changes.^h

Source: Compiled by the Commission.

^a World Bank Group, “World Development Report 2014,” 2013, 190–191.

^b World Economic Forum, “The Global Competitiveness Report 2014–2015,” September 2014, 18.

^c BJP, *Election Manifesto 2014*, April 7, 2014, 29–31.

^d Government of Punjab, Department of Labor, “The Industrial Disputes Act, 1947,” n.d., 35–39, http://pblabour.gov.in/pdf/acts_rules/inustrial_disputes_act_1947.pdf (accessed July 9, 2015).

^e *Economic Times*, “Industrial Relations Bill: Trade Unions to Press,” May 5, 2015; *Times of India*, “Govt’s Push for Labour Reforms,” May 5, 2015.

^f Government of India, “Prime Minister Inaugurates Shramev Jayate,” October 16, 2014.

^g Jha, “President Okays Rajasthan Labour Reforms,” November 8, 2014; Rai and Vaishnav, “Narendra Modi’s One Year Ledger,” May 24, 2015; Jha, “Modi Govt Questions Madhya Pradesh’s Labour Reforms,” April 21, 2015.

^h Surabhi, “Make in India Brings Labour Reforms Back,” December 30, 2014; Kakodkar, “Maharashtra Scraps Ordinance Plan to Amend Factories Act,” July 5, 2015.

Taxation Policies under the Modi Government

India's tax policies and practices are longstanding concerns for U.S. businesses. In *India 2014*, the Commission reported that variability and uncertainty related to taxation created significant challenges and additional costs for foreign firms.¹¹³ In particular, that report found that "taxes and financial issues are the second most widespread issue affecting companies," with reported problems including high, variable, and nontransparent taxes; unpredictable state-level excise taxes; export taxes; and high and discriminatory entertainment taxes.¹¹⁴ In preparing this report, the Commission heard that those issues remain problematic for U.S. businesses.¹¹⁵

The BJP election manifesto promised to provide a simpler and "non-adversarial" tax system.¹¹⁶ The Modi government has committed to providing fair tax treatment to foreign investors. Government officials have pledged "to end the previous Indian government's record of 'tax terrorism'" and restore the rule of law and sanctity of contract.¹¹⁷ The Modi government is also seeking to simplify India's complicated tax structure by creating a single national tax, the Goods and Services Tax (GST).

This section provides information on four tax-related issues of particular interest to foreign investors that received attention from the Modi government between May 2014 and July 2015: retroactive taxation; the minimum alternative tax (a specific type of retroactive taxation); tax audits on transfer pricing; and the GST. Overall, although the Modi government has made positive statements and has taken some steps to change India's taxation environment, it remains too soon to evaluate whether these will improve foreign companies' experiences.

Retroactive or Retrospective Taxation

A legal provision dating to 2012 allows Indian tax authorities to bring certain new tax claims against companies for previously concluded transactions (e.g., the indirect transfer of shares of an Indian company between two non-Indian companies).¹¹⁸ Cases based on such claims

¹¹³ USITC, *India 2014*, 2014, 243.

¹¹⁴ USITC, *India 2014*, 2014, 69, 72–75, 116, 120, 241–243, 254, 266, 287, 341.

¹¹⁵ USITC, hearing transcript, May 5, 2015, 25, 76, 150, 154–5 (testimony of Michael Schlesinger, International Intellectual Property Alliance); hearing transcript, May 5, 2015, 154 (testimony of Richard Rossow, Center for Strategic and International Studies); industry representative, interview by USITC staff, New Delhi, May 13, 2015; industry representatives, interviews by USITC staff, Bangalore, April 20, 2015.

¹¹⁶ BJP, *Election Manifesto 2014*, April 7, 2014, 27.

¹¹⁷ Jaitley, "India Promises Investors a Fair Deal," April 26, 2015.

¹¹⁸ The government of India has indicated its intention to ordinarily not make any change retrospectively which creates a new liability, and stated its intention to review cases before undertaking any action. A committee was established on August 28, 2014, to consider this matter further. Government of India, Ministry of Finance, "Concept of Retrospective Taxation," December 12, 2014. See also Jaitley, "India Promises Investors a Fair Deal," April 26, 2015.

affected a number of companies based in the United States and elsewhere. The Modi government has acknowledged the impact of retroactive taxation on foreign investors, and has stated that “retrospective tax provisions adversely impact the stability and predictability of the taxation regime and resort to such provisions shall be avoided.”¹¹⁹ Foreign investors—including several witnesses at the Commission’s hearing for this investigation—acknowledged that the Indian government has taken some positive steps to reduce the scope of retroactive taxation; they also stated that retroactive taxation policies continue to reduce India’s attractiveness as an investment destination.¹²⁰ An industry representative and a research official expressed disappointment that the government had not changed the law to eliminate retroactive taxation.¹²¹

Minimum Alternative Tax

The Minimum Alternative Tax (MAT) is another type of retroactive taxation that was originally imposed on domestic companies to ensure they paid their taxes due to the Indian government. According to reports in early 2015, Indian tax authorities were retroactively applying the MAT to foreign portfolio fund investors.¹²² Foreign fund managers in India expressed concern about this practice, which can reportedly result in tax demands of 20 percent of their profits, and have sought relief in Indian courts.¹²³

India’s 2015 Finance Bill exempts foreign institutional investors with income from securities transactions, royalties, and technical services from the MAT from April 1, 2015, onward.¹²⁴ After its approval by Parliament, the Finance Bill was implemented on May 14, 2015,¹²⁵ and the Indian government has stated that it would begin paring back retroactive MAT assessments on

¹¹⁹ Jaitley, “Budget 2015–2016: Speech of Arun Jaitley,” February 28, 2015. See also Confederation of Indian Industry, written submission to the USITC, April 24, 2015, 5.

¹²⁰ USITC, hearing transcript, May 5, 2015, 18, 148 (testimony of Richard Rossow, Center for Strategic and International Studies); hearing transcript, May 5, 2015, 25, 76, 160–1 (testimony of Mukesh Aghi, U.S.-India Business Council); Roy and Kala, “India Won’t Make Retrospective Changes,” March 19, 2015.

¹²¹ Research official, interview by USITC staff, New Delhi, May 13, 2015; industry representative, interview by USITC staff, Hyderabad, April 17, 2015.

¹²² USITC, hearing transcript, May 5, 2015, 19, 148 (testimony of Richard Rossow, Center for Strategic and International Studies); USITC, hearing transcript, May 5, 2015, 160–1, 229 (testimony of Mukesh Aghi); Pilling, “India Should Carve Its Tax Code in Stone,” May 13, 2015.

¹²³ Anand, “Foreign Investors Fight Back in India,” April 30, 2015; *Times of India*, “Minimum Alternate Tax Demand on Foreign Investors,” May 4, 2015.

¹²⁴ The 2015 Finance Bill was introduced as part of the 2015–16 Union Budget. Government of India, “Union Budget 2015–2016: Finance Bill,” <http://indiabudget.nic.in/bill.asp> (accessed August 3, 2015); Confederation of Indian Industry, written submission to the USITC, April 24, 2015, 5. See also Deloitte, “Budget 2015: Impact on Foreign Portfolio Investors,” February 2015; *Gazette of India*, “The Finance Act, 2015,” May 14, 2015; Shearman & Sterling LLP, “India: Recent Developments,” July 13, 2015.

¹²⁵ *Gazette of India*, “The Finance Act, 2015,” May 14, 2015.

foreign institutional investors.¹²⁶ It remains too early, however, to gauge the effectiveness of these new practices.

Tax Audits on Transfer Pricing

Transfer pricing is the value at which multinational enterprises (MNEs) trade products, services, or assets between the MNEs' different units or groups across borders.¹²⁷ Revenue authorities in many countries are increasingly scrutinizing the activities of MNEs because of the possibility that transfer pricing "could be used to shift profits into low tax jurisdictions even if the MNE carries out little business activity in that jurisdiction."¹²⁸

Transfer pricing has been a longstanding concern in U.S.-India commercial relations,¹²⁹ resulting in a backlog of mutual agreement procedure (MAP)¹³⁰ cases involving U.S. firms operating in India's information technology (IT) and IT-enabled services sectors.¹³¹ In January 2015, during President Obama's trip to India, U.S. and Indian negotiators announced an agreement on a framework to resolve pending double-taxation cases arising from transfer pricing.¹³² The United States also initiated a process for accepting bilateral advance-pricing agreements.¹³³ Although it

¹²⁶ Anand, "India to Ease Up on Demands," May 1, 2015. In September 2015, the Ministry of Finance stated that the Modi government would seek to amend India's Income-tax Act to clarify that the MAT would not apply retroactively to foreign investors' profits prior to April 1, 2015. Government of India, "Government Accepts the Recommendation of the Justice A.P. Shah Committee," September 1, 2015.

¹²⁷ The Organisation for Economic Co-operation and Development (OECD) explains that transfer pricing rules generally "require MNEs to price, for tax purposes, their internal or intra-group transactions and calculate profits as if the transactions had taken place between independent businesses—the arm's length principle." The arm's-length principle seeks to ensure a consistent basis for allocating profit and to help protect MNEs from double taxation (taxation of the same profit by more than one tax administration), thus ensuring parity of tax treatment for MNEs and domestic firms. OECD, *Dealing Effectively with the Challenges of Transfer Pricing*, 2012, 14.

¹²⁸ OECD Observer, "Transfer Pricing: Keeping It at Arm's Length," January 3, 2002.

¹²⁹ USITC, hearing transcript, May 5, 2015, 18, 140, 146 (testimony of Richard Rossow, Center for Strategic and International Studies). See also Confederation of Indian Industry, written submission to the USITC, April 24, 2015, 5–6.

¹³⁰ Tax treaties typically contain MAPs, under which taxpayers may request designated representatives ("competent authorities") to resolve international tax disputes involving double taxation as well as inconsistencies in the application or interpretation of a convention. OECD, *Manual on Effective Mutual Agreement Procedures*, 2007, 8.

¹³¹ According to press reports, Indian tax authorities were concerned that foreign firms were under-invoicing the value of products, services, or shares offered to parent companies and thereby lowering their tax liabilities in India. Chatterjee, "India, U.S. Near Tax Pact," January 22, 2015.

¹³² Confederation of Indian Industry, written submission to the USITC, April 24, 2015, 6; Deloitte, "India, United States Reach Agreement," January 21, 2015.

¹³³ These are agreements between a taxpayer and tax authority determining the methodology for pricing the taxpayer's international transfers for future years. Confederation of Indian Industry, written submission to the USITC, April 24, 2015, 5. For U.S. procedures, see U.S. Department of Treasury, "Acceptance of Pre-filing Conference Requests," March 11, 2015.

is still too early to assess the effectiveness of these new measures, recent reporting indicates that these tax dispute cases remain problematic for U.S. investors in India.¹³⁴

Goods and Services Tax

India has long debated replacing its complicated central government and state-level indirect tax structure with a single national tax, the Goods and Services Tax (GST). The GST aims to drastically simplify India's existing indirect tax structure by subsuming all indirect taxes on products or services,¹³⁵ except customs duties,¹³⁶ at the state and central levels and consolidating them into a single tax structure jointly administered by the state and central governments.¹³⁷ It is estimated that the GST would increase Indian GDP by 1 to 2 percent.¹³⁸ Many foreign and Indian industry representatives report that the GST would reduce their tax compliance costs, make it easier to trade across Indian states, and improve the ease of doing business in India.¹³⁹

As presented to Parliament in May 2015, the GST would cover all goods and services—with the exception of alcohol—with a single value-added rate specific to each product and set by the GST Commission, which could change those rates at any time.¹⁴⁰ Currently, there are a wide variety of state and central taxes, each with different rates for different products.¹⁴¹ State governments maintain state value-added taxes as well as taxes on the shipment of goods into their territories, while the central government maintains separate taxes for the interstate movement of goods, as well as one value-added tax on the manufacture of goods and another on the provision of services.¹⁴² Under the GST, as noted above, these taxes would be subsumed into a single tax jointly administered by the state and central governments. By applying the tax

¹³⁴ Beniwal and Shrivastava, "Modi's Goal of Tax-Friendly India," June 7, 2015; industry representative, interview by USITC staff, Hyderabad, April 16, 2015; industry representative, interview by USITC staff, Bangalore, April 21, 2015.

¹³⁵ An indirect tax is a tax on products or services (e.g., sales tax or value added tax) or production (e.g., payroll tax on labor). OECD, *National Accounts*, 2014, 92. The GST would generally cover taxes on products or services but not taxes on production.

¹³⁶ The GST would include other duties that India applies to imported goods, such as the Additional Customs Duty, the Special Additional Duty, and assorted cesses. *India 2014* describes these in more detail. USITC, *India 2014*, 2014, 115–17; KPMG India, "India Inc.," April 2015; Government of India, Empowered Committee of State Finance Ministers, "Goods and Services Tax," n.d. (accessed July 22, 2015).

¹³⁷ Jaitley, "Tax Reforms in India," April 16, 2015.

¹³⁸ Jaitley, "Tax Reforms in India," April 16, 2015; research official, email message to USITC staff, May 6, 2015; NCAER, "Moving to Goods and Service Tax in India," December 2009.

¹³⁹ USITC, hearing transcript, May 5, 2015, 131 (testimony of Michael Schlesinger, International Intellectual Property Alliance) and 153–54 (testimony of Richard Rossow, Center for Strategic and International Studies); industry representatives, interviews by USITC staff, Mumbai, April 23–24, 2015, and New Delhi, May 12–15, 2015.

¹⁴⁰ Jaitley, "Tax Reforms in India," April 16, 2015.

¹⁴¹ PRS, "GST Bill," n.d. (accessed July, 7 2015).

¹⁴² KPMG India, "India Inc.," April 2015.

on imports only once, the GST would reduce the effect of different duties being compounded onto one another.¹⁴³

Additionally, the GST would fundamentally alter India's tax structure by basing taxation on the location of consumption instead of the location of production. Currently, value-added taxes are collected in the states where goods and services are produced, which results in the few states with large manufacturing industries collecting the major share of tax revenue. Under the GST, taxes would be based on consumption, which would lead to a more equal distribution of tax revenue among the states.¹⁴⁴

On December 19, 2014, the Modi government introduced a constitutional amendment in Parliament that would allow the government to implement the GST.¹⁴⁵ The lower house of Parliament approved the amendment on May 6, 2015, but the upper house did not act upon the amendment during the monsoon session (July 21–August 13, 2015) of Parliament.¹⁴⁶ The government had originally targeted an implementation date of April 2016, but the path forward for the GST is currently unclear. Nevertheless, Indian industry representatives and research officials expressed the belief that the GST will ultimately be passed.¹⁴⁷

¹⁴³ The Indian tariff system compounds duties and taxes on imported goods, which can add significantly to the cost of importing. USITC, *India 2014*, 2014, 115–17.

¹⁴⁴ KPMG India, "India Inc.," April 2015.

¹⁴⁵ PRS, "GST Bill," n.d. (accessed July 7, 2015); *Economic Times*, "Government Moves Bill to Roll Out GST," December 20, 2014.

¹⁴⁶ Jaitley, "Union Budget Speech," February 28, 2015; Kazmin, "India's Modi Suffers GST Tax Blow," May 12, 2015.

¹⁴⁷ Research officials, interviews by USITC staff, New Delhi, India, May 12 and 14, 2015; industry representatives, interviews by USITC staff, New Delhi, May 15, 2015, and Mumbai, April 24, 2015.

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Chapter 3

Foreign Direct Investment

Since the Modi government took office in May 2014, India has made a number of policy changes liberalizing foreign direct investment (FDI) rules. This chapter reviews those changes, highlighting the industries that have experienced the most significant policy modifications. In *India 2014*, the Commission listed several types of FDI policy barriers in India; the new rules have liberalized three of these (table 3.1). Since May 2014, India has raised FDI equity caps in two industries (insurance and defense); removed the requirements for pre-investment authorization in several cases; and permitted FDI in certain segments of the railways industry, in which FDI had previously been prohibited entirely. The Commission has not found any FDI changes that have increased restrictions on U.S. firms seeking to do business in India.

Table 3.1: Indian FDI and services policies and practices

Policy or practice	Description of barrier pre-May 2014	Changes found under Modi government
FDI equity limits	For certain industries, India limits the total equity stake that foreign investors can hold in an Indian firm, and/or limits the aggregate share that all foreign investors can hold.	Equity caps raised from 26 percent to 49 percent in both insurance (March 2015) and defense (August 2014), with up to 100 percent in defense authorized on a case-by-case basis.
Foreign investment authorization process	Investment proposals in certain industries and in certain circumstances are subject to pre-authorization by India's Foreign Investment Promotion Board (FIPB).	Authorization no longer needed for FDI in medical devices. For all industries, a higher level of government scrutiny is now required only for investments valued at Rs 30 billion (\$484.3 million) or more—an amount raised from Rs 20 billion (\$322.8 million). FIPB approval is not needed for acquisitions in sectors where FDI is permitted without prior approval (June 2015).
Prohibition on FDI in certain industries	Foreigners are not permitted to invest in certain industries in India.	FDI is now permitted in certain segments of the railway industry (August 2014). No changes have been found for other industries.
Restrictions on the form of establishment (i.e., FDI via a branch or an affiliate)	The choice of the form FDI may take is restricted.	No changes have been found.

Source: Compiled by the Commission.

Economy-wide FDI Changes

While India has kept many of its preexisting barriers to FDI, the Modi government has taken steps to liberalize the rules. There have been two changes to the FDI authorization process that apply across industries. As stated in *India 2014*, prior to the Modi administration, foreigners were able to invest in India through either the automatic route or the government route. Most FDI is permitted without prior approval (the “automatic route”). However, for high-value investments and for FDI in certain industries, prior approval from the FIPB or the Cabinet Committee on Economic Affairs (CCEA) was required.¹⁴⁸ Under the Modi government, there have been two changes¹⁴⁹ to the process:

- The value of FDI projects requiring approval by the CCEA, rather than the FIPB, has been raised from Rs 20 billion (\$322.8 million) to Rs 30 billion (\$484.3 million).¹⁵⁰
- FIPB approval is no longer required in cases of mergers and acquisitions for industries where such approval is not required for greenfield investment (one involving new operations and facilities).¹⁵¹

Industry-specific FDI Changes

The Modi government has also liberalized policies restricting FDI in specific industries, notably insurance, defense, railways, construction, and medical devices. The new government has taken steps to encourage FDI in India’s mining and civil nuclear energy sectors as well (table 3.2). FDI equity caps have been raised in the insurance and defense industries. The limit is set at 49 percent in both cases, although in the defense industry, it is possible to get approval for 100 percent FDI equity on a case-by-case basis. As previously noted, FDI in railway infrastructure has been permitted for the first time.

¹⁴⁸ USITC, *India 2014*, 2014, 207–8.

¹⁴⁹ On July 30, 2015, the Modi government introduced an additional change, to simplify the method of calculating a firm’s total investment in an Indian company, for most sectors subject to FDI equity caps. Government of India, MOCI, DIPP, Press Note No. 8 (2015), July 30, 2015.

¹⁵⁰ Government of India, MOCI, DIPP, Press Note No. 6 (2015), June 3, 2015. Rs is a generally accepted symbol for Indian rupees. For this report, all rupee amounts are converted to U.S. dollars at the rate of 61.95 rupees per dollar—the exchange rate on December 10, 2014. Dollar amounts above \$1 million are rounded to the nearest hundred thousand dollars; other dollar amounts are rounded to the nearest hundred dollars. IMF, “Exchange Rate Archives by Month,” https://www.imf.org/external/np/fin/data/param_rms_mth.aspx (accessed September 10, 2015).

¹⁵¹ *Economic Times*, “No FIPB Nod Required for M&As,” May 28, 2015.

Table 3.1: Industry-specific FDI changes under the Modi administration

Sector	Change	Date
Insurance	FDI equity cap raised from 26 percent to 49 percent	December 2014 (executive order) March 2015 (legislation passed)
Defense/aerospace	FDI equity cap raised from 26 percent to 49 percent; up to 100 percent on a case-by-case basis	August 2014
Railway infrastructure	FDI permitted at 100 percent foreign equity	August 2014
Construction	Permits FDI in smaller construction projects	October 2014
Medical devices	Permits 100 percent foreign equity in existing medical device firms through the automatic route	December 2014
Mining	Permits coal mining by private merchants	March 2015
Civil nuclear energy	Domestic liability law interpreted to limit liability to suppliers	January 2015

Source: Compiled by the Commission.

In the construction industry, limits on FDI in smaller projects remain—but the definition of a small project has changed under the Modi administration, as described below. Requirements for prior government approval of FDI in medical devices have been removed. Investment in medical devices in brownfield projects (i.e., involving acquisition of pre-existing companies) is now permitted through the automatic route up to 100 percent foreign equity. Previously, a more than 49 percent investment in brownfield projects needed government approval.¹⁵² In the mining sector, new legislation potentially allows private investors to lease particular mining areas (coal blocks) designated for the sale of coal on the open market, greatly expanding market opportunities.¹⁵³ In civil nuclear energy, the Modi administration has interpreted existing domestic law to limit liability of equipment suppliers in case of a nuclear accident.

U.S. industry representatives have welcomed the liberalization of India's FDI policy,¹⁵⁴ while also voicing concerns that India still maintains substantial barriers to FDI in some industries through policies such as equity caps and local-production or -sourcing requirements.¹⁵⁵ Foreign equity limits remain in two closely watched sectors: e-commerce and multibrand retail. Industry groups have stated that removing these FDI restrictions would likely lead to increased

¹⁵² Medical devices are covered in more detail in chapter 6. See USITC, hearing transcript, May 5, 2015, 52–55 (testimony of Vince Suneja, TwoFour Insight Group, LLC); U.S.-India Business Council, written submission to the USITC, June 2, 2015, 2.

¹⁵³ Implementing regulations are not yet in place, so the final impact of the new legislation is not yet clear.

¹⁵⁴ Ezell and Atkinson, written submission to the USITC, June 2, 2015.

¹⁵⁵ USITC, hearing transcript, May 5, 2015, 33 (testimony of Linda Dempsey, National Association of Manufacturers).

investment in distribution services such as warehouses, supply chain management, and logistics services. (FDI in both sectors is capped at 51 percent and faces other significant conditions.)¹⁵⁶ FDI equity caps also remain in place for segments of the telecommunications industry, including cable news (49 percent); FM radio (20 percent); direct-to-home broadcasting (49 percent); news broadcasting (26 percent); and newspapers (26 percent).¹⁵⁷ There have been several changes to banking regulations that are not FDI-related.¹⁵⁸

Industry representatives and academics interviewed have also cited several other Indian policies as disincentives to investment, including land acquisition issues and the existing regime for protection of intellectual property.¹⁵⁹ While these have not notably worsened under the Modi government, neither have they improved.¹⁶⁰ For example, difficulties in acquiring land continue to create problems both in attracting new investment to India and in accommodating foreign and domestic companies interested in expanding existing investments.¹⁶¹

Another concern voiced by U.S. industry representatives relates to India's recently released model bilateral investment treaty (BIT).¹⁶² While each country's model BIT serves only as the starting point in its negotiations with partner countries, it does show a country's preferred policies with regard to foreign investment. Industry representatives have stated that India's new model BIT is highly limited in scope compared to existing BITs signed by the United States,

¹⁵⁶ U.S.-India Business Council, written submission to the USITC, June 2, 2015, 3.

¹⁵⁷ USTR, "India," 2015, 179; Ezell and Atkinson, written submission to the USITC, June 2, 2015, 5.

¹⁵⁸ The Reserve Bank of India (RBI) has allowed certain banks to offer insurance broking services through a joint venture. In addition, on August 19, 2015, the RBI granted preliminary approval for the formation of 11 "payments banks," or non-full-service banks intended for small-scale users. These licenses are the first issued under the RBI's November 2014 *Guidelines for Licensing of Payments Banks*, which limits the banks to a maximum deposit of Rs 100,000 (\$1,600) per customer and prohibits these banks from making loans or issuing credit cards. RBI, "Entry of Banks into the Insurance Business," January 15, 2015; *Reuters*, "RBI Allows Banks to Offer Insurance Broking Services," January 15, 2015; RBI, *Guidelines for Licensing of Payments Banks*, 2014; *Times of India*, "Banking Revolution on Cards," August 20, 2015. The Commission has not identified any other substantive changes in policy in the service sectors covered in *India 2014*.

¹⁵⁹ This is particularly true of companies in the pharmaceutical sector. PhRMA, written submission to the USITC, May 5, 2015; Intellectual Property Owners Association, written submission to the USITC, June 2, 2015. Intellectual property rights are discussed in chapter 7.

¹⁶⁰ USITC, hearing transcript, May 5, 2015, 160–62 (testimony of Mukesh Aghi, U.S.-India Business Council); NAM, written submission to the USITC, April 23, 2015, 2; industry representatives, interviews by USITC staff, New Delhi, May 11–12, 2015; Hyderabad, April 17, 2015; and Bangalore, April 21, 2015. For more detail on issues related to intellectual property rights, see chapter 7 of this report.

¹⁶¹ Industry representatives, interviews by USITC staff, Bangalore, April 20, 2015; New Delhi, May 12–15, 2015; Gurgaon, May 15, 2015. The status of a land acquisition bill introduced by the Modi administration to address this issue is discussed in appendix H.

¹⁶² India's model BIT was released in April 2015 and is available online at https://mygov.in/sites/default/files/master_image/Model%20Text%20for%20the%20Indian%20Bilateral%20Investment%20Treaty.pdf.

India, and other countries, and provides less protection to investors. As such, this signaling of India’s intentions may in fact discourage potential new investment in India.¹⁶³

FDI Changes in Selected Sectors

This section describes FDI policy changes under the Modi government in six of the seven sectors shown in table 3.2—insurance, defense and aerospace, railway infrastructure, construction, mining, and civil nuclear energy. FDI changes in the medical devices sector are discussed in a case study in chapter 6.

Insurance

As stated in *India 2014*, India maintained a 26 percent FDI equity cap in insurance from 2000, when it first permitted private investment in the insurance industry, until changes made by legislation passed in March 2015. The initial proposal to raise this 26 percent FDI equity cap was first introduced in Parliament in 2008, but the legislation did not pass at that time. The Modi government issued an ordinance¹⁶⁴ on December 27, 2014, temporarily raising the FDI limit from 26 percent to 49 percent.¹⁶⁵ After the Insurance Laws (Amendment) Bill 2015 cleared the upper house in Parliament, the temporary ordinance became law in March 2015. Under the new law, foreign investment up to 26 percent is permitted through the automatic route; investment of up to 49 percent is permitted through the government approval route.¹⁶⁶

As of June 2015, India’s Insurance Regulatory and Development Authority (IRDA) had not yet released implementing regulations for the new insurance legislation. Under the legislation, majority ownership and control of Indian insurance companies will have to remain with resident Indians. But foreign carriers are waiting for further clarification on management terms and voting rights, and they remain reluctant to move forward with increased investment in

¹⁶³ NAM, written submission to the USITC, April 23, 2015, 7; PhRMA, written submission to the USITC, May 5, 2015, 3; NAM, “Comments on Draft Indian Model Bilateral Investment Treaty,” April 10, 2015.

¹⁶⁴ Ordinances are discussed in more detail in chapter 2.

¹⁶⁵ PRS Legislative Research, “Monthly Policy Review, December 2014,” January 2, 2015, 5–6; Government of India, MOCI, DIPP, Press Note No. 3 (2015), March 2, 2015.

¹⁶⁶ PRS Legislative Research, “Monthly Policy Review, March 2015,” April 1, 2015, 3; Khaitan & Co., “Insurance FDI,” March 12, 2015.

India until final implementing regulations have been released.¹⁶⁷ According to U.S. insurance industry representatives, the higher foreign equity cap represents a significant and positive policy change for foreign investors. Foreign insurance carriers currently operating in India at the existing 26 percent equity limit are expected to take advantage of this new opportunity by increasing their investments to the new 49 percent equity limit.¹⁶⁸ Joint ventures between foreign and domestic carriers account for the majority of the insurance firms in India's market.¹⁶⁹ As a result, industry representatives expect a substantial inflow of much-needed new investment into India's insurance industry in the next few years, estimated at between \$2 billion and \$10 billion.¹⁷⁰

In addition to the new FDI equity cap, the insurance legislation also addresses the reinsurance industry.¹⁷¹ Before the Modi government took office, regulations permitted foreign reinsurers to provide insurance only through cross-border channels. The new law will allow foreign reinsurers to set up branch offices in India for the first time. Details of the approval process and eligibility standards for foreign reinsurers have been released only as drafts;¹⁷² however, GIC Re, India's monopoly domestic reinsurer, reportedly will be given the right of first refusal on all reinsurance business. According to U.S. industry representatives, under such conditions, it may be impractical for foreign reinsurers to invest in India.¹⁷³

Like its insurance sector, India's pension sector is regulated by the IRDA, under the Insurance Regulatory and Development Authority Act, 2013. The FDI equity limit in pension companies

¹⁶⁷ U.S. industry representative, interview by USITC staff, Washington, DC, April 16, 2015; *Insurance Journal*, "A.M. Best: India Law to Raise Foreign Investment," March 24, 2015; Krishnan and Antony, "India Raises Insurance Investment Cap," March 12, 2015; U.S. industry representative, interview by USITC staff, Bangalore, April 20, 2015. On July 3, 2015, the Ministry of Finance issued an amendment to the Indian Insurance Companies (Foreign Investment) Rules, 2015, that clarifies the definition of majority Indian ownership. U.S. industry representatives stated to the Commission that they have not yet determined how the amendment might affect their investment decisions. Vaish Associates Advocates, "Foreign Holding in Insurers' Parent," August 7, 2015; industry representative, email message to USITC staff, August 27, 2015.

¹⁶⁸ USITC, hearing transcript, May 5, 2015, 39–40 (testimony of Steve Simchak, AIA); Krishnan and Antony, "India Raises Insurance Investment Cap," March 12, 2015; industry representative, interview by USITC staff, Mumbai, April 23, 2015.

¹⁶⁹ USITC, hearing transcript, May 5, 2015, 40 (testimony of Steve Simchak, AIA).

¹⁷⁰ USITC, industry representative, interview by USITC staff, New Delhi, April 15, 2015; Krishnan and Antony, "India Raises Insurance Investment Cap," March 12, 2015.

¹⁷¹ Reinsurance is purchased by primary insurance underwriters to hedge against large risks by passing on part of such risks to other insurers.

¹⁷² *Business Standard* (India), "IRDAI Draft Norms Says Foreign Reinsurer's Branch," April 7, 2015; *Economic Times*, "Insurance Law: Reinsurance Companies," March 13, 2015.

¹⁷³ U.S. industry representatives, interview by USITC staff, Washington, DC, April 16, 2015; *Business Standard* (India), "IRDAI Draft Norms Says Foreign Reinsurer's Branch," April 7, 2015.

has also been increased to 49 percent. As in the insurance sector, an investment level higher than 26 percent requires approval through the government route.¹⁷⁴

Defense and Civil Aerospace

As noted in tables 3.1 and 3.2, and as the Commission reported in *India 2014*, the Modi government raised the FDI cap on investment in defense industries in 2014, but this is not likely to significantly increase U.S. investment in Indian defense manufacturing. The Indian government continues to prohibit foreign investor control of joint ventures that manufacture defense equipment. In August 2014, the Indian government issued regulations permitting FDI in the defense industry up to 49 percent through the government approval route (via the FIPB); higher equity levels may be approved on a case-by-case basis by the Cabinet Committee on Security (CCS), “wherever it is likely to result in access to modern and ‘state-of-art’ technology in the country.”¹⁷⁵ According to several U.S. companies, however, the cap on equity is still too low to encourage investment, and offset requirements remain quite onerous.¹⁷⁶ Despite these concerns, most U.S. defense companies see India as a very important market.

Indian companies do not always have the technological knowledge to produce the high-end products desired by the military, and are open to having joint ventures fill that gap.¹⁷⁷ Increasing domestic defense production is a priority for the Modi administration, and one of the sectors included in Modi’s Make in India program.¹⁷⁸ Private Indian companies were not allowed to enter the defense sector until 2001.¹⁷⁹ Indian experts acknowledge that India’s research and development (R&D) and manufacturing capability for defense is underdeveloped, particularly for advanced subsystems and components.¹⁸⁰ As a result, since early 2013, tenders worth a total of \$15 billion lapsed without any domestic firms bidding on those contracts.¹⁸¹

U.S. industry representatives have repeatedly asserted that defense companies need a controlling stake in joint ventures to protect their intellectual property, and most are not

¹⁷⁴ This was first noted in the Commission’s 2014 report, *India 2014*, 2014. See also USITC, hearing testimony, May 5, 2015, 17 (testimony of Richard Rossow, CSIS); *Insurance Journal*, “A.M. Best: India Law to Raise Foreign Investment,” March 24, 2015; Government of India, MOCI, DIPP, Press Note No. 4 (2015), April 24, 2015.

¹⁷⁵ Government of India, MOCI, DIPP, Press Note No. 7 (2014), August 26, 2014.

¹⁷⁶ The current policy requires a minimum of 30 percent offset for defense equipment of Rs 3 billion (about \$48.4 million) or more procured under the Defence Procurement Procedure (DPP). Offset requirements are discussed in more detail in chapter 5.

¹⁷⁷ Suman, “FDI in Defence,” July 8, 2014.

¹⁷⁸ For more on Make in India, see chapter 2.

¹⁷⁹ Behera, “Private Sector Participation in Defense Production,” January 27, 2012.

¹⁸⁰ Mishra, “Make in India: Challenges Before Defence Manufacturing,” March 12, 2015; Behera, “A Case for Increasing FDI up to 100 percent,” December 30, 2010, 1.

¹⁸¹ Miglani and Wilkes, “Lapsed Tenders Hurt Modi’s ‘Make in India,’” April 8, 2015.

interested in investing if they are restricted to a minority stake.¹⁸² Under Indian Company Law, increasing the equity cap from 26 to 49 percent does not allow foreign investors to gain any additional control of the joint venture.¹⁸³ One industry representative reported that his company may be willing to bring state-of-the-art technology to India through the case-by-case approval process if they are permitted to take a 74 percent or 100 percent stake.¹⁸⁴

As of June 2015, no U.S.-based defense company had applied to invest in a joint venture in India at the 49 percent level. However, at least one foreign firm (Rafael Air Defense Systems, an Israeli company) had announced a joint venture focused on the production of defense products.¹⁸⁵ An industry representative reported that some European defense companies may have contemplated creative ownership structures with Indian businesses or the Indian government where the European company would own 49 percent of the joint venture, but would also own more shares than any other investor.¹⁸⁶

U.S. defense and aerospace companies have reported that the Modi government is more accessible than the previous government, and that the process of developing new rules and regulations is more transparent. For example, the forthcoming revisions to the offset policy have been released to interested parties in draft form, and other policies have been released for public comment as well.¹⁸⁷ U.S. companies believe that this transparency and accessibility will lead to better future policy outcomes.

India is the world's largest importer of weapons, accounting for 15 percent of global arms imports from 2010 to 2014.¹⁸⁸ It annually imports about 70 percent of its defense requirements. According to the aerospace policy statement issued by the state of Karnataka in 2013, India is projected to spend approximately \$100 billion in total defense and aerospace from 2014 through 2023, making it one of the top three markets globally.¹⁸⁹ The United States

¹⁸² See chapter 7 for further information on intellectual property issues in India. Suman, "FDI in Defence," July 8, 2014; industry representative, interview by USITC staff, New Delhi, May 14, 2015; industry representative, interview by USITC staff, Bangalore, April 21, 2015; industry representative, interview by USITC staff, Bangalore, April 20, 2015; U.S. industry representative, interview by USITC staff, Washington, DC, April 9, 2015; U.S. industry representative, telephone interview by USITC staff, April 7, 2015; USITC, *India 2014*, 2014, 212.

¹⁸³ Behera, "A Case for Increasing FDI up to 100 percent," December 30, 2010, 13.

¹⁸⁴ Industry representative, interview by USITC staff, New Delhi, May 14, 2015.

¹⁸⁵ Kulkarni, "Kalyani Group-Rafael JV to Develop Defence Products," February 20, 2015.

¹⁸⁶ U.S. industry representative, interview by USITC staff, New Delhi, May 13, 2015.

¹⁸⁷ For more on defense offsets see chapter 5. Kulkarni, "Explained: New in New Defence Procurement Procedure," June 2, 2015; industry representative, interview by USITC staff, New Delhi, May 14, 2015.

¹⁸⁸ SIPRI, "Developments in Arms Transfers, 2014," 2015.

¹⁸⁹ Government of Karnataka, *Karnataka Aerospace Policy, 2013–23*, January 2013, 1.

passed Russia to become India’s biggest supplier of defense products in 2013, and India is also the biggest buyer of U.S. defense products.¹⁹⁰

Railways

Before 2014, India’s railways were closed to all private investment, from both foreign and domestic sources. The railway system was strictly a government-owned monopoly, except for the mass rapid transport segment. As part of an effort to mobilize resources to upgrade the national railway infrastructure, the Modi government, as of August 22, 2014, has permitted both domestic and foreign investment in certain rail infrastructure segments in India that the Ministry of Railways is targeting for development. The changes apply only to new investment; existing passenger rail operations remain closed to foreign and domestic investment.¹⁹¹ The ministry plans to fund much of its upcoming investment through public-private partnerships (PPPs).¹⁹² In the past, railways have been funded by public resources, while roads and highways have been open to FDI.¹⁹³ Inviting private sector investment in India’s railways is part of a more general focus on improving India’s infrastructure.¹⁹⁴

The specific industry segments for which private investment is now permitted include:

- suburban corridor projects through PPPs,
- high-speed train projects,
- dedicated freight lines,
- rolling stock, including train sets, locomotive/coach manufacturing, and maintenance facilities,
- railway electrification,
- signaling systems,
- freight terminals,
- passenger terminals,

¹⁹⁰ Plimmer and Mallet, “India Becomes Biggest Foreign Buyer of U.S. Weapons,” February 24, 2014.

¹⁹¹ *Economic Times*, “Cabinet Approves Raising FDI Cap in Defence,” August 7, 2014; PRS Legislative Research, “Monthly Policy Review, August 2014,” September 1, 2014, 6.

¹⁹² PPPs are arrangements between an Indian government entity and a private entity for the provision of public assets or public services, through investments made by the private entity for a specified period of time.

Government of India, Ministry of Finance, “Public Private Partnerships in India: FAQs” (accessed August 4, 2015).

¹⁹³ PRS Legislative Research, “Railways Budget 2014–15,” July 10, 2014.

¹⁹⁴ Indian government official, interview by USITC staff, New Delhi, May 12, 2015; industry representative, interview by USITC staff, New Delhi, 2015.

- infrastructure in industrial parks pertaining to railway line/sidings, including electrified railway lines and connections to main railway lines, and
- mass rapid transport systems.

For the newly approved segments, up to 100 percent FDI will be permitted. FDI is limited to 49 percent in certain segments that are considered sensitive from the point of view of security, with 100 percent FDI permitted on a case-by-case basis with approval from the CCS.¹⁹⁵

While the government welcomes investment in new passenger and freight rail terminals at existing stations, observers generally agreed that as of mid-July 2015, the business models for investors were not yet clear. They commented that it remains too early to judge the extent of interest by foreign or domestic companies and the impact of the rule changes.¹⁹⁶ However, the sector will likely undergo significant transformation as the rules are clarified.¹⁹⁷ One possible business model would be for companies to fund FDI improvements in passenger terminals, in return receiving the right to keep revenue from concessions in those terminals—a significant source of rail revenue in some countries. India’s extensive passenger rail traffic could generate substantial concession revenues for investors. Alternatively, the Ministry could raise revenue by leasing for non-railway purposes land owned by the railways but currently unused.

The Ministry is also interested in investors building new passenger terminals with short tracks to connect to existing lines, or adding freight terminals to new or existing mines or industrial parks to promote shipping of products to market. There were 13 or 14 such rail connectivity projects ongoing as of May 2015, funded through private investment. In the business model for freight lines, revenue from shippers is paid to the railway, and a portion of that revenue is paid to the owner of the connecting track. Several such lines are already operating. In another type of business model, India Rail has floated a tender to create a suburban rail line. The tender process is ongoing, and several companies have expressed interest.¹⁹⁸

¹⁹⁵ Indian government official, interview by USITC staff, “Central Government Permits FDI in Railways,” August 2014; Government of India, MOCI, DIPP, “Policy for Private Investment in Rail Infrastructure,” August 27, 2014; Indian government official, interview by USITC staff, New Delhi, May 12, 2015.

¹⁹⁶ Industry representatives, interviews by USITC staff, New Delhi, May 11 and May 15, 2015; Indian government official, interview by USITC staff, New Delhi, May 12, 2015; Indian research official, interview by USITC staff, New Delhi, May 12, 2015.

¹⁹⁷ USITC, hearing transcript, May 5, 2015 (testimony of Richard Rossow, CSIS), 16.

¹⁹⁸ Indian government official, interview by USITC staff, New Delhi, May 12, 2015; Indian research official, interview by USITC staff, New Delhi, May 12, 2015.

Construction

In an effort to attract more investment into projects such as affordable housing and Smart Cities projects,¹⁹⁹ the Indian government approved changes to its FDI policy for construction development projects in December 2014.²⁰⁰ Construction development accounted for almost 10 percent of cumulative FDI equity inflows into India between 2000 and 2015.²⁰¹ Previously, up to 100 percent foreign equity in construction projects was permitted, subject to certain conditions related to the minimum size and investment value of the project. Those requirements were substantially lowered in October 2014, representing a liberalization of FDI in the construction sector for smaller projects. One industry representative described the new rules as “dramatically [easing] requirements governing FDI in the construction sector.”²⁰²

Under the new regulation, 100 percent foreign equity is permitted in construction development projects with a minimum floor area of 20,000 m² (down from 50,000 m² previously) and a minimum investment amount of \$5 million. Previously, the minimum investment requirement was \$10 million, or \$5 million in a joint venture with an Indian partner. For development of serviced plots, a requirement for a minimum development area of 10 hectares has been removed. Certain additional requirements and exceptions related to minimum investment amount and square footage also apply.²⁰³ No limiting conditions apply to development of hotels and tourist resorts, hospitals, special economic zones, educational institutions, old-age homes, and investment by non-resident Indians, or to projects which commit at least 30 percent of the total project cost for affordable housing.²⁰⁴

Mining

The Modi government has introduced significant investment policy changes in India’s mining sectors, although the impact of these efforts for U.S. investors remains unclear. Two bills that passed Parliament in March 2015—the Coal Mines (Special Provisions) Bill and the Minerals and Mines Development and Regulation (MMDR) Bill—enacted investment-friendly changes in

¹⁹⁹ See chapter 2 for a discussion of India’s Smart Cities program.

²⁰⁰ Construction development is defined as including, but not limited to, development of townships and construction of residential/commercial premises, roads or bridges, hotels, resorts, hospitals, educational institutions, recreational facilities, and city and regional infrastructure. The changes were approved by the Cabinet in October 2014. *Indian Express*, “Government Relaxes FDI Norms,” October 29, 2014; Government of India, MOCI, DIPP, Press Note No. 10 (2014), December 3, 2014.

²⁰¹ Government of India, MOCI, DIPP, “Fact Sheet on FDI,” April 2015.

²⁰² USITC, hearing transcript, May 5, 2015 (testimony of Richard Rossow, CSIS), 16.

²⁰³ PRS Legislative Research, “Foreign Direct Investment Policy in the Construction,” October 2014, 7; *Indian Express*, “Government Relaxes FDI Norms,” October 29, 2014; Government of India, MOCI, DIPP, Press Note 10 (2014), December 3, 2014.

²⁰⁴ Government of India, MOCI, DIPP, Press Note No. 10 (2014), December 3, 2014; Government of India, Make in India, “Construction FDI Policy” (accessed June 29, 2015).

India's mining sectors. Both the coal and mineral mining changes are described by industry representatives as significant improvements for investors; most of the implementing regulations, however, are still forthcoming.

Coal Mining

The Coal Mines (Special Provisions) Bill made permanent an ordinance the Modi government promulgated in October 2014²⁰⁵ (see box 3.1 for further context on India's coal policy changes). This bill made several substantial changes to coal mining laws in India. First, it designated online auctions as the means of allocating invalidated coal blocks and all future coal mines to prospective investors. It potentially opens the door for private companies, including foreign investors, to bid for merchant mining operations through online auctions.²⁰⁶ This could be a significant change, as previously only government companies were allowed to mine and sell coal in open markets. Private companies were allowed to mine coal for captive use only (i.e., use having a specified in-house purpose, such as power generation or steel production), but never for sale in the open market.²⁰⁷

According to an Indian industry source, observers expect the new measures to be implemented to address the most urgent issues first—in particular, allocating mines to companies with stalled projects due to a recent Supreme Court allocation decision (see box 3.1). Long-term changes will be implemented later.²⁰⁸

Three online auctions for captive coal blocks had taken place as of August 2015.²⁰⁹ Only firms with proven investment projects directly related to coal mining already in place were able to bid in the first two e-auctions, which allocated operational mines and mines close to being operational.²¹⁰ The next challenge is to allocate greenfield projects (mines not close to being operational) through auction.²¹¹ Only then do observers expect that private sector merchant mining will be addressed, even though it is permitted under the new legislation. The Ministry of

²⁰⁵ Coal Mines (Special Provisions) Ordinance, 2014, of October 21, 2014. See appendix E for a more detailed description.

²⁰⁶ PRS Legislative Research, "Bill Summary: The Coal Mines (Special Provisions) Bill, 2014," December 19, 2014. According to industry representatives, further concrete steps by the central government are needed for private merchant mining by domestic or foreign companies to be permitted. Industry representatives, email messages to USITC staff, September 2–3, 2015. See also USDOE, EIA, "India's Coal Industry in Flux," August 15, 2015.

²⁰⁷ FDI of up to 100 percent had previously been allowed in captive coal mining before the Coal Mines Bill.

²⁰⁸ As one industry representative remarked, "The first priority was to clear to logjam of raw materials for end use." Industry representative, telephone interview by USITC staff, June 11, 2015.

²⁰⁹ All coal auction information is published on the auction website at <http://www.mstcecommerce.com/auctionhome/coalblock/index.jsp> (accessed on June 30, 2015).

²¹⁰ Industry representative, telephone interview by USITC staff, June 19, 2015.

²¹¹ Ibid.

Coal has not announced a concrete date to implement mining auctions for private sector merchants.²¹²

Box 3.1: Historical Context to India’s Coal Mining Policy Changes

Under the 1973 Coal Mines Nationalization Act (CMN), coal mining was exclusively reserved for the public sector, and state-owned Coal India Limited (established in 1975) was given a monopoly on coal production. Only government companies were allowed to mine and sell coal in open markets. Through subsequent amendments to CMN, private companies in certain sectors were allowed to mine coal for captive use.^a Coal block allocation became a critical issue in 2012 when the government’s auditor issued a report claiming that the government had lost \$33 billion in potential revenues through its allocation practices.^b The Ministry of Coal had allocated 218 coal blocks to public and private companies between 1993 and 2011, following a 1993 amendment to CMN.^c The licenses associated with these allocations were distributed free of charge.^d Industry officials point to the allocation mishandling as a cause of decreased coal production.^e Public-interest litigation contesting the allocations was filed with the Supreme Court shortly after the auditor’s report.^f In September 2014, the Indian Supreme Court declared all allocations of coal blocks since 1993 illegal, canceling the allocation of 204 out of 218 coal blocks.^g Public and private companies that had invested in projects lost their licenses as a result.

^a Iron and steel industries in 1976, power generation in 1993, and cement production in 1996. See Aggarwal, “Captive Coal Mining—Issues and Challenges,” March 5, 2009.

^b For further details, see Mishra, “Coal Block Allocations and the 2015 Bill,” March 7, 2015; see also Crabtree, “India: At the Coalface,” March 31, 2015.

^c A screening committee was established to allocate private captive blocks, while the Ministry of Coal allocated blocks to government companies directly. See Mishra “Coal Block Allocations and the 2015 Bill,” March 7, 2015.

^d Because downstream coal use (electricity) is regulated by the government with fixed prices, free licenses were reportedly issued with the intended purpose of increasing the production of coal. Industry representative, telephone interview by USITC staff, June 11, 2015.

^e Industry representative, telephone interview by USITC staff, June 11, 2015.

^f The government outlined the potential corruption involved with these allocations, leading to allegations of “coal scams.” For an example see Kaul, “All You Wanted to Know,” March 11, 2015.

^g While the Supreme Court rendered the allocations illegal, they did not specify or suggest how the coal blocks should be allocated.

Early reactions to the coal mining changes have ranged from celebrating the possibility of open commercial coal mining in India to criticizing the government’s slow progress towards commercially open merchant coal mining and breaking up the Coal India monopoly.²¹³ The openness and transparency of e-auctions were received favorably as significant improvements upon the old system of coal block allocations²¹⁴ and are seen as an example of the Modi

²¹² When asked about the timing of commercial mining in May 2015, coal minister Piyush Goyal responded that there is currently no firm timetable for such auctions. Goyal, “Working on Contingencies to Provide Power,” June 3, 2015.

²¹³ Industry representative, interview by USITC staff, New Delhi, India, May 15, 2015; Rossow, hearing transcript, May 5, 2015, 152; Joshi, “Energy Reforms: An Uneven Road,” May 26, 2015; industry representative, email message to USITC staff, June 11, 2015.

²¹⁴ Industry representative, telephone interview by USITC staff, June 11, 2015; industry representative, telephone interview by USITC staff, June 19, 2015; industry representative, interview by USITC staff, May 15, 2015.

government's efforts to improve the business environment.²¹⁵ The new system of coal block allocations and the resulting increase of coal production are expected to reduce coal imports by as much as an estimated \$17 billion annually.²¹⁶ The first online auctions yielded \$33 billion in revenues to be shared between central and state governments.²¹⁷

Mining industry representatives reported that mining companies are encouraged by the Modi government's policy changes following the Supreme Court ruling, and that auctions have so far proceeded smoothly.²¹⁸ They remain cautious, however, because most regulations under the new law have not yet been implemented. As of mid-July 2015, these industry representatives expected auctions for private sector commercial mining to occur soon, but they expressed caution that many challenges remain even if such auctions are announced.²¹⁹

Mining industry representatives also reported that the most immediate hurdle is the need to streamline the government clearances necessary to begin mining operations. These clearances, including land acquisition, planning, and environmental approvals, are currently estimated to take about five years.²²⁰ While the Modi government has promised to expedite these approvals, industry representatives expressed concerns that the government may not succeed in this goal. In addition, industry representatives state that the quality of the government's geological data needs to improve so that the government can give necessary information to potential private investors.²²¹ Industry representatives voiced an additional concern that potential upstream private coal merchants would not be able to be profitable in an environment characterized by fixed coal prices for downstream users, including electric power plants.²²²

²¹⁵ Industry representative, telephone interview by USITC staff, June 11, 2015; Confederation of Indian Industry, written testimony submitted to the U.S. International Trade Commission, April 28, 2015; industry representative, interview by USITC staff, New Delhi, May 15, 2015.

²¹⁶ The \$17 billion figure is cited by Richard Rossow at CSIS. See Rossow, "A Strong Start to the Budget Session," *US-India Insight*, April 2015. One U.S. industry representative also predicted reduced coal imports, but did not specify a figure. U.S. industry representative, interview by USITC staff, New Delhi, May 15, 2015.

²¹⁷ The revenues from the auctions will accrue over a period of 30 years as payments continue to be made on the basis of production. Industry representative, email message to USITC staff, September 3, 2015; Rossow, "A Strong Start to the Budget Session," *US-India Insight*, April 2015.

²¹⁸ One industry representative was hesitant to describe it as a "success," but was comfortable with saying it was so far going "smoothly," as many of the auctions remained to be held; industry representative, telephone interview by USITC staff, June 19, 2015.

²¹⁹ Industry representative, telephone interview by USITC staff, June 19, 2015; industry representative, telephone interview by USITC staff, June 11, 2015.

²²⁰ Industry representative, telephone interview by USITC staff, June 11, 2015.

²²¹ Industry representative, telephone interview by USITC staff, June 19, 2015.

²²² *Ibid.*

Mineral Mining

There is no legal barrier restricting FDI in India’s mineral mining sector, as reported in *India 2014*.²²³ The MMDR passed in March 2015 is considered an investment-friendly changes for domestic and foreign firms alike, as it clarifies licensing rights and procedures.²²⁴ This legislation, which covers several important minerals (bauxite, iron ore, limestone, and manganese ore), requires competitive bidding and online auction for specified mineral mining leases. It also extends the life of mining licenses for these minerals from 20 or 30 years to 50 years.²²⁵ Once the license expires, the leases are put up for auction. The MMDR also simplifies the transfer of mining rights.

Mineral mine auctions are to be administered by Indian state governments. As of June 2015, however, no such auctions have yet taken place.

Even though this new policy is in the early stages of implementation, industry representatives identified three positive changes they expect from it:²²⁶

- The MMDR clarifies licensing rights regarding renewals and transfer processes, making the value of licenses easier to estimate and making investments more attractive.
- The new measures address the issue of significant underspending on mining exploration by granting non-exclusive reconnaissance licenses. In areas where geological survey information is poor, firms can obtain licenses to explore and then bid for a composite license (allowing for both exploration and mining) after their findings. This enables firms with expertise in mining exploration to more easily enter the market.
- The new policy specifies financial transfers to the government for local area development through three separate sources: royalties, auctions, and contributions to a newly created “District Mineral Foundation” established for the benefit of persons negatively affected by mineral mining operations.

²²³ USITC, *India 2014*, 2014, 205, 427.

²²⁴ Industry representative, telephone interview by USITC staff, June 11, 2015; industry representative, telephone interview by USITC staff, June 19, 2015.

²²⁵ These minerals are referred to as “notified minerals.” See MMDR, section 3.

²²⁶ Industry representative, telephone interview by USITC staff, June 11, 2015; industry representative, telephone interview by USITC staff, June 19, 2015.

Civil Nuclear Energy

Potential foreign investors' concerns about suppliers' legal liability under Indian domestic law have severely limited FDI in India's civil nuclear energy sector.²²⁷ Civil nuclear energy was not discussed in *India 2014*, but has been a focus of U.S.-India engagement under the Modi government. The U.S. and Indian governments established a high-level Contact Group in September 2014 to facilitate the commercialization of U.S.-India civil nuclear cooperation.²²⁸ In January 2015, President Obama and Prime Minister Modi announced a "breakthrough understanding" between the two governments to clarify the supplier liability issue.²²⁹ While the understanding between the U.S. and Indian governments is considered a positive step, persons interviewed did not yet view it as a sufficient basis for foreign firms to sign commercial contracts with nuclear power operators.²³⁰ Several more concrete steps, particularly implementation of India's announced commitments to address the supplier liability issue (described later in this section), are likely necessary before major foreign investments will commence.²³¹

Two U.S. firms, Westinghouse and General Electric, have received approval from the Indian authorities to build nuclear reactors in the states of Gujarat and Andhra Pradesh, respectively (table 3.3).²³² Neither of these companies, however, can act as the operator of a nuclear power plant, because all plants are operated by the Nuclear Power Corporation of India (NPCIL), a company owned and operated by the central government.²³³ Moreover, despite their interest, neither company was willing to move forward with its investment due to concerns over India's Civil Liability for Nuclear Damage Act (CLNDA) of 2010, which foreign firms claim deviates from

²²⁷ See Lal, "India's Nuclear Energy Imperative," October 8, 2014.

²²⁸ Allowing the sale of U.S. nuclear reactors (for power generation) in India had already been approved by the U.S. Congress in the 2006 Hyde Act. The U.S.-India Civil Nuclear Agreement was signed in September 2008, allowing India access to nuclear technology and fuel under International Atomic Energy Agency safeguards. This was a significant agreement for India, which faces the daunting task of meeting its growing domestic energy demands. Because India is not rich in conventional nuclear fuels, access to foreign materials and technology is critical to meeting the government target of supplying 25 percent of electricity from nuclear power by 2050. Lazzarin, "India-US Civil Nuclear Agreement: A Breakthrough?" February 25, 2015; see also World Nuclear Association, "Nuclear Power in India," May 2015.

²²⁹ White House, "Statements by President Obama and Prime Minister Modi," January 25, 2015.

²³⁰ Industry representative, telephone interview by USITC staff, June 11, 2015; U.S. government official, email message to USITC staff, June 9, 2015.

²³¹ *Ibid.*

²³² Einhorn and Sidhu, "Operationalizing the US-India Civil Nuclear Cooperation," January 2015.

²³³ In a potential deal, NPCIL would be the sole customer for nuclear technology, equipment, services, and fuel. Potential supplier companies would provide NPCIL with engineering and construction of a nuclear power plant, components, and fuel. NPCIL would compensate the supplier company through a negotiated payment schedule, relying on revenues derived from power generation. Industry representative, email correspondence with USITC staff, September 2, 2015.

Table 3.2: U.S. firms in preliminary commercial discussions with NPCIL

Company	Number of reactors	Approved site in India
General Electric	6	Kovvada, Andhra Pradesh
Westinghouse	6	Mithi Viridi, Gujarat

Sources: World Nuclear Association, “Nuclear Power in India,” May 2015; Westinghouse, “Westinghouse Accompanies Historic US Delegation to India,” January 26, 2015.

international norms of liability.²³⁴ CLNDA allows nuclear power plant operators to seek recourse from equipment suppliers in case of nuclear reactor accidents, and suppliers potentially face unlimited liability in perpetuity.²³⁵ Indian energy policy experts also recognize the incompatibility of CLNDA with the need to attract foreign investments in the nuclear energy sector.²³⁶

Between November 2014 and January 2015, the Indian delegation at the U.S.-India Nuclear Contact Group presented case law and legislative history, clarifying that liability is channeled to the power plant operators, not to the equipment suppliers.²³⁷ The government of India issued a memorandum of law outlining these interpretations, and the U.S. government has subsequently concluded that India’s domestic law complies with the main principles of the Convention on Supplementary Compensation for Nuclear Damage (CSC).²³⁸ The “breakthrough understanding” announced by President Obama and Prime Minister Modi in January 2015 signaled the Indian government’s willingness to adopt international norms. The announcement included the following details:²³⁹

²³⁴ U.S. industry representative, telephone interview by USITC staff, June 22, 2015. India is not a party to the three major international agreements on nuclear liability: the Paris Convention of 1960, the Vienna Convention of 1963, and the Convention on Supplementary Compensation for Nuclear Damage of 1997.

²³⁵ The maximum liability under CLNDA for each nuclear incident is set at 300 million special drawing rights (SDR), but a higher amount could be specified by the central government. Section 17 (b) of CLNDA sets a no-fault liability cap on the operator at Rs 5 billion (roughly \$80.7 million); the rest of the liability is set by the central government. No limit is set on the supplier. Section 46, which states that CLNDA is not in derogation but rather an addition to existing law, had been interpreted as creating potential unlimited liability for suppliers; for more details, see PRS Research Summary, “The Civil Liability for Nuclear Damage Bill 2010,” May 7, 2010. The SDR is an international reserve asset, created by the IMF in 1969 to supplement its member countries’ official reserves. Its value is based on a basket of four key international currencies, and SDRs can be exchanged for freely usable currencies. As of September 1, 2015, 1 SDR was equivalent to \$1.40 U.S. Dollars. IMF, “Factsheet: Special Drawing Rights (SDRs),” April 9, 2015, <http://www.imf.org/external/np/exr/facts/sdr.htm>.

²³⁶ K. Ramanathan of the Tata Energy Research Institute, for example, stated that “The choice is clear—either we amend the law or jettison our plans to make nuclear power a major component of our energy profile.” Cited in Lal, “India’s Nuclear Energy Imperative,” October 8, 2014. See also Sood, “Solving India’s Nuclear Liability Conundrum,” January 2015.

²³⁷ U.S. government official, email message to USITC staff, June 9, 2015.

²³⁸ U.S. government official, email message to USITC staff, June 9, 2015; Chellaney, “The US-India Nuclear Breakthrough That Wasn’t,” February 11, 2015.

²³⁹ Government of India, “Frequently Asked Questions and Answers on Civil Liability,” February 8, 2015.

- India will ratify the 1997 CSC.
- CLNDA Section 17 (b), which allows a “right of recourse” by the operator, is clarified to be “not a mandatory” but an enabling provision to be specified in the commercial contract.
- The India Nuclear Insurance Pool is to be instituted at an amount currently understood to be \$234 million.²⁴⁰
- CLNDA Section 46 does not create legal grounds for victims to seek claims for damages in foreign courts.²⁴¹

However, the “understanding” is legally limited. Before the January announcement, foreign nuclear equipment supplier companies had pushed for an amendment of domestic liability laws.²⁴² According to a senior U.S. administration official, the understanding between the United States and India falls short because it is not a signed piece of legislation, but rather a part of a process to move forward.²⁴³ According to industry representatives, significant risks remain because there were no formal amendments to CLNDA.²⁴⁴

Industry representatives recognize that much of the policy efforts in ratifying the CSC treaty are “workaround” provisions to the existing domestic liability law.²⁴⁵ Because of this, the current changes taking place are described by U.S. government and industry officials as “a moving target.”²⁴⁶ More policy changes are expected to occur through 2015 and beyond, further clarifying investment risks as details of these new measures emerge. For now, foreign investors say they require more legal certainty before commercial contracts can be concluded.²⁴⁷ Industry representatives identified at least three necessary conditions before foreign investors would be willing to finalize civil nuclear deals in India:

²⁴⁰ Government of India, Chellaney, “The US-India Nuclear Breakthrough That Wasn’t,” February 11, 2015; Reuters, “Factbox: The US-India Nuclear Deal,” February 3, 2015.

²⁴¹ For example, courts in the United States, or another country in which the supplier company has its headquarters.

²⁴² Baker and Barry, “Obama Clears a Hurdle to Better Ties,” January 25, 2015.

²⁴³ Gowen and Mufson, “Is the India Nuclear Agreement Really the ‘Breakthrough’?” February 4, 2015.

²⁴⁴ U.S. industry representative, telephone interview by USITC staff, June 11, 2015; U.S. industry representative, telephone interview by USITC staff, June 22, 2015.

²⁴⁵ U.S. industry representative, telephone interview by USITC staff, June 11, 2015; U.S. government official, email message to USITC staff, June 9, 2015.

²⁴⁶ Ibid.

²⁴⁷ Dempsey, post-hearing submission to the USITC, May 12, 2015, 11–12.

- India needs to join and ratify the CSC. The details of the ratification have not yet been made public.
- The Indian government needs to set up a viable liability insurance pool for investments, the details of which are expected to be revealed in the fourth quarter of 2015.
- The Indian government must satisfactorily implement new land acquisition policies. While positive intent has been expressed in the senior government levels, industry representatives note that enthusiasm for new land acquisition policies has not yet filtered down to the lower levels of the Indian government.²⁴⁸

²⁴⁸ Industry representative, telephone interview by USITC staff, June 11, 2015; Dempsey, post-hearing submission to the USITC, May 12, 2015.

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Chapter 4

Tariffs and Customs Procedures

India 2014 reported that U.S. companies found their exports of agricultural and food products and certain manufactured products to India to be particularly hindered by high tariffs and slow and complicated customs procedures. Since the Modi government took office in May 2014, India has made a small number of changes in its tariffs and customs procedures—some of which have improved U.S. access to the Indian market. Table 4.1 summarizes the key findings in this chapter on changes made to India’s tariff and customs procedures since *India 2014* that the Commission had identified as of mid-July 2015.

Table 4.1: India’s tariff and customs policies and practices, May 2014–July 2015

Policy or practice	Description of barrier pre-May 2014	Changes found under Modi government
Tariffs: Non-agricultural goods	High trade-weighted tariff rates that often exceed averages in other developing countries.	February 2015: tariffs reduced for selected goods, including medical device components and consumer electronics; tariffs increased for several telecommunications-related products—including cellphones, tablet computers, and digital video cameras.
Tariffs: Agricultural goods	High trade-weighted tariffs, particularly for agricultural goods	August 2015: duty on wheat raised from zero to 10 percent.
Customs: Clearance delays	Lack of manpower to facilitate timely customs clearances	December 2014: Customs commissioners made available 24/7 at major sea- and airports.
Customs: Complicated procedures	Clearance or permits required from multiple agencies	April 2015: Customs Clearance Facilitation Committees established at major sea- and airports.
Customs: Agriculture-specific procedures	Permits required from multiple agencies for trade in agricultural products	April 2015: announced formation of a “single window” through which permits from all regulatory agencies would be obtained online from Customs.

Source: Compiled by the Commission.

This chapter first describes notable tariff changes that occurred under the Modi government. The Modi government appears to have prioritized the reduction of duties for selected industries. The second part describes notable changes in customs procedures under the Modi government.

Tariffs

India's tariff and customs policies remain largely unchanged since *India 2014*. The most significant changes identified include (1) adjustments to the tariff rates across a variety of sectors and (2) steps taken to expedite the port clearance process.

Tariff Adjustments in Selected Sectors to Promote Domestic Manufacturing

In an effort to encourage domestic manufacturing in accordance with its Make in India initiative, the Modi government has increased tariffs in several sectors and reduced them in others.²⁴⁹ India's 2014–15 Union Budget²⁵⁰ increased tariffs for several telecommunications-related products—including cellphones, tablet computers, and digital video cameras—that India has asserted are not covered by the multilateral Information Technology Agreement (ITA).²⁵¹ This measure has prompted concern from some U.S. industry representatives. For instance, in its pre-hearing statement to the Commission, the National Association of Manufacturers raised concerns about whether India's "increased tariffs from zero percent to ten percent on four broad categories of telecommunications equipment and technologies" are in violation of the ITA.²⁵² The statement said that because these information and communications technology (ICT) goods may be covered by the ITA, they should receive duty-free treatment.²⁵³

India's 2015–16 Union Budget also announced duty reductions for imported components across various manufacturing sectors. The list encompassed 22 ICT-related products, including high-definition televisions; a number of clean energy goods, such as solar water heaters; textiles and apparel, such as leather footwear; and medical devices, including medical video endoscopes

²⁴⁹ Sharma, "How Modi Government Is Working," February 8, 2015; Chawla, "Budget 2015," February 28, 2015. The Make in India initiative is described in chapter 2.

²⁵⁰ India's 2015–16 Union Budget, which was released in February 2015, is described in more detail in chapter 2.

²⁵¹ Parbat, "DoT Backs 10% Customs Duty," August 11, 2014; Jaitley, "Budget Speech 2014–2015," July 10, 2014, 37. The ITA is a WTO-negotiated agreement on which negotiations concluded in December 1996. The ITA requires its 80 signatories to provide duty-free treatment to various information and communications technology (ICT) goods that are covered by the agreement. India became a signatory to this agreement in 1997. As of this report, India has not participated in negotiations to broaden the scope of the ITA—to create an ITA-2—by requiring duty-free treatment for additional products. Among other things, India has stated concerns about the potential adverse impact of an ITA-2 on its domestic ICT sector. Government of India, MOCI, "Brief Note on Status Regarding Information Technology Agreement," n.d. (accessed September 10, 2015); WTO, "Information Technology Agreement," n.d. (accessed July 23, 2015).

²⁵² Dempsey, written testimony to the USITC, April 23, 2015, 2.

²⁵³ Ibid.

and parts for pacemakers.²⁵⁴ Some of the tariff reductions on these goods were also intended to address an inverted tariff structure on certain goods, in which lower duties were applied to imports of finished goods than to imported components.²⁵⁵ The 2015–16 Union Budget also raised tariff rates on a number of goods, including certain steel products, gold and silver, and commercial vehicles. Notably:

- Base duties on certain steel products were raised by 5 percent to 15 percent in an effort to limit low-cost steel imports from China.²⁵⁶
- Duties were raised for gold and silver in April 2015 in response to declining global prices for the metals; the government feared that the lower prices would encourage demand for these goods over other savings instruments.²⁵⁷ Gold is India’s second-largest imported good by value after petroleum, and high imports of the commodity can raise the country’s already high current account deficit.²⁵⁸
- Import duties on commercial vehicles were doubled, rising to 10 percent—one of the most substantial tariff increases introduced.²⁵⁹

Agricultural Tariffs

One of the most prominent and longstanding concerns about India’s tariff regime reported in *India 2014* has been the country’s high tariff rates, especially for agricultural goods. Despite reductions in the trade-weighted tariffs for most goods since the mid-1990s, the trade-weighted average applied tariff for agricultural goods remained relatively high at 48 percent.²⁶⁰

²⁵⁴ Medical devices are discussed in chapter 6. The duty on solar water heaters was cut from 12 percent to zero. Duty reductions were set for organic chemicals, pharmaceuticals, bituminous coal, and components for various consumer electronics. How to Export Import.com, “Indian Union Budget,” April 11, 2015; Mukherjee, “Budget 2015,” March 2, 2015; First Post, “Budget 2015,” February 28, 2015.

²⁵⁵ Seth, “Budget 2015: FM Arun Jaitley,” March 1, 2015. Finance Minister Arun Jaitley, in presenting the 2015–16 budget, proposed reducing “the rates of basic customs duty on certain inputs, raw materials, intermediates, and components (in all 22 items) so as to minimize the impact of duty inversion and reduce the manufacturing costs in several sectors.” Jaitley, “Budget Speech,” February 28, 2015, 24.

²⁵⁶ How to Export Import.com, “Indian Union Budget,” April 11, 2015. During the most recent fiscal year, India’s imports of steel from China nearly doubled. Moreover, during April 2014 to January 2015, about 35 percent of India’s total steel imports were from China. Darabshaw, “India’s Budget,” March 6, 2015.

²⁵⁷ NDTV, “Government Hikes Import Tariff,” April 1, 2015.

²⁵⁸ Ibid.

²⁵⁹ *Economic Times*, “Budget 2015,” February 28, 2015.

²⁶⁰ USITC, *India 2014*, 2014, 109. Trade-weighted average tariff rates are applied tariff rates adjusted to account for import volumes. Trade-weighted averages are a useful measure of tariff restrictiveness, but may understate the effects of duties in cases where rates are so high that they deter trade.

Moreover, India's bound tariff rates on agricultural imports, which can range between 100 and 300 percent ad valorem, were reported as being among the world's highest.²⁶¹

In August 2015, the Ministry of Finance announced a 10-percent duty on wheat—imports of which had previously been duty free.²⁶² This tariff increase reportedly was made to help Indian farmers following years of high wheat imports.²⁶³ The Commission has not identified any other significant changes to India's agricultural tariffs since *India 2014*.

Customs Procedures

Delayed processing of goods through customs was another problem noted by U.S. firms in *India 2014*.²⁶⁴ That report described situations in which importers required permission from several authorities, none of whom could coordinate the processing of import clearance documents.²⁶⁵ For example, although many of India's major ports operate 24 hours a day and 7 days per week, sometimes cargoes could not be unloaded because shippers lacked the necessary clearance from agencies such as the Food Safety and Standards Authority of India (FSSAI). In an effort to reduce delays, in October 2014 India's central customs authority, the Central Board of Excise and Customs (CBEC), asked the various customs clearance agencies to list the infrastructure and manpower needs that would have to be met in order to support full-time port operations.²⁶⁶

Steps to Expedite Customs Clearance

Under the Modi government, the CBEC has recognized the need to expedite the customs clearance process as a means to make it easier to do business in India.²⁶⁷ As of December 2014, 24/7 customs clearance is available at 18 major seaports and 17 air cargo ports in India.²⁶⁸ Further, in December 2014 the Cochin Port Trust and the Cochin Customs Commissioner

²⁶¹ USITC, *India 2014*, 2014, 109. Applied rates are the rates that are currently in effect. Bound rates are the maximum rates that may be applied on a particular product imported from another WTO member state. Bound rates are part of a country's WTO commitments or concessions. Ad valorem rates are tariff rates that are calculated as a percentage of the import's value, as opposed to tariff rates calculated per unit or by weight.

²⁶² Government of India, Ministry of Finance, "Notification No. 44/2015," August 7, 2015.

²⁶³ Reuters, "Update 1—India Restores Wheat Tariff After Big Imports," August 7, 2015.

²⁶⁴ Additionally, the report discussed the inconsistent interpretation of customs valuation rules and the uneven application of India's Customs Electronic Commerce/Electronic Data Interchange Gateway (IceGate). However, the Commission's research did not uncover any new policies or measures that addressed these barriers. USITC, *India 2014*, 2014, 124–28.

²⁶⁵ USITC, *India 2014*, 2014, 125.

²⁶⁶ *Indian Express*, "CBEC to Port Regulators," October 7, 2014. Infrastructure problems are a hindrance across India's economy, affecting both domestic firms and foreign companies operating in India. Policies to address some of India's infrastructure problems are discussed in chapter 2.

²⁶⁷ *Economic Times*, "Government Sets Up CCFs," July 7, 2015.

²⁶⁸ Government of India, Ministry of Finance, Central Board of Excise and Customs, "Circular No. 19/2014," December 12, 2014.

announced that clearance time at the International Container Transshipment Terminal at Vallarpadam would be reduced from an average of 15 days to only 3 days.²⁶⁹ At nearly the same time, India Gateway Terminal Private Limited, which handles the physical unloading of cargo at the terminal, announced a proposal to reduce the period of time a container can stay in the shipyard without incurring demurrage charges from 7 days to 3 days.²⁷⁰ A few months later, these improvements had reportedly reduced clearance times from 16 days to 7 days for goods transported by vessel, while air freight clearance times had been reduced to 2 or 3 days.²⁷¹

For the agricultural sector, the Modi government introduced what it terms a single-window system—in which importers deal with one ministry to obtain clearances, as opposed to several—in the 2015–20 Foreign Trade Policy²⁷² to speed customs clearance in agricultural products.²⁷³ As a result, the CBEC is coordinating with other agencies to reduce the number of government contacts required, shorten the clearance process, and lower import costs. The FSSAI and the Department of Plant Protection, Quarantine, and Storage are particularly involved with this effort.²⁷⁴ A Customs Clearance Facilitation Committee was established in April 2015 at major ports, bringing together representatives from each of the regulatory agencies commonly involved in clearing shipments.²⁷⁵ In addition, the 2015–20 Foreign Trade Policy introduced the Merchandise Exports from India Scheme to simplify requirements for exporters by combining five different support programs and offering more support for most agricultural products.²⁷⁶

Customs Concerns Persist

Despite various improvements in customs clearance policies under the Modi government, recent Commission fieldwork in India revealed additional concerns regarding customs

²⁶⁹ *Deccan Chronicle*, “Clearance Time at Vallarpadam to Be Down,” December 10, 2014.

²⁷⁰ *Business Standard*, “ICTT Kochi Plans to Reduce Free Period,” January 20, 2015. A demurrage charge is a charge to compensate the owner of a vessel for loading or unloading time.

²⁷¹ Industry representative, interview by USITC staff, Mumbai, April 22, 2015.

²⁷² India’s 2015–20 Foreign Trade Policy is described in more detail in chapter 2.

²⁷³ Government of India, MOCI, Department of Commerce, “Highlights of the Foreign Trade Policy,” 2015.

However, the single-window system is reportedly not yet operational, and importers of agricultural products may still need to deal with multiple ministries to obtain clearance. U.S. government official, email message to USITC staff, September 11, 2015.

²⁷⁴ The role of the FSSAI in administering standards and technical regulations is described in chapter 6.

Government of India, Ministry of Finance, “Circular No. 09/2015-Customs,” March 31, 2015.

²⁷⁵ Each CCFC is to be headed by the Chief Customs Commissioner at the port, plus the most senior representatives of each of the other relevant agencies. Government of India, Ministry of Finance, Central Board of Excise and Customs, “Circular No 13/2015-Customs,” April 13, 2015.

²⁷⁶ Government of India, MOCI, Department of Commerce, “Highlights of the Foreign Trade Policy 2015–2020,” 2015.

procedures that remain unresolved. For instance, industry representatives in Bangalore stated that India's ban on imports of used electronics makes sourcing such articles—including refurbished mobile phones, servers, data storage equipment, and networking products²⁷⁷—difficult. They also expressed reservations about the duties that are applied to re-exported products and discussed challenges associated with importing goods into special economic zones in a timely way.²⁷⁸

Other industry representatives reported that customs delays principally affected the 5 to 7 percent of cases where the contents of a shipment were “flagged” for additional inspection, which translated into up to 10 days of processing for the goods to clear customs.²⁷⁹ Delayed adoption of electronic data interchange (EDI) facilities may account for some of these delays, as only 134 of India's 377 customs offices had these capabilities as of June 2015.²⁸⁰

²⁷⁷ *Indian Express*, “Top Tech Firms Denied Permission to Import Second Hand Equipment,” July 31, 2015.

²⁷⁸ Industry representatives, interviews by USITC staff, Bangalore, April 20, 2015.

²⁷⁹ Industry representative, interview by USITC staff, Mumbai, April 24, 2015.

²⁸⁰ *Icegate.gov*, “About ICES,” n.d. (accessed June 1, 2015); WTO, *Trade Policy Review*, April 28, 2015.

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Chapter 5

Local-content and Localization Requirements

Local-content and localization requirements are broadly defined in this report as policies that require foreign firms to purchase Indian inputs, conduct a share of business in India, conduct certain business activities in India, or submit to India-specific testing or registration. *India 2014* identified a number of local-content requirements as impediments to U.S. access to the Indian market. The two domains principally affected by these rules were information and communications technology (ICT) and solar power generation. During May 2014–July 2015, requirements in these sectors and other sectors continued to impede U.S. market access in India. Moreover, the Modi government has expanded—or proposed expanding—some local-content and localization requirements (table 5.1).

This chapter describes notable changes to India’s policies and practices regarding local-content requirements and localization measures. Many of these policies affect primarily ICT products, including the Preferential Market Access (PMA) policy, the Compulsory Registration Order (CRO), telecommunications license amendments, offsets, and the National Telecom Roadmap. Local-content requirements in the solar industry also are described.

Preferential Market Access Policy

The PMA established local-content requirements for government procurement of certain manufactured electronic products and telecommunications equipment. As explained in *India 2014*, the PMA was first issued in February 2012 under the previous government.²⁸¹ It was originally written to apply to both public and private procurement in India. But the previous government, in July 2013, limited the PMA to the central government’s procurement of ICT goods as well as all goods purchased by government ministries except the Ministry of

²⁸¹ USITC, *India 2014*, 2014, 187–89.

Table 5.1: Local-content and localization requirements, May 2014–July 2015

Policy or practice	Description of barrier pre-May 2014	Changes found under Modi government
Preferential Market Access (PMA) policy	Requires certain ICT products to include a specified share of Indian content when procured by government entities.	<p>In November 2014 three products were added to the list—biometric iris sensors, biometric access/authentication devices, and biometric fingerprint sensors.</p> <p>December 2014 saw implementation of an online system to monitor government procurement to enforce compliance with the PMA policy.</p> <p>In December 2014 the Indian government published guidelines directing all ministries to give preference to domestically produced ICT goods in government procurement as part of the Make in India initiative.</p>
Compulsory Registration Order (CRO)	Requires mandatory registration of electronic products, whether imported or manufactured in India, with a goal of ensuring consumer safety.	In November 2014 CRO expanded to cover most ICT products, including highly specialized equipment and ICT products that are installed, operated, and maintained by professionals.
Policies for certain ICT products	Policies encourage indigenous manufacturing and establish preferences for certain domestically manufactured ICT products.	The May 2015 National Telecom Roadmap proposed new guidelines for certain ICT products, including: preference for servers and data centers to be located in India, restrictions on use of foreign SIM cards, plans to make Internet-connected devices subject to the PMA policy, and mandatory certification and registration policies.
Offset policies	Requires foreign companies selling goods or services to the Indian government or state-run firms to purchase a preset percentage of the sales value from Indian manufacturers and suppliers.	2015 draft National Offset Policy reportedly would require foreign companies selling goods or services to the Indian government or government-run firms to purchase 30 percent of the total procurement sales value from Indian manufacturers and suppliers.
Telecommunications license amendments	Requires testing of imported equipment in Indian laboratories; requires vendors to allow inspection of manufacturing facilities; and imposes liability when vendor has taken “inadequate” precautionary security measures.	Implementation has been delayed, although no official notification about the extension has been made.
Policy for solar energy products	Requires that certain solar energy projects use a specified share of local products.	No changes identified. New tender in June 2015 contains local-content requirements.

Source: Compiled by the Commission.

Defense.²⁸² The Modi government appears to have continued implementing the PMA only for public procurement.

In November 2014, three new products were added to the list of domestically manufactured products to which the government is expected to give preference in procurement: biometric iris sensors, biometric access control/authentication devices, and biometric fingerprint sensors; all of these are potential U.S. exports to India.²⁸³ To enforce compliance with the PMA, the Department of Indian Electronics and Telecommunications set up an online monitoring system to record procurement of ministries and state governments in real time.²⁸⁴

PMA-type policies also appear in the Make in India and Digital India initiatives.²⁸⁵ In December 2014, India released a statement that “to boost electronics production, as part of Prime Minister Narendra Modi’s Make in India initiative, the Union government has issued strict guidelines to all ministries to provide preference to domestically manufactured electronic products in government procurement.”²⁸⁶ In addition, the Digital India website states that the initiative “focuses on promoting electronics manufacturing in the country with the target of NET ZERO Imports by 2020” and includes the following: “preference to domestically manufactured goods in Government procurement. Extent of government procurement will not be less than 30 percent. Around 30 electronic products are already notified under this scheme.”²⁸⁷

PMA may not affect U.S. business as significantly as once thought. Based on the published regulations, it originally appeared that the PMA would have a potentially serious negative impact on U.S. companies because the Indian government and public sector activities account for an estimated 30 percent of India’s ICT marketplace.²⁸⁸ However, information suggests that the PMA has not been widely implemented. As a result, the PMA appears to have had a limited

²⁸² The PMA for domestically manufactured specified IT products ranges from 50 to 100 percent, while the percentage of value addition required for the products to be classified as domestically manufactured ranges from 25 to 45 percent. Both PMA and value-added requirements increase every year. Similarly, a specified share of each telecommunications product, starting at 30 percent and rising potentially to 100 percent by 2020, would have to be filled by Indian-based manufacturers. Ezell and Atkinson, “The Indian Economy at a Crossroads,” April 2014, 21.

²⁸³ For each of these, at least 50 percent of procurements should show a preference for domestically manufactured products. For year 1, the minimum domestic content necessary for each of the three products to be classified as domestically manufactured is 30 percent. The domestic value required will automatically increase by 5 percent per year for all products. Government of India, MCIT, “Notification: Policy for Preference,” October 1, 2014.

²⁸⁴ Government of India, Prime Minister’s Office, “Ensure Preference to Domestically Manufactured Electronic Products,” December 27, 2014.

²⁸⁵ The Make in India and Digital India initiatives are discussed in chapter 2.

²⁸⁶ Government of India, Prime Minister’s Office, “Ensure Preference to Domestically Manufactured Electronic Products,” December 27, 2014.

²⁸⁷ Government of India, DEITY, “Electronics Manufacturing,” updated June 26, 2015.

²⁸⁸ Ezell and Atkinson, “The Indian Economy at a Crossroads,” April 2014, 21.

effect on U.S. companies' ability to sell ICT products to the Indian government. For example, several companies noted in the spring of 2015 that because of weak local manufacturing in the ICT industry and repeated implementation delays, the policy had not affected their operations.²⁸⁹ Industry representatives stated that a number of Indian ministries have not implemented the PMA and that few Indian companies are positioned to take advantage of it, limiting the PMA's negative impacts.²⁹⁰

Nevertheless, other industry representatives reported that policies like the PMA have increased the perceived risk of operating in the Indian market.²⁹¹ They cite the PMA as a potential barrier to market access for foreign goods and suppliers, including U.S. ICT firms—particularly those that have already made a commitment to the Indian market. Some industry representatives are concerned that, if the government directs the Indian public sector to procure 80 percent of its ICT and electronics products from domestic sources by 2020, as indicated in the October 2012 “Notification of Policy for Preference,” the PMA will become increasingly harmful to U.S. firms.²⁹²

Compulsory Registration Order Policy

The original CRO policy (CRO I) became effective in January 2014 under India's previous government. CRO I established mandatory registration and testing of 15 categories of electronic products—whether imported or manufactured in India—with the stated goal of ensuring consumer safety.²⁹³ *India 2014* reported that some U.S. companies found India's compulsory registration for ICT products led to significant compliance and liability costs.²⁹⁴

India announced a broadening of the scope of its CRO policy in November 2014 with the addition of a new program, CRO II.²⁹⁵ While the CRO I applies only to consumer electronic

²⁸⁹ Industry representative, interview by USITC staff, New Delhi, May 12, 2015; industry representative, interview by USITC staff, New Delhi, May 15, 2015; industry representatives, interviews by USITC staff, Washington, DC, May 1, 2015, Mumbai, April 24, 2015, and Bangalore, April 20, 2015.

²⁹⁰ *Ibid.*

²⁹¹ Industry representatives, interview by USITC staff, Washington, DC, May 1, 2015, and July 22, 2015; Telecommunications Industry Association, “Updated U.S.-India ICT Dialogue: Issues and Recommendations,” July 2015, 9.

²⁹² Government of India, MCIT, DOT, “Notification of Policy for Preference,” October 12, 2012; industry representatives, interview by USITC staff, Washington, DC, May 1, 2015, and July 22, 2015.

²⁹³ Those 15 products are amplifiers; automated data processing machines; electronic clocks; electronic musical systems; laptops/notebooks/tablets; LCD/LED/plasma TVs; microwave ovens; optical disc players; printers and plotters; scanners; set-top boxes; telephone answering machines; video games; visual display units; and wireless keyboards. Government of India, Bureau of Indian Standards, “Electronics and Information Technology Goods,” 2012; Government of India, MCIT, DOT, “Notification,” November 7, 2014.

²⁹⁴ USITC, *India 2014*, 2014, 341.

²⁹⁵ Government of India, MCIT, DOT, “Notification,” November 7, 2014.

products, the CRO II, which became effective in May 2015, applies to 15 additional ICT product categories.²⁹⁶ In addition, the CRO II requires that:

- The “manufacturing unit” (i.e., factory) for each product—rather than the company that designs the product—must register with the Bureau of Indian Standards (BIS);
- Manufacturers (or importers upon authorization from manufacturers) must submit product samples from each manufacturing unit for testing by one of four “BIS recognized laboratories” located in India; and
- Each product placed on the Indian market must contain a “self-declaration mark” confirming conformity with the relevant Indian standards for that product.²⁹⁷

A U.S. industry association stated that frequent updates and changes during the implementation of the CRO policy have caused companies to make costly last-minute adjustments that could halt or delay shipments of ICT products to India.²⁹⁸ U.S. and other government representatives expressed concerns about India’s CRO policy at a November 2014 WTO meeting on technical barriers to trade, including:

- Requirements that manufacturers who already test to an international standard must retest to an identical BIS standard;
- Registration renewal rules requiring information that is difficult to gather;
- Intrusive labeling requirements;
- Burdensome battery registration requirements; and
- Insufficient testing capacity in India, leading to delays and fines for noncompliance.²⁹⁹

²⁹⁶ Those 15 products are power adapters for information technology equipment; power adapters for audio, video, and similar electronic apparatus; certain UPS/invertors; DC or AC supplied electronic control gear for LED modules; sealed secondary cells/batteries for use in portable applications; ballasted LED lamps for general lighting; fixed general-purpose LED luminaires; mobile phones; cash registers; point of sale terminals; copying machines and duplicators; smart card readers; mail processing/postage/franking machines; passport readers; and power banks for use in portable applications. Government of India, MCIT, DOT, “Guidelines for Series Approval,” 2015; Government of India, MCIT, DOT, “Notification,” October 3, 2012.

²⁹⁷ USTR, *2015 National Trade Estimate Report*, March 2015, 178.

²⁹⁸ ICT companies need at least 12 months to adjust manufacturing and supply chains to comply with new regulatory requirements. ITIC, “Technology Policy Recommendations for the Government,” June 2014, 3.

²⁹⁹ WTO, Committee on Technical Barriers to Trade, “Minutes of 5–6 November 2014,” March 6, 2015.

According to U.S. industry representatives, not a single product design is known to have been changed as a result of the duplicative CRO testing and registration requirements.³⁰⁰ Moreover, the CRO testing and registration requirements create a considerable expense to companies. One U.S. company reported that, from June 2014 to June 2015, it spent more on compliance costs in India alone than in all of the 100-plus other countries in which it operates.³⁰¹

ICT Products and National Telecom Roadmap³⁰²

In May 2015, the Modi government released the National Telecom Machine-to-Machine (M2M) Roadmap (Roadmap).³⁰³ It builds on policies set out in 2012, and describes policy and regulatory approaches, standard development initiatives, and actions the government plans to take to further the growth of an M2M ecosystem in India. The Roadmap aims to provide a framework for India's deployment of M2M Internet technologies as an integral part of the country's future economic growth and development, and it links to other Indian government initiatives, including Make in India, Digital India, and Smart Cities.³⁰⁴

The Roadmap references India's 2012 National Telecom Policy (NTP), which required both indigenous manufacturing of telecommunications equipment and preferential treatment to indigenous manufacturers.³⁰⁵ The Roadmap specifically cites two NTP objectives and strategies: (1) "promoting the ecosystem for design, R&D, IPR creation, testing, standardization and manufacturing Indian telecom sector demand to the extent of 60% and 80% by the year 2017 and 2020, respectively" and (2) "providing preference to domestically manufactured telecommunication products, in procurement of those telecommunication products which have security implications for the country and in Government procurement for its own use, consistent with WTO commitments."³⁰⁶

The Roadmap provides guidelines proposing certain local-content and localization measures to achieve its goals, including:

³⁰⁰ U.S. industry representatives, interviews by USITC staff, Washington, DC, May 1, 2015.

³⁰¹ U.S. industry representative, interview by USITC staff, Washington, DC, July 1, 2015.

³⁰² The Indian government's official name for this plan is the "National Telecom Machine-to-Machine (M2M) Roadmap."

³⁰³ Government of India, MCIT, "Roadmap," May 12, 2015. M2M communications involves a network of Internet-connected devices that communicate among themselves and without human intervention. It is also referred to as the "Internet of things." Examples of the use of M2M communications can be found in USITC, *Digital Trade, Part 2*, 2014, 159–66.

³⁰⁴ Government of India, MCIT, "Roadmap," May 12, 2015. Make in India, Digital India, and Smart Cities are described in chapter 2.

³⁰⁵ Government of India, MCIT, "Roadmap," May 12, 2015, 29.

³⁰⁶ *Ibid.*

- **Data localization:** The Roadmap states that “from [a] security perspective, there is a strong case for all M2M Gateways and application servers, servicing the customers in India, to be physically located in India.”³⁰⁷ It goes on to say that this may not be economically feasible in some cases—such as M2M providers serving a small customer base in India. In addition, it states that a “decision regarding location of servers in various other services i.e. e-mail, social media etc. is likely to have a bearing on M2M services as well. All such relevant factors need consideration and physical location shall be in consonance with decisions in other services”³⁰⁸
- **Restrictions on the use of foreign SIMs**³⁰⁹: The Roadmap states that “to begin with, machines sold and manufactured in India may be allowed to be equipped with SIMs of Indian TSPs (telecommunications service providers) only,” but goes on to say that “in the long run, foreign SIMs should be permitted in the devices to be used in India only on the condition of fulfillment of traceability criteria.”³¹⁰
- **Including M2M devices in the PMA policy:** The Roadmap states that “keeping in view future M2M growth in India and increased M2M products manufacturing, a number of products can be brought into PMA framework.”³¹¹
- **Mandatory certification:** The Roadmap states that “Network Device Certification is a non-negotiable requirement for bringing new devices onto existing carrier networks. Regardless of whether the module (modem) component within a device has passed certification, any new device is required to pass certification prior to allowing commercial deployment.”³¹²
- **Registration of M2M service providers:** The Roadmap states that “all M2M service providers utilizing telecom facilities from authorized TSPs should have MSP (M2M service provider) registration.”³¹³

U.S. industry representatives expressed a wide range of views and concerns about some of policies included in the Roadmap. For example, the American Chamber of Commerce in India (AmCham India) stated that mandatory data localization would not achieve India’s stated goal of improving data security. AmCham India further stated that “localization mandates simply

³⁰⁷ Government of India, MCIT, “Roadmap,” May 12, 2015, 23.

³⁰⁸ Ibid.

³⁰⁹ A SIM (“subscriber identity module”) card is a component of mobile devices, such as cellphones and tablets. The main use of the SIM card is to securely store information used to identify and authenticate subscribers on mobile networks.

³¹⁰ Traceability refers to the ability of the telecommunications service provider to be able to locate the customer registered to use the SIM. Government of India, MCIT, “Roadmap,” May 12, 2015, 20–21.

³¹¹ Government of India, MCIT, “Roadmap,” May 12, 2015, 30.

³¹² Ibid., 31.

³¹³ Ibid., 20.

drive up the cost of operations and these cost are ultimately passed on to consumers,” which would discourage success of the Make in India initiative.³¹⁴ According to one U.S. industry association, the Roadmap’s reliance on local data storage “risks setting a dangerous precedent,” and it recommends that India develop technology standards in line with global standards.³¹⁵ Other U.S. industry sources said that requiring foreign companies to use Indian ICT infrastructure (such as servers and data centers) to provide digital services in India would increase the cost and complexity of doing business in India, and make it difficult for foreign providers to offer cloud computing services in India.³¹⁶ Other sources reported that India’s enforcement of these Roadmap provisions could be difficult: because ICT components are produced in global supply chains, prohibiting the use of foreign SIMs would be technically infeasible.³¹⁷

In addition, the Roadmap’s broad definition of an M2M service provider and its registration requirements for Internet-connected services and products lead some in the industry to believe that the Roadmap could make it difficult for foreign companies to enter the Indian market.³¹⁸ According to one U.S. industry representative, the Roadmap’s “focus on developing capacity within India’s borders goes too far by focusing on supporting indigenous innovation at the expense of innovation as a whole.”³¹⁹

Offset Policies

India 2014 identified India’s defense and civil aerospace offset policy as a barrier to U.S. companies operating in India. As described in that report, the program encourages industrial activity in India by requiring 30 to 50 percent of the value of any major defense contract with a foreign company to be offset through that company’s purchase of locally produced goods.³²⁰

³¹⁴ American Chamber of Commerce in India, “AmCham Comments on Draft National Telecom M2M Roadmap,” February 25, 2015. Make in India is described in chapter 2.

³¹⁵ ITIF, written submission to USITC, June 2, 2015, 5.

³¹⁶ Industry representative, interview by USITC staff, Washington, DC, July 29, 2015; BSA, “Special 301 Submission to USTR,” February 6, 2015; Parbat, “Telecom Department Suggests All M2M Servers Be Based in India,” December 17, 2014.

³¹⁷ Industry representative, interview by USITC staff, Washington, DC, July 15, 2015; TIA, “Views on May 2015 India Department of Telecommunications National Telecom M2M Roadmap,” October 29, 2014, 7.

³¹⁸ Telecommunications Industry Association, “Telecommunications Industry Association Views on 2015 India M2M Roadmap,” July 20, 2015.

³¹⁹ ITIF, written submission to USITC, June 2, 2015, 5.

³²⁰ USITC, *India 2014*, 2014, 212.

2015 Draft National Offset Policy

Press reports indicate that the Modi government is considering creating a new offset policy or mechanism covering non-defense government procurement in a number of sectors, but many of the details remain unclear. India’s Ministry of Commerce and Industry has reportedly prepared a draft National Offset Policy (NOP), which would require foreign companies selling goods or services to the Indian government or state-run firms to purchase a predetermined percentage of their sales values from Indian manufacturers and suppliers.³²¹ Under that draft policy, the minimum share of the offsets obligation would reportedly be 30 percent of the total procurement from a company—the same share as under the defense and civil aerospace offset program, as described below.³²² Press reports indicate that foreign firms selling goods worth over Rs 3 billion (\$48.4 million) would have to source part of their supplies from domestic manufacturers.³²³ Sectors which could be included are telecommunications, medicine, civil aerospace, power, fertilizer, railways, ports and shipyards, and mining.³²⁴ To spread the increased domestic manufacturing and technology transfer across sectors, the NOP would also include cross-sector offsetting, under which foreign suppliers can fulfill their offset obligations via purchases in a different sector.³²⁵ In response to feedback from other ministries, the Ministry of Commerce and Industry is reportedly considering reducing the number of sectors covered and increasing the threshold to Rs 10 billion (\$161.4 million), as well as changing the name to “offset mechanism” due to the reduced coverage.³²⁶ National media reports indicate that the policy is awaiting approval by the Cabinet.³²⁷

New Defense Procurement Procedures Planned

As stated in *India 2014*, India’s defense offset policy dates to 2005, but it existed informally before then. The current policy requires a minimum of a 30 percent offset for defense

³²¹ Moneycontrol.com, “Com Min to Soon Seek Cabinet Nod,” May 12, 2015.

³²² *Economic Times*, “Commerce and Industry Ministry to Soon Seek Cabinet Nod,” March 20, 2015.

³²³ Moneycontrol.com, “Com Min to Soon Seek Cabinet Nod,” May 12, 2015; *Economic Times*, “Commerce and Industry Ministry to Soon Seek Cabinet Nod,” March 20, 2015.

³²⁴ *Economic Times*, “Commerce and Industry Ministry to Soon Seek Cabinet Nod,” March 20, 2015.

³²⁵ Sen, “Centre Reworking Draft Offset Policy,” March 16, 2015.

³²⁶ *Ibid.*

³²⁷ *Economic Times*, “Commerce Ministry to Soon Seek Cabinet Nod,” May 11, 2015.

equipment of Rs 3 billion (about \$48.4million) or more, procured under the Defence Procurement Procedure.³²⁸

U.S. industry representatives report that the offset program limits their investment opportunities in India. Their specific concerns include:

- **Offset obligations not allowed to be completed after the main contract.** India's offset policy requires that all offset work be completed within the timeline of the main contract. However, defense contracts tend to last five years, while completing high-tech technology transfer programs, which the Indian government prefers as offset obligations, can take much longer.³²⁹
- **Limitation of offset responsibility for direct suppliers.** Direct suppliers³³⁰ are not allowed to participate in offsets beyond their contribution (by value) to the full contract. Thus, if a supplier provides 10 percent of the value of the project, then it can only provide 10 percent of the value for the offset. This removes the incentive for direct suppliers to participate in a program for a total that goes beyond a 30 percent offset.³³¹
- **No retroactive changes.** The Indian government modifies the procurement policy every two years, but older contracts are governed by the procurement policy in place when the contract was signed. Thus, even if the Indian government makes the offset policy easier to comply with some time later, companies that agreed to a contract under the previous system cannot take advantage of the revised policy. Companies are thus hesitant to commit to a contract if they think the rules may soon improve.³³² Industry representatives also reported that the biennial updates to the offset program's rules make it difficult for companies to plan how to meet offset requirements for future projects.³³³
- **Inflexible contracts.** The Indian government does not allow companies to change how they will complete their offset requirements once the contract has been finalized. This

³²⁸ USITC, *India 2014*, 2014, 213. Defense products purchased via intergovernmental agreements do not necessarily require offsets, and they are not governed by the DPP, which was created in 2002. Historically, most Indian defense purchases were made through intergovernmental agreements (primarily with Russia), but purchases under the DPP have been increasing. Chibber and Dhawan, "A Bright Future for India's Defense Industry?" 2013.

³²⁹ Lall, "Evolving Defence Procurement," April 12, 2010; industry representative, interview by USITC staff, New Delhi, May 14, 2015.

³³⁰ A direct supplier (also known as a Tier 1 subvendor) develops and produces significant portions of the final product for the original equipment manufacturer.

³³¹ CII, "Ensuring Ease of Doing Business," February 2015; industry representative, interview by USITC staff, New Delhi, May 14, 2015.

³³² CII, "Attracting Foreign Investment," November 2014; industry representative, interview by USITC staff, New Delhi, May 14, 2015.

³³³ Industry representative, telephone interview by USITC staff, April 7, 2015.

can create difficulties if the situation changes—for example, if demand no longer exists for the product that a company agreed to produce in India (using Indian components) to fulfill its offset requirements.³³⁴

- **Exclusion of services.** Since May 2013, original equipment manufacturers (OEMs) may not use services to discharge offset requirements. This restriction hamstrings OEMs that provide training services (including simulator use) and maintenance as part of their contracts, as they could otherwise arrange to provide these services using Indian companies or joint ventures.³³⁵

Media reports indicate that India may release a draft set of new defense procurement procedures later in 2015. The draft procedures reportedly may include changes that would help U.S. and other foreign defense companies meet their offset obligations.³³⁶

Rules on Telecommunications Licenses

Over the years, amendments to the rules governing India’s telecommunications licenses have introduced local-content requirements. *India 2014* described these telecommunications license amendments, which:

- require testing of imported equipment in Indian laboratories; this differs from internationally accepted procedures, which accept ICT goods that have been tested in internationally accredited labs, regardless of the location;
- require vendors to allow inspection of manufacturing facilities; and
- impose liability when a vendor has taken “inadequate” precautionary security measures.³³⁷

³³⁴ CII, “Ensuring Ease of Doing Business,” February 2015; industry representative, telephone interview by USITC staff, April 7, 2015; industry representative, interview by USITC staff, Washington, DC, April 9, 2015; industry representative, interview by USITC staff, New Delhi, June 1, 2015.

³³⁵ Anand and Bogra, “Offsets,” June 2014.

³³⁶ *Economic Times*, “New Defence Offset Policy in the Offing,” March 30, 2015; Raghuvanshi, “India Proposes To Simplify Offset Process,” June 21, 2015.

³³⁷ USITC, *India 2014*, 2014, 173, 190–91.

U.S. ICT manufacturers reported that these policies act as barriers to U.S. exports. They said India lacks the capacity and resources to manage the volume and type of ICT hardware that enters the market, resulting in significant shipment delays.³³⁸

The Modi government postponed implementation of these telecommunications license amendments, reportedly due to the lack of adequate infrastructure and testing facilities in India.³³⁹ This postponement, announced in April 2015 by the Indian Department of Telecommunications, delayed implementation of the requirement for telecommunications equipment vendors to test and certify all imported ICT equipment to current Indian or international security standards at authorized and certified labs or agencies in India.³⁴⁰ Although there have been reports that the implementation date would be extended to April 2016, there has been no official notification of a new date.³⁴¹

Solar Industry Policies

As described in India 2014, the Indian government maintains local-content requirements for firms bidding on some projects related to the Jawaharlal Nehru National Solar Mission (JNNSM).³⁴² It also offers incentives such as long-term, contractually guaranteed rates to project developers who agree to use locally sourced equipment. The Modi government did not change its policy toward the JNNSM's local-content requirements during May 2014–July 2015.³⁴³

Local-content requirements for the JNNSM continued to be implemented in 2015. As described in the March 2015 announcement of Phase II of the JNNSM, for each tranche of the tenders offered, the Indian government will evaluate current market conditions and decide on the

³³⁸ USITC, *India 2014*, 2014, 191.

³³⁹ WTO, Committee on Technical Barriers to Trade, “Minutes of 18–19 March, 2015,” May 28, 2015.

³⁴⁰ The amendments also include (1) requirements to give both Indian government agencies and the telecommunications service provider (TSP) that contracted with the vendor the right to inspect the vendor's manufacturing facilities and supply chain and to perform security checks for the duration of the contract to supply equipment to the TSP; and (2) a provision imposing on vendors, without the right to appeal or other due-process guarantees, strict liability and possible “blacklisting for doing business in the country” if the vendor has taken inadequate precautionary security measures. USTR, *2015 National Trade Estimate Report*, March 2015, 178–79.

³⁴¹ Government representative, interview by USITC staff, Washington, DC, June 11, 2015, and June 25, 2015; WTO, Committee on Technical Barriers to Trade, “Minutes of 18–19 March, 2015,” May 28, 2015.

³⁴² USITC, *India 2014*, 2014, 174–82.

³⁴³ The United States initiated a WTO case challenging these requirements in February 2013. On March 24, 2015, the Chair of the panel informed the WTO Dispute Settlement Body that the panel expected to issue its final report to the parties by late August 2015, in accordance with the timetable adopted after consultation with the parties. As of September 16, 2015, a panel report in this dispute had not been circulated to members and the USTR had not issued a press release. USTR, *2015 National Trade Estimate Report*, March 2015, 182–83; WTO, “India—Certain Measures Relating to Solar Cells and Solar Modules,” DS456 (accessed July 10, 2015); Roy, “WTO Panel Rules against India's Solar Program,” September 1, 2015.

share of projects to be reserved for domestically manufactured solar cells and modules. Domestic content requirements will be applied equally to both crystalline and thin-film solar cells and modules.³⁴⁴ For the June 2015 tender offer, India plans to contract for 2,000 megawatts (MW) of grid-connected photovoltaic (PV) solar power by 2017. Of the 2,000 MW total, 250 MW are to be reserved for domestic-content projects, using solar PV cells and modules manufactured in India.³⁴⁵

³⁴⁴ Government of India, Ministry of New and Renewable Energy, “Implementation of Project,” March 5, 2015.

³⁴⁵ Government of India, Ministry of New and Renewable Energy, “Implementation of Scheme,” June 17, 2015.

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Chapter 6

Standards and Case Studies

India 2014 reported that many experts perceived a large number of India’s standards, technical regulations,³⁴⁶ and conformity assessments³⁴⁷ as restricting U.S. exports of certain goods, particularly agricultural and food products.³⁴⁸ Policies and practices described as particularly burdensome included sanitary and phytosanitary (SPS) measures that may differ from international norms; consumer labeling requirements; local-testing requirements;³⁴⁹ and other measures—particularly those involving agricultural products—that were seen as scientifically unwarranted. While some policies described in *India 2014* were of general application, others were sector-specific, such as special requirements for medical devices and wines.³⁵⁰ Table 6.1 summarizes significant changes in relevant policies and practices made by the Modi government.

According to a number of U.S. government and industry representatives, the Modi government has addressed some of these concerns since May 2014, particularly in its stated commitments

³⁴⁶ The WTO describes standards and technical regulations as policies that “set out specific characteristics of a product—such as its size, shape, design, functions and performance, or the way it is labelled or packaged before it is put on sale.” The difference between standards and regulations is that “while conformity with standards is voluntary, technical regulations are by nature mandatory.” WTO, World Trade Organization (WTO). “Technical Information on Technical Barriers to Trade,” n.d. (accessed July 30, 2015). The WTO goes on to say, “If an imported product does not fulfil the requirements of a technical regulation, it will not be allowed to be put on sale. In case of standards, non-complying imported products will be allowed on the market, but then their market share may be affected if consumers prefer products that meet local standards.” The American National Standards Institute (ANSI) further describes technical regulations as being developed by government regulators, while standards are developed by a consensus process generally open to all stakeholders through nongovernmental standards organizations, standards bodies, standards-developing organizations, or standards-setting organizations. ANSI, <http://www.ansi.org/>; International Organization for Standardization, <http://www.iso.org/>.

³⁴⁷ Conformity assessments—involving testing, verification, inspection, and certification—determine whether products meet established standards and technical regulations. Exporters typically bear the cost of these procedures. The WTO notes that “non-transparent and discriminatory conformity assessment procedures can become effective protectionist tools.” WTO, “Technical Information on Technical Barriers to Trade,” n.d. (accessed July 30, 2015); WTO, Secretariat, *Trade Policy Review: India*, 2015, 59.

³⁴⁸ The WTO Agreement on Technical Barriers to Trade (TBT) “aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade.” WTO, World Trade Organization (WTO). “Technical Information on Technical Barriers to Trade,” n.d. (accessed July 30, 2015).

³⁴⁹ USITC, *India 2014*, 2014, 53, 77, 191, 241, 255.

³⁵⁰ *Ibid.*, 249, 252, 262, 352.

Table 6.1: Standards, technical regulations, and case studies, policies and practices, May 2014–July 2015

Sector	Description of barrier pre-May 2014	Changes found under Modi government
Overall standards and technical regulations environment	India-unique mandatory standards create additional costs, paperwork, and time burden for exporters.	Some efforts have been made to harmonize with international standards. New standards in late 2014 and 2015 add more India-unique standards.
Agricultural products	Certain sanitary and phytosanitary restrictions are not scientifically warranted and inconsistent with international standards, posing obstacles for certain exports.	New standards in late 2014 and 2015 on bovine genetics, pork imports, antibiotic use, and meat and poultry compliance certification could create new barriers.
Food products	India-unique mandatory standards and technical regulations (particularly on packaging/labeling and product approval) create uncertainty, delays, and additional costs for exporters.	Efforts to clarify packaging and labeling in 2015 have not addressed exporters' concerns. Steps were taken in late 2014 and 2015 to improve transparency and streamline product approval process. In 2015 India continued work to harmonize with international standards.
Alcoholic beverages	India-unique mandatory standards and labeling requirements create challenges for exporters.	New labeling requirements could create additional challenges for certain U.S. exports.
Cosmetics and personal care products	Registration process creates uncertainty and challenges for exporters.	Imports of animal-tested cosmetics were banned in late 2014. New test requirements in 2015 to detect trace heavy metals, proposed new in-country testing requirements, and changes to product approval procedures could create new barriers.
Medical devices	Medical devices and pharmaceuticals are regulated under the same standards, a regulatory framework that discourages foreign participation in the Indian market. FDI is subject to prior approval. There are high tariffs on medical device inputs and price controls on various medical devices (as well as pharmaceuticals).	January 2015 bill proposed separate regulatory treatment of medical devices and pharmaceuticals. FDI in medical devices is approved automatically (January 2015). Duties raised on some medical devices and components (February 2015). June 2015 Drug Price Control Order and other measures place additional products under threat of price controls.
Clinical trials	A lack of clear regulations, uncertain legal liabilities, and a burdensome operating environment reportedly deter foreign firms from operating in India.	New measures and proposals in late 2014 and 2015 may lead to an improved environment for foreign firms.

Source: Compiled by the Commission.

to keep working to harmonize India’s standards with international ones.³⁵¹ U.S. observers likewise welcome the steps India has taken since late 2014 to increase engagement with the United States on standards. Nevertheless, they also report that the Modi government has created new India-unique mandatory standards and technical requirements that increase costs, delay time to market, and operate to exclude certain U.S. products from the Indian market.

The first part of this chapter describes notable changes to India’s policies and practices regarding standards, technical regulations, and conformity assessments³⁵² since May 2014, highlighting changes that have improved U.S. access to the Indian market and reporting areas where improvements have not taken place. The second part offers case studies illustrating (1) notable changes in India’s standards-related policies and practices for four areas: agricultural products, food products, alcoholic beverages, and cosmetics and personal care products; and (2) broader developments in late 2014 and 2015 concerning two aspects of the healthcare sector: medical devices and clinical trials. As indicated in chapter 1, in most instances it is too soon to assess the long-term effects on U.S. exports of India’s recent policy changes: too little time has passed for U.S. companies to fully adjust to the new policies.

Standards under the Modi Government

Improvements Observed

U.S. industry and government representatives have expressed support for specific steps towards harmonization with international standards that have been taken by the Modi government since May 2014, even though these steps have occurred unevenly throughout different Indian ministries and departments.³⁵³ Examples of these positive steps include the

³⁵¹ According to the WTO, standards in India are formulated as follows: a preliminary draft standard is first approved by a Bureau of Indian Standards (BIS) technical committee, then circulated among the various stakeholders and posted on the BIS website for comments for 60 days. The technical committee then finalizes the draft standard, taking any comments into account. The finalized standard, including revisions and amendments, is published in India’s official gazette. Technical regulations are stipulated under various laws and regulations in India. The creation of technical regulations in India follows a process similar to the one for standards. WTO, Secretariat, *Trade Policy Review: India*, 2015, 59–60. More detailed information about India’s standards-setting system is presented in appendix G.

³⁵² The BIS is India’s national certifying body for conformity assessments. According to the WTO, conformity assessment procedures in India “have largely remained unchanged” since 2011. WTO, Secretariat, *Trade Policy Review: India*, 2015, 59.

³⁵³ See appendix G for a more historical view of the Indian government’s approach to standards.

commitments made in India's 2015–20 Foreign Trade Policy (described in chapter 2) to harmonize with international standards.³⁵⁴

Some Indian ministries and departments publicly acknowledge the importance of regulatory harmonization if India is to become a global player in international trade, and they appear to be working towards that goal.³⁵⁵ Information obtained for this report points to improvements made under the Modi government in two areas: (1) greater attention to harmonizing India's standards and technical regulations with international standards, and (2) increasing willingness to engage with the United State on standards and technical regulations. The Modi government's progress in these two areas since May 2014 is summarized below.

Harmonizing with International Standards

U.S. government and industry representatives generally report that the Modi government is making promising statements on removing technical and SPS barriers to trade by harmonizing Indian standards³⁵⁶ with international ones.³⁵⁷ India's 2015–20 Foreign Trade Policy sets out a detailed roadmap for achieving harmonization through legislative and institutional reforms.³⁵⁸ Key changes are (1) authorizing the use of independent, third-party conformity assessment bodies to administer regulations; and (2) eventually allowing conformity assessment for low-risk items through Supplier's Declaration of Conformity (SDoC) procedures.³⁵⁹ The Foreign Trade Policy statement also discusses specific actions India plans to take to reach a "Certified Once, Accepted Everywhere" policy. Such actions would minimize requirements for retesting and recertification of products, decreasing nontariff barriers to trade.³⁶⁰

³⁵⁴ India's 2015–20 Foreign Trade Policy is described in more detail in chapter 2. For example, according to this policy, India developed its consumer protection roadmap "recognising the increasing role of standards in global trade and the steps India needs to take both to strengthen its own standards as well as to meet the challenges posed to its exports." Government of India, MOCI, *Foreign Trade Policy Statement 2015–2020*, April 1, 2015, 14.

³⁵⁵ For example, India's 2015–20 Foreign Trade Policy states that one of India's objectives is "to create an architecture for India's global trade engagement with a view to expanding its markets and better integrating with major regions." Government of India, MOCI, *Foreign Trade Policy Statement 2015–2020*, April 1, 2015, 14.

³⁵⁶ The WTO reports that India had around 19,313 standards as of yearend 2014. The Indian government reports that 5,862 of these standards (about 30 percent) had corresponding international standards. The WTO further reports that 5,238 of these 5,862 standards (almost 90 percent) were harmonized with the international standards. This represents an increase from 84 percent as of 2010. WTO, Secretariat, *Trade Policy Review: India*, 2015, 59–60.

³⁵⁷ Government official, interview by USITC staff, Washington, DC, June 9, 2015; industry representative, telephone interview by USITC staff, June 18, 2015.

³⁵⁸ An overview of India's 2015–20 Foreign Trade Policy is provided in chapter 2.

³⁵⁹ In line with international practice, the Foreign Trade Policy statement also clarifies that a new legal framework for product liability, in addition to market surveillance systems, would need to be created before a SDoC policy could be implemented. Government of India, MOCI, *Foreign Trade Policy Statement 2015–2020*, April 1, 2015.

³⁶⁰ Government of India, MOCI, *Foreign Trade Policy Statement 2015–2020*, April 1, 2015.

The statement also supports funding that would increase Indian participation in international standard-setting processes so that international standards reflect country-specific production and trade interests. Finally, for years India has promised to harmonize with Codex Alimentarius (Codex) food standards.³⁶¹ To this end, India’s Food Safety and Standards Authority (FSSAI)³⁶² announced in May 2015 that it had finalized the harmonization of more than 11,000 standards for food additives and ingredients with Codex; this process is ongoing.³⁶³

Increasing Engagement with the United States

U.S. industry and government representatives also report that since the Modi government took office, India has shown greater willingness to engage the United States than in the past. Since May 2014, the United States and India have held multiple working-level and senior-level meetings involving bilateral standards and technical requirements.³⁶⁴

In the India-United States Trade Policy Forum, which resumed in November 2014 after a four-year hiatus, the two countries have held discussions on key standards issues of bilateral concern. Through the Trade Policy Forum, the United States and India agreed to start a technical dialogue on agriculture issues. The dialogue focuses primarily on standards pertaining to plant health, animal health, and food safety issues in a way that supports bilateral trade.³⁶⁵ A similar bilateral dialogue focuses on promoting investment in manufacturing. The countries also agreed to discuss international standards and systems for conformity assessment procedures,

³⁶¹ The Codex serves as a collection of internationally recognized standards, codes of practice, guidelines, and other recommendations relating to foods, food production and food safety. Its texts are developed and maintained by the Codex Alimentarius Commission, a joint body composed of representatives of the Food and Agriculture Organization of the United Nations and the World Health Organization. The Codex Commission’s main goals are to protect the health of consumers and ensure fair practices in the international food trade. The WTO recognizes the Codex as an international reference point for resolving disputes on food safety and consumer protection. Codex Alimentarius website, <http://www.codexalimentarius.org/> (accessed July 24, 2015).

³⁶² The FSSAI is an independent statutory authority within India’s Ministry of Health and Family Welfare. It is tasked with setting science-based standards for food articles and regulating their manufacture, storage, distribution, sale, and import to ensure that Indians have access to safe and wholesome food. The FSSAI was established in 2011 under section 4 of India’s Food Safety and Standards Act 2006. See FSSAI website <http://www.fssai.gov.in/AboutFSSAI/introduction.aspx> (accessed July 25, 2015). The Ministry of Health and Family Welfare is also involved in creating and implementing SPS measures, along with the Ministry of Agriculture. WTO, Secretariat, *Trade Policy Review: India*, 2015, 63.

³⁶³ FSSAI, “Scheme of Product Approvals,” May 11, 2015; U.S. government official, interview by USITC staff, Washington, DC, June 9, 2015; *Business Standard*, “FSSAI Sets 12,000 Standards,” July 13, 2015.

³⁶⁴ U.S. government official, telephone interview by USITC staff, June 11, 2015; U.S. government official, interview by USITC staff, Washington, DC, May 29, 2015; U.S. government official, interview by USITC staff, Washington, DC, June 9, 2015.

³⁶⁵ USTR, “India-U.S. Joint Statement on the Trade Policy Forum,” November 25, 2014.

with a specific focus on understanding each government’s approach to testing, packaging, and labeling requirements.³⁶⁶

The Modi government has also stepped up engagement with the United States on underlying differences between the U.S.’s and India’s technical and SPS standards and regulations.³⁶⁷ For example, President Obama and Prime Minister Modi agreed in September 2014 to hold a public-private discussion in 2015 on new areas of cooperation, including harmonization of manufacturing standards. The discussion would be organized through a partnership between the Manufacturing Extension Partnership Program of the U.S. National Institute of Standards and Technology and its Indian counterparts.³⁶⁸

Remaining Challenges

Despite their general agreement that the Modi government is making positive statements about removing technical barriers to trade, numerous observers have expressed concerns about a lack of Indian government follow-through on these statements as of July 2015.³⁶⁹ Moreover, under the Modi government, the Bureau of Indian Standards (BIS)³⁷⁰ and other Indian standard-making bodies have released a number of new India-unique mandatory standards and conformity assessment requirements. These rules affect certain food products, alcoholic beverages, and cosmetics and personal care products, as indicated in the case studies below, along with information and communications technology (ICT) goods, as described in chapter 5. As mentioned earlier in this chapter, such country-unique rules are considered to be burdensome for U.S. exporters because they increase costs, delay time to market, and tend to exclude certain U.S. products from the Indian market.

In its 2015 review of India’s trade policies, the WTO acknowledged its concerns about India’s technical regulations and certification procedures for certain specific products, stating:

While some Members commended India’s recent initiatives to improve the transparency and predictability of its trade and related policies, such as inviting public comments on new legislation, Members urged India to provide timely public

³⁶⁶ U.S. government official, telephone interview by USITC staff, May 29, 2015.

³⁶⁷ USITC hearing transcript, May 5, 2015 (testimony of Linda Dempsey, NAM), 127–28.

³⁶⁸ White House, “U.S.-India Joint Statement,” September 30, 2014.

³⁶⁹ U.S. government official, interview by USITC staff, Washington, DC, June 9, 2015; industry representative, telephone interview by USITC staff, June 18, 2015.

³⁷⁰ The Bureau of Indian Standards (BIS) is India’s main standard-setting agency. According to the WTO, the BIS both (1) formulates and enforces standards for certain sectors of the Indian economy, and (2) develops “activities relating to certification of product and quality systems, testing and calibration, enforcement, international cooperation, and creating awareness among consumers.” The BIS is responsible for disseminating information on standards, technical regulations, and certification under the WTO TBT Agreement. WTO, Secretariat, *Trade Policy Review: India*, 2015, 59–60.

consultations on draft regulations, submit notifications on a regular basis to the WTO, and provide a reasonable period between the announcement of new regulations and their entering into force.³⁷¹

Case Studies

This section presents six case studies that examine developments in a variety of policy areas reported in *India 2014* as barriers to U.S. trade and investment in India. They focus on the late 2014 through July 2015 period. In some instances, policy developments were ongoing as of the publication of this report, and the case studies may not reflect policy changes that occurred after July 2015.

As noted earlier, U.S. exporters have expressed concern that new India-unique mandatory standards and technical requirements implemented in late 2014 and 2015 increase costs, delay time to market, and operate to exclude certain U.S. products from the Indian market. Four product-focused case studies examine the impact of India-unique mandatory standards and technical requirements: agricultural products, food products, alcoholic beverages, and cosmetics and personal care products.

Two case studies examine broader developments in late 2014 and 2015 concerning two aspects of India’s healthcare sector: medical devices and clinical trials. *India 2014* identified these healthcare sectors as having barriers that impede U.S. economic engagement in India. In 2015, industry representatives are guardedly optimistic about increased engagement and policy improvement in medical devices and clinical trials, although concerns about price controls for pharmaceutical and medical devices persist.

Agricultural Products

The Commission reported in *India 2014* that difficulty complying with Indian standards “substantially affects” a larger share of U.S. firms in the agriculture and food sector³⁷² than any other factor reported by firms in any sector.³⁷³ U.S. industry sources state that these concerns persist in the agricultural goods sector under the Modi government. Although some measures have been introduced that appear to ease restrictions on U.S. exporters, U.S. exporters assert that certain new measures—and the continued existence of others—still present obstacles to U.S. exports. An additional factor to consider in this sector is that multiple ministries and

³⁷¹ WTO, “Concluding Remarks by the Chairperson,” June 2–4, 2015.

³⁷² In *India 2014*, agricultural products and food products were considered a single sector. This report considers them as separate sectors to provide more detailed information about developments that affect agricultural and food products differently.

³⁷³ USITC, *India 2014*, 2014, 250.

agencies issue such requirements. The Department of Animal Husbandry, Dairying, and Fisheries (DAHDF) in the Ministry of Agriculture and the FSSAI both have jurisdiction over agricultural imports, and both issued notices in late 2014 and 2015 with updated requirements for agricultural imports. The effects of many of these updated requirements on U.S. exporters are unclear.

This case study addresses developments regarding technical requirements in India during late 2014 through mid-2015 that affect, or may affect, U.S. agricultural exports. It has three sections. First, it describes how changes introduced in late 2014 to India's restrictive import requirements for bovine genetics do not fully address U.S. concerns about trade barriers in this area. Next, it examines changes introduced in a number of India's meat and poultry import requirements during 2015, and describes how they could affect U.S. agricultural exports. Finally, it describes how a 2015 WTO ruling may benefit certain U.S. agricultural exports to India.

Bovine Genetics Import Requirements Have Changed, but Still Restrict Trade

One area noted in *India 2014* as a problem for potential U.S. exports is the export of bovine genetics.³⁷⁴ New draft health certificates for the importation of bovine semen and embryos were published by the DAHDF in 2014.³⁷⁵ The new sanitary requirements may be more easily met by potential U.S. exporters. Other requirements, however, may still act as barriers to U.S. exports, such as milk quality requirements.³⁷⁶ Additionally, as described in *India 2014*, imports must still obtain a "no objection certificate" (NOC) from the relevant state government to receive a license to import; delays in obtaining NOCs have created challenges for importers.³⁷⁷

U.S. industry sources speculate that recent developments may affect importers' ability to secure a NOC. In early 2015, a number of bulls were imported from Germany and sent to production stations in India.³⁷⁸ One U.S. industry representative expressed concern that in some Indian states, the presence of these newly imported young bulls in production stations

³⁷⁴ USITC, *India 2014*, 2014, 255, table 8.5. Bovine genetics includes semen and cattle embryos.

³⁷⁵ Government of India, DAHDF, "Veterinary Certificate for Import of In Vivo Derived Bovine Embryo," 2015; DAHDF, "Notification on Draft Health Certificate for the Import of Bovine Semen," 2015.

³⁷⁶ USDA, FAS, *India: FAIRS Export Certificate Report*, January 2, 2015. Quality requirements include minimum milk production level, milk protein level, and milk fat level for daughter cows of the sires.

³⁷⁷ Criteria for the NOC may differ by state. Obtaining a license to import takes an estimated four to six months if the required data are available and if an NOC is granted. USITC, *India 2014*, 2014, 252.

³⁷⁸ Current guidelines allow importation of young bulls without burdensome quality requirements if the animal's sire has been genomically tested. USDA, FAS, *India: Bovine Germplasm Guidelines for Trade*, February 12, 2015, 2, 7.

may limit the perceived need for imported frozen genetic material and make an NOC more difficult to obtain.³⁷⁹

New Meat and Poultry Import Requirements in 2015

New Pork and Pork Products Certificate

On March 16, 2015, India’s draft veterinary certificate for imported pork and pork products was published on the WTO website for comment.³⁸⁰ The proposed veterinary certificate would potentially improve U.S. access to the Indian market for pork and pork products. India’s current “Veterinary Certificate for Import of Pork into India” prohibits the use of feed containing products of ruminant origin.³⁸¹ The draft certificate would remove this requirement, which U.S. pork producers perceive to be a barrier to U.S. exports of pork to India.³⁸² The draft certificate would also eliminate requirements that the exporting country be free of specific diseases, instead simply requiring the country to adhere to international guidelines established by the World Organisation for Animal Health (OIE).³⁸³

The draft certificate also eliminates some uncertainty about pesticide, drug, and other chemical residues. It requires compliance with the Indian Food Safety and Standard regulation or with international standards established by the Codex.³⁸⁴ The current certificate, on the other hand, requires that residues in imported pork not exceed “Maximum Residue Limits prescribed internationally” without specifying either the chemicals or the international standards to be followed.³⁸⁵

New Rules for Antibiotic Use in Food-Producing Animals

New regulations in 2015 concerning antibiotic use in food-producing animals potentially could adversely affect some U.S. exports to India. The regulations appear to be aimed at production practices rather than residue levels. A June 13, 2015, advisory from DAHDF issued guidelines that discourage the use of antibiotics in feed premix for food-producing animals as growth promoters; recommend that hormones not be used as growth promoters in food-producing animals; and call for eliminating all antibiotics and hormones in animal feed, rather than requiring adherence to maximum residue levels established by the Codex.³⁸⁶ Again, a

³⁷⁹ Industry representative, email message to USITC staff, June 12, 2015.

³⁸⁰ USDA, FAS, *India: Deadline for Comment—Draft Certificate*, March 24, 2015, 1.

³⁸¹ DAHDF, “Veterinary Certificate for Import of Pork,” 2015.

³⁸² The U.S. pork industry does commonly use feed ingredients of ruminant origin. NPPC, written submission to the USITC, May 28, 2015, 2.

³⁸³ USDA, FAS, *India: Draft Veterinary Certificate for Pork*, February 17, 2015, 2.

³⁸⁴ DAHDF, “Veterinary Certificate for Import of Pork,” 2015.

³⁸⁵ National Pork Producers Council (NPPC), written submission to USITC, May 28, 2015, 3.

³⁸⁶ DAHDF, “Use of Antibiotics for Treatment of Food Producing Animals,” June 3, 2015.

December 2, 2014, advisory from DAHDF issued guidelines that recommend the elimination of antibiotics used as growth promoters in commercial production, with antibiotics to be used only with a veterinary prescription or under veterinary supervision.³⁸⁷

New Compliance Certification

On January 19, 2015, the FSSAI published a draft order covering requirements for both domestic and imported meat and poultry products, to enter into effect July 1, 2015.³⁸⁸ This order, too, could adversely affect some U.S. exports of these products. For imports, the draft order notes that FSSAI and DAHDF will develop a procedure for monitoring and inspection that includes requiring the competent authority in the exporting country to certify compliance. However, it is unclear if the proposed regulation would require inspection and certification of individual establishments by Indian authorities, or if the competent authority in the exporting country would certify compliance by individual establishments.³⁸⁹

Among the requirements in the FSSAI draft order is that meat animals, including poultry, not be given feed that contains meat and bone meal from cattle or swine, or any tissues from cattle or swine other than milk or milk products.³⁹⁰ According to the National Pork Producers Council (NPPC), the U.S. pork industry uses such ingredients in its feed, and U.S. authorities would be unable to provide the required certification.³⁹¹ (Reportedly, India's domestic poultry industry also uses such products in its feed.³⁹²) Additionally, cattle or swine are not to be slaughtered or processed in establishments that produce poultry meat for human consumption. A third requirement for both domestic production and imports is that the use of antibiotics in food-producing animals must comply with advisories issued by DAHDF, reviewed above.³⁹³

³⁸⁷ DAHDF, "Use of Antibiotics in Food Producing Animals," December 2, 2014.

³⁸⁸ FSSAI, "Order (Regarding Placing Meat and Poultry Products on the Indian Market)," January 16, 2015, paragraph 13 (c).

³⁸⁹ India currently imports some lamb meat from Australia. Exporters wishing to export to India must demonstrate their compliance with India's requirements to Australia's Department of Agriculture, which then provides Indian authorities with a list of establishments, subject to approval by Indian authorities. Australian government official, email message to USITC staff, June 26, 2015.

³⁹⁰ This requirement is similar to the current requirement from DAHDF prohibiting imports of pork from swine fed ingredients of ruminant origin, but is broader in that it also covers imports of poultry meat and includes a ban on feed ingredients derived from either cattle or swine. DAHDF, "Veterinary Certificate for Import of Pork into India," n.d. (accessed July 7, 2015).

³⁹¹ NPPC, written submission to the USITC, May 28, 2015, 2.

³⁹² NPPC, written submission to the USITC, May 28, 2015, 3; Indian industry representative, written submission to FSSAI, March 10, 2015.

³⁹³ FSSAI, "Order (Regarding Placing Meat and Poultry Products on the Indian Market)," January 16, 2015, paragraph 13 (c), referencing DAHDF advisories 102-74/2014-Trade, dated June 3 and December 12, 2014.

2015 WTO Ruling Could Help U.S. Agricultural Exports

A WTO Appellate Body ruling adopted on June 19, 2015, upheld an earlier panel ruling that India’s 2007 ban on various U.S. agricultural products, including poultry meat, eggs, and live pigs, violates India’s trade obligations under the General Agreement on Tariffs and Trade 1994³⁹⁴ and the WTO SPS Agreement.³⁹⁵ A 2012 statement by the National Chicken Council (U.S.) estimated that U.S. poultry exports to India could reach \$300 million annually if the ban were lifted.³⁹⁶

India has informed the WTO’s Dispute Settlement Body (DSB) that it intends to implement the DSB’s recommendations and rulings in a manner that respects its WTO obligations, but will need a reasonable amount of time to do so. India’s poultry producers reportedly do not perceive this implementation as an immediate threat, since the majority of poultry sold in India is live whole birds.³⁹⁷ Nevertheless, India’s Ministry of Commerce and Industry is said to have asked domestic poultry industry associations to examine the feasibility of restrictions that could be scientifically justified in order to protect India’s 400,000 poultry farmers from imports from the United States. Reportedly, the use of feed with genetically modified ingredients or the practice of freezing poultry for long periods were being considered as possible justifications for a barrier.³⁹⁸

Food Products

In 2015, India’s mandatory food standards and technical regulations remain problematic for U.S. exporters of food products to India,³⁹⁹ though various changes under the Modi government appear to address some of the challenges in the sector. This section expands upon the information and analysis in *India 2014* by more closely examining standards and regulatory changes in India’s food sector under the Modi government. It has three parts. The first part identifies regulatory changes in India that appear to be seeking to balance industry’s desire to improve the ease of doing business in India with Indian consumers’ food safety concerns. It

³⁹⁴ The General Agreement on Tariffs and Trade (GATT) 1994 is a WTO agreement that includes various non-discrimination requirements and other trade-related rules.

³⁹⁵ The WTO panel and Appellate Body agreed with U.S. claims that, for example, India’s ban is not based on international standards or a risk assessment; that India discriminates against U.S. products in favor of Indian products; that India’s measures are more trade restrictive than necessary because it is safe to import U.S. products meeting international standards; and that India’s restrictions are not adapted to the characteristics of U.S. exporting regions. USTR, “WTO Affirms U.S. Trade Enforcement Win,” June 4, 2015. See also WTO, “India—Measures Concerning the Importation of Certain Agricultural Products from the United States,” June 19, 2015. The reports of the panel and Appellate Body were adopted by the WTO Dispute Settlement Body on June 19, 2015.

³⁹⁶ National Chicken Council, “India Fails to Lift Restrictions on U.S. Poultry,” May 11, 2012.

³⁹⁷ *Indian Express*, “US-India Exports: WTO’s Poultry Ruling,” June 6, 2015.

³⁹⁸ *Hindu Business Line*, “WTO Ruling on US Chicken: Govt Mulls,” June 5, 2015.

³⁹⁹ USDA, FAS, *Food and Agricultural Import Regulations and Standards—Narrative*, January 5, 2015, 2.

touches on issues related to food standards, testing, packaging, and labeling. The second part describes ways some of India's labeling and packaging requirements are considered to adversely affect U.S. exporters of agricultural and food products. The third part describes the Modi government's efforts to change India's food product approval (PA) system to reduce certain longstanding complaints of exporters. It summarizes two key rulings in India's judiciary system on the legality of the FSSAI's PA scheme and on the status of Codex standards in India's food system; describes changes under the Modi government to facilitate the PA process; and describes the FSSAI's ongoing work to update and harmonize India's national food standards.

2014–15 Regulatory Changes

India has changed its food labeling and packaging requirements and its food PA system in numerous ways since May 2014. These changes were principally triggered by ongoing pressure from India's food producers and importers, who have called on the Indian government to make it easier to do business in India. At the same time, growing consumer concerns about food safety ("adulteration"⁴⁰⁰) in India have led to demands for stronger regulatory oversight to ensure food safety.⁴⁰¹ Developments in 2015 as a result of several food adulteration concerns are described in box 6.1.

U.S. industry and government representatives have expressed support for some of the FSSAI's actions since May 2014. They note in particular steps taken to improve transparency in FSSAI operations, including more frequent updates to the FSSAI website, and greater flexibility in FSSAI labeling, packaging, and PA requirements, as described below.⁴⁰² Overall, however, U.S. industry representatives contacted for this report hesitated to categorize the trend as clearly positive, as they believe that the underlying requirements remain impediments to U.S. food exports.⁴⁰³

⁴⁰⁰ Food adulteration in India broadly pertains to food that, for example, contains an ingredient that reduces the food's quality; contains an unlisted ingredient or is otherwise not what the food is represented or labeled to be; is kept in unsanitary conditions; or is otherwise dangerous to human health or unfit for human consumption.

Government of India, *Prevention of Food Adulteration Act, 1954*, <http://agmarknet.nic.in/amrscheme/amrstandpreven.htm> (accessed August 18, 2015).

⁴⁰¹ Kishore, "Legal Opinion: The Sleeping FSSAI Giant Awakes," June 26, 2015; FSSAI, "Scheme of Product Approvals" and accompanying cover letter, May 11, 2015.

⁴⁰² FSSAI's website offers links to information on advisories/orders; notifications and draft notifications involving product approvals, licenses, and registration; newly published explanatory/guidance notes and standard operating procedures for imports; and other resources. Government officials, telephone interviews by USITC staff, May 29, 2015, June 15, and June 17, 2015.

⁴⁰³ Government official, interview by USITC staff, Washington, DC, May 29, 2015; industry representative, interview by USITC staff, Washington, DC, July 14, 2015; industry representatives, telephone interviews by USITC staff, June 9, 17, and 19, 2015.

Box 6.1: Food Safety Concerns in India in 2015

Indian authorities are increasingly sensitive to domestic food safety as a result of recent cases of illnesses and deaths caused by food adulteration. In the latest analysis of international food safety violations by Food Sentry, a food safety group, India was ranked as the world’s worst offender in terms of food adulteration in 2013.^a In response to growing domestic concerns, Indian authorities have stepped up their regulatory oversight of food safety in recent years—and have even called the safety of some U.S. food products in the Indian market into question.

In May 2015, the FSSAI initiated a nationwide recall of Nestlé India’s highly popular Maggi instant ramen noodles. The noodles were recalled for containing a higher-than-permitted quantity of lead and for including monosodium glutamate (MSG) when the label stated “Contains No MSG.”^b The recall has brought food adulteration and the FSSAI to the forefront of domestic public attention, igniting a widespread debate in India.

Based in Switzerland, Nestlé is just one of many well-known companies negatively impacted by recent FSSAI testing. In June 2015 Tata Starbucks^c was forced to suspend the use of various ingredients that “meet Starbucks global standards” but were not approved by the FSSAI. Kellogg’s also had to pull its Special K Red Berries cereal from Indian shelves in 2015, while KFC has been fighting allegations that the rice used in its meals contains harmful artificial coloring.^d

^a Witt and Solomon, “Analysis of International Food Safety Violations—2013” (accessed July 22, 2015).

^b FSSAI, “Order: M/S Nestle Limited’s ‘Maggi Instant Noodles,’” June 5, 2015; *Financial Express*, “Nestle India Buckles, Pulls Maggi Noodles,” June 6, 2015. In August 2015, FSSAI filed a lawsuit against Nestlé’s Indian branch alleging Rs 6.4 billion (\$103.3 million) in damages to consumers. At the same time, although the Bombay High Court ruled in favor of Nestlé and lifted a ban on the sale of Maggi noodles, the court ordered new tests before the company could begin selling again. Singh, “Maggi Row: Bombay High Court Lifts Ban,” August 13, 2015; Reuters, “India Hits Nestle with \$99 Million Lawsuit,” August 12, 2015.

^c Tata Starbucks is a 50–50 joint venture between U.S.-based Starbucks and India-based Tata Global Beverages.

^d Sudgen, “Starbucks Stops Selling Some Syrups in India,” *Wall Street Journal* (blog), June 15, 2015; *Times of India*, “Tata Starbucks Suspends Use of Ingredients,” June 15, 2015; *Indian Express*, “Starbucks, Kellogg’s, Venky’s Products on FSSAI Blacklist,” June 16, 2015; FoodSafetyHelpLine.com, “Food Safety Dept Says Food at KFC,” December 6, 2014.

Labeling and Packaging

The Commission found in *India 2014* that complying with India’s labeling requirements posed burdens and resulted in delays to some U.S. exporters, particularly hampering U.S. exporters of agricultural and food products.⁴⁰⁴ In 2015 India introduced changes aimed at reducing the burdens of its labeling rules. However, India has also created new labeling requirements that—while supported by Indian consumers—are viewed as problematic by U.S. government and industry representatives.⁴⁰⁵

⁴⁰⁴ USITC, *India 2014*, 2014, 77, 249, 254.

⁴⁰⁵ At WTO Committee meetings under the Modi government, WTO members continue to describe India’s labeling practices as too burdensome. They have particularly cited India’s labeling of prepackaged foods as not being in compliance with Article 2.2 and 2.4 of the WTO TBT Agreement nor in accordance with the relevant Codex standards (CODEX STAN 1 1985). WTO, Committee on Technical Barriers to Trade, “Minutes of Meeting 18,” March 19, 2015.

Stickers in Place of Labels Still Burdensome

U.S. government and industry representatives have continued to express concern with India-unique labeling requirements in the food sector, which have been continued by the Modi government. However, they have also noted that in 2015 India introduced new flexibilities regarding implementation timelines. It also began accepting stickers affixed at the port of entry for some of India's many country-specific labeling requirements, particularly the existing requirement to declare the maximum retail price (MRP) on the original packaging, as reported in *India 2014*.⁴⁰⁶ These new flexibilities apply to both the food and alcoholic beverage industries.

Industry representatives support the acceptance of stickers in lieu of labels printed on the packaging, but they also express concern that Indian customs facilities often lack the physical space to guarantee that packages can be stickered at the port of entry. Thus U.S. exporters report that they have to adapt their export process to place stickers on their products before shipment.⁴⁰⁷

Wholesale vs. Retail Labeling Remains Problematic

India 2014 also reported on a problem with U.S. exports of wholesale raw commodities in 50-pound containers. While these products are intended to be processed and repackaged before retail sale, they are nevertheless classified by India as being for "retail sale" and therefore are not exempt from the labeling and packaging requirements applied to foods individually

⁴⁰⁶ The newly amended Legal Metrology (Packaged Commodities) (Amendment) Rules, 2015, published on May 14, 2015, permits the affixing of a label (or sticker) on imported packages for MRP declarations (and those of all other requirements and provisions from "rule 6" of the Metrology Act). Separately, in February 2015, the FSSAI issued a fifth consecutive extension for an impending regulation requiring all Indian food-oriented businesses, per Schedule I of the Food Safety and Standards (Licensing and Registration) Regulations, 2011, to obtain Food Business Operator (FBO) licenses. The recent extension was further postponed later in 2015. USDA, FAS, *India: Timeline on License and Registration*, February 24, 2015. The FSSAI also delayed the implementation of recent requirements that retail packages must bear the FSSAI logo and registration number of the FBO (or importer), and also reclassified this requirement as being rectifiable by sticker, as opposed to having it printed on the original package (as is the case with other Indian packaging and labeling requirements). Separately, the pre-Modi requirement of including the FSSAI license number on original packaging has also been reclassified as "rectifiable" by stickering at the border. The enforcement of the FSSAI license number was likewise delayed in 2015. USDA, FAS, *India: Compliance Date Extended for FSSAI*, December 19, 2014; USITC, *India 2014*, 2014, 251, 254.

⁴⁰⁷ Industry representative, telephone interview by USITC staff, June 19, 2015; industry representative, interview by USITC staff, Washington, DC, July 9, 2015.

packaged for retail sale in India.⁴⁰⁸ U.S. exporters report that varying interpretation and enforcement of these and similar requirements by Indian customs and regulatory officials has created an uncertain environment for them. This uncertainty has resulted in the detention of shipments at the port of entry because the shipments lacked information on ingredients, and has even led to the cancelation of import contracts.⁴⁰⁹ Because of these difficulties, some U.S. wholesale agricultural exporters shifted to using sticker labels on their raw commodity exports to comply with Indian requirements for retail packages. But since mid-2014, U.S. shipments of certain commodities began to again be held at the border by Indian officials for using stickers instead of attached labels.⁴¹⁰

At the November 2014 India-U.S. Trade Policy Forum, the United States and India discussed the issue of labeling raw commodities and the need to reconcile different Indian definitions of wholesale and retail packaging. The Ministry of Consumer Affairs published new rules on retail packaging on May 14, 2015, that take into account some of the concerns raised during the Trade Policy Forum.⁴¹¹ The new rules clarify FSSAI requirements for food products over other requirements; create new categories of raw commodity products for wholesale packages; and create wholesale and retail labeling requirements to register consumer complaints.⁴¹² However, U.S. industry representatives reported that the India-unique information required on the package remains burdensome, and that the new changes would have little effect on their concerns with India’s food labeling policies.⁴¹³

India’s Food Product Approval Process

PAs are often considered a key requirement for obtaining the license necessary to market food products in India. Indian and foreign food companies generally report that India’s PA process is

⁴⁰⁸ Standard U.S. 50-pound (approximately 22.7 kilograms) sacks of raw commodities do not meet the 25 kilogram minimum weight required by India to be considered a wholesale package. USITC, *India 2014*, 2014, 254. A recent USTR report states, “As the United States does not impose specific standards for packaging size, and U.S. package sizes tend to be in English rather than metric units, the list of package sizes effectively bars many U.S.-origin products from entering India.” USTR, “India,” March 2015, 168. In addition, the FSSAI and the Ministry of Consumer Affairs, Food and Public Distribution reportedly maintain conflicting provisions for labeling and packaging. Government official, email message to USITC staff, July 15, 2015.

⁴⁰⁹ USTR, “India,” 2014; government official, interview by USITC staff, Washington, DC, May 29, 2015; industry representative, email message to USITC staff, June 18, 2015.

⁴¹⁰ Government official, interview by USITC staff, Washington, DC, May 29, 2015; industry representative, telephone interview by USITC staff, June 19, 2015; industry representative, interview by USITC staff, Washington, DC, June 14, 2015.

⁴¹¹ USTR, “India,” 2015; *Gazette of India*, “G.S.R. 385 (E),” May 14, 2015.

⁴¹² *Gazette of India*, “G.S.R. 385 (E),” May 14, 2015.

⁴¹³ Industry representative, interview by USITC staff, Washington, DC, June 18, 2015; industry representative, telephone interview by USITC staff, June 19, 2015; government official, email message to USITC staff, July 15, 2015.

highly restrictive, creates unnecessary red tape, and delays exports.⁴¹⁴ Food manufacturers and importers also report that they have experienced challenges due to changing requirements, most of which centered on India's food PA process. U.S. industry sources state that a jurisdictional overlap between the FSSAI and other Indian regulatory agencies is creating additional barriers to international trade and domestic commerce. Prime Minister Modi entered into office while the FSSAI was in the process of revamping India's food safety and PA systems. In addition, the FSSAI has announced numerous changes since May 2014 that appear to address some U.S. industry concerns regarding India's PA system. One longstanding source of difficulty for manufacturers and importers is the issue of proprietary versus standardized food. India's Food Safety and Standards Regulations provide standards for different kinds of food articles and additives⁴¹⁵ that are allowed in food products. Only food items and additives that are specifically included (and therefore "standardized") under the regulations are permitted. India has standardized fewer than 400 food items in its regulations, compared to 5,000 to 10,000 individual standards in other countries.⁴¹⁶ The regulations categorize all non-standardized food products as "proprietary food" and require that they receive PAs before a food license is granted, thus creating a need for a large share of food products to obtain PAs.⁴¹⁷

These difficulties may have been compounded by the outcomes of two legal cases in 2014 in which a group of Indian food sector trade associations contested the legality of some FSSAI requirements as described in box 6.2.⁴¹⁸ The resulting decisions created significant legal uncertainty for India's food industry. On August 19, 2015, India's Supreme Court upheld one of the 2014 rulings against the FSSAI's food PA process.⁴¹⁹ As a result, the FSSAI published notices in late August 2015 that it would no longer continue the food PA process and that it would seek assistance to formulate new food PA regulations.⁴²⁰

⁴¹⁴ USDA, FAS, *India: FSSAI Publishes Guidelines on Product Approvals*, June 17, 2015; Bhan, "SC Stays Order Quashing FSSAI Advisory," August 19, 2014; Whithead, "New Products Failing to Come to Indian Market Due to Regulatory Delays," *Food Navigator*, June 30, 2015.

⁴¹⁵ Food product standards are for the final end product, such as cheese, while additive standards pertain to specific additives within the product. FSSAI, "Scheme of Product Approvals," May 11, 2015.

⁴¹⁶ Kishore, "Legal Opinion: The Sleeping FSSAI Giant Awakes," June 26, 2015; Government of India, Ministry of Health and Family Welfare, FSSAI, "Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011," August 1, 2011; *Business Standard*, "FSSAI Sets 12,000 Standards," July 13, 2015.

⁴¹⁷ FSSAI, "Explanatory/Guidance Notes," May 12, 2015; Kishore, "Legal Opinion: The Sleeping FSSAI Giant Awakes," June 26, 2015; FSSAI, "Enforcement of Provisions of the FSS Act," June 8, 2015.

⁴¹⁸ Bhan, "SC Stays Order Quashing FSSAI Advisory," August 19, 2014.

⁴¹⁹ Government of India, FSSAI, "F.No.P-15025/SCJ/2015-PA/FSSAI," August 26, 2015; Government of India, FSSAI, "Public Notice," August 31, 2015.

⁴²⁰ *Ibid.*

Box 6.2: Food Product Approvals in the Indian Judiciary

Two legal cases during 2014 and a Supreme Court order in 2015 have led the FSSAI to announce plans to change its food PA process.

Validity of FSSAI advisories on imported products (Writ Petition No. 2746 of 2013^a)

June 30, 2014: The Mumbai High Court’s judgment stated that the FSSAI Proprietary Food PA Advisories (January 2012–May 2013) on imported products were illegal and had no force of law because the advisories were not within the scope of the FSSAI’s powers.^b Following the judgment, companies were unsure whether food licenses would be issued per preexisting licensing regulations (and therefore allow food business operators to keep selling previously licensed products), or if this would in effect halt all licensing processes.^c

August 13, 2014: The Supreme Court stayed the order of the Mumbai High Court after the FSSAI alleged that the impugned order had paralyzed the mechanism for enforcing food safety norms on all imported food items,^d and the FSSAI continued to require PAs for all “proprietary” food.^e

August 19, 2015: India’s Supreme Court issued an order that upheld the Mumbai High Court’s judgement. On August 26, 2015, the FSSAI published a notice that it would no longer continue the food PA process. On August 31, 2015, the FSSAI published a notice seeking legal assistance to formulate new food PA regulations.^f

Validity of Codex food standards in India (W.P.(C) No. 3668/2013 “Lok Jagriti vs. Union of India”)

August 27, 2014: The High Court of Delhi at New Delhi ruled that Codex food standards were valid in India only if specifically included in India’s Food Safety and Standards Regulations.^g

Source: Compiled by the Commission.

^a Available at <http://www.idma-assn.org/pdf/04-02-2014-letter-to-fssai-on-stay.pdf>.

^b The PA Advisory issued on May 11, 2013, made it mandatory for makers of packaged foods, beverages, health drinks, and supplements to disclose any ingredient or formulation change to the FSSAI. Bhan, “SC Stays Order Quashing FSSAI Advisory,” August 19, 2014.

^c *Business Standard*, “Mumbai HC Judgement to Give Fillip,” July 17, 2014.

^d Bhan, “SC Stays Order Quashing FSSAI Advisory,” August 19, 2014.

^e Government of India, FSSAI, “F.No.P-15025/SCJ/2015-PA/FSSAI,” August 26, 2015; Government of India, FSSAI, “Public Notice,” August 31, 2015.

^f Government of India, FSSAI, “F.No.P-15025/SCJ/2015-PA/FSSAI,” August 26, 2015; Government of India, FSSAI, “Public Notice,” August 31, 2015.

^g High Court of Delhi at New Delhi, W.P.(C) No. 3668/2013, “Lok Jagriti vs. Union of India,” August 27, 2014. http://delhihighcourt.nic.in/dhcqrdisp_o.asp?pn=165116&yr=2014.

Improving the ease of doing business under the PA process

Since late 2014, the FSSAI has taken several steps to improve the ease of doing business under India’s PA process. These steps include meeting more frequently with the private sector and maintaining current notifications, guidance, and other information on the FSSAI website. Moreover, the FSSAI in 2015 has worked to clarify the overall rationale, process, and requirements for PAs.

New PA draft regulations. The FSSAI, along with India’s Ministry of Health and Ministry of Food Processing Industry, created a task force in August 2014 to develop new draft regulations on PAs.⁴²¹ In addition, the FSSAI has prepared an action plan for timely processing of ongoing PA applications and issued detailed guidance in May 2015 on the PA application process.⁴²²

On March 1, 2015, the FSSAI also ended its requirement that food business operators submit multiple sworn affidavits to obtain PAs, licensing, registration, and food import clearances, replacing it with a new “self-declaration” requirement.⁴²³ The FSSAI also announced in February 2015 that the issuance of licenses would no longer be held up or denied due to lack of physical pre-inspection of the premises by FSSAI agents, and in May 2015 it announced likely new PA flexibilities for certain changes of ingredients.⁴²⁴

Developing more/new food standards. To address the industry’s underlying need to seek PAs because of the lack of food product standards in India, the FSSAI announced an action plan in 2015. The plan includes detailed timelines for reviewing a preexisting food product standard or developing a new one, as well as plans to establish scientific panels to develop and renew certain standards.⁴²⁵

Increasing technical capacity. To speed up the PA process, the FSSAI began recruiting additional scientists and technical officers in 2015. It also began updating its testing requirements and manuals in 2015.⁴²⁶

Online food approval system. In September 2014 the FSSAI launched its “On-line Food Product Approval System,” which addresses longstanding food industry concerns about PA transparency and PAs’ effects on the ease of doing business in India. The new system allows companies to apply for and receive PAs online. This system (and the FSSAI website) also provides information

⁴²¹ FSSAI, “Scheme of Product Approvals,” May 11, 2015.

⁴²² FSSAI, “Explanatory/Guidance Notes on Various Points,” May 12, 2015.

⁴²³ “Self-declaration” is a widely accepted process to facilitate the business environment. In India it allows traders and food business operators to make declarations for licensing, import, registration, and product approval processes and documents, rather than having to procure multiple notarized affidavits throughout each step of the processes. FSSAI, “Introduction of Self Declaration System,” March 26, 2015; FSSAI, “Abolition of Affidavits and Promotion of Self-certification,” February 12, 2015.

⁴²⁴ Proposed changes to the PA system would permit and approve a range of ingredients in the product, subject to the limits prescribed in the applicable vertical and horizontal standards, without undertaking a fresh risk assessment. FSSAI, “Scheme of Product Approvals,” May 11, 2015; FSSAI, “File No. 1(56)2012/Advisory/FSSAI,” March 26, 2015; FSSAI, “Inspection of Premises before Issue of License,” February 12, 2015.

⁴²⁵ The timeline, which includes details as to when public notification for comment should take place, went into effect on July 1, 2015. According to the new timeline, WTO notification for comment would take place 18–29 months after domestic consultations are undertaken. FSSAI, “Scheme of Product Approvals,” May 11, 2015.

⁴²⁶ FSSAI, “Scheme of Product Approvals” and accompanying cover letter, May 11, 2015; *Indian Express*, “India’s Food Safety Panel Chief Wants Sweeping Reforms,” June 17, 2015.

on domestic standards and international standards, as well as new rules and guidelines to ensure faster and more efficient evaluations on submitted applications.⁴²⁷

Updating and harmonizing India’s food safety and standards

The FSSAI continued to work in 2015 to update India’s food standards and harmonize them with Codex standards. Thus far, the FSSAI has finalized its efforts to harmonize more than 11,000 standards of additives with those of Codex.⁴²⁸ Harmonization with international standards would benefit U.S. food exporters by allowing them to export to India many products also sold in other markets without the need to get an India-specific PA.

Alcoholic Beverages

In *India 2014*, U.S. companies reported that exports of wines and spirits to India are impeded by very high tariffs and state excise taxes, price controls that discriminate against imports, and heavy counterfeiting of U.S. brands. They also contended that foreign investment to produce alcoholic beverages in India is discouraged by high excise taxes on the movement of inputs, in addition to other nontariff measures.⁴²⁹ U.S. industry representatives state that India could be a growth market for U.S. alcoholic beverages if India’s restrictive trade barriers were removed.⁴³⁰

The Modi government has not yet implemented any policies or practices that address the barriers specific to the wine and spirits industry identified in *India 2014*.⁴³¹ On the contrary, in late 2014 and 2015 the Modi government revised its guidelines on labeling requirements in a way that imposes an additional burden on U.S. producers.

India-unique labeling requirements for alcoholic beverages have been a significant impediment to U.S. exports to India because they add to exporters’ costs and create shipping challenges. *India 2014* reported on U.S. wine industry concerns about the inability of importers to adjust packaging labels for mandatory information not already included on the production label.⁴³²

⁴²⁷ USDA, FAS, *India: FSSAI Launches the Online Food Product*, September 16, 2014; USDA, FAS, *India: FSSAI Publishes FAQs on Product Approvals*, November 13, 2014; FSSAI, “Scheme of Product Approvals,” May 11, 2015.

⁴²⁸ India’s process of harmonization with international standards began in January 2013. Kokje, “With Codex Harmonisation,” December 15, 2014; *Business Standard*, “FSSAI Sets 12,000 Standards,” July 13, 2015.

⁴²⁹ USITC, *India 2014*, 2014, 120–21.

⁴³⁰ U.S. industry representative, email message to USITC staff, June 18, 2015; U.S. industry representative, email message to USITC staff, July 10, 2015.

⁴³¹ However, certain cross-cutting barriers affecting wine and spirits were partially addressed by the FSSAI while amending requirements for the wider food industry (see the “Labeling and Packing” subsection of the Food Standards and Regulations case study). The FSSAI made new allowances for rectifying labels by affixing stickers that contain certain India-specific information requirements (for both food products and alcoholic beverages) and delayed implementation of other requirements.

⁴³² USITC, *India 2014*, 2014, 352.

However, another labeling hurdle that U.S. exporters of alcoholic beverages commented on is India's labeling requirement for listing product ingredients. Until 2014, India accepted wine and spirits as a single-ingredient food, and allowed exporters to provide other required India-specific information via an additional "rework" sticker label (a standard practice allowed in many countries). In July 2014, the FSSAI posted new guidelines stating that these beverages no longer qualified as a single-ingredient food, and would require an ingredient list on the original packaging and label.⁴³³ U.S. industry representatives reported that the FSSAI issued additional revisions in December 2014 and in June 2015 that further changed the information required on labels, resulting in shipment delays for some U.S. exports.⁴³⁴

Cosmetics and Personal Care Products

Under the Modi government, U.S. cosmetics and personal care goods manufacturers have faced new regulatory requirements that restrict their ability to export their products to India. At the same time, the Modi government has addressed certain specific longstanding U.S. industry concerns. With 4 of the world's 10 largest cosmetics companies headquartered in the United States, U.S. companies are particularly interested in increasing their presence in India's cosmetics market, and they have expressed concerns about the effects of the new requirements on their ability to do so.⁴³⁵

⁴³³ FSSAI, "Labelling for Alcoholic Beverages and Canola Oil," 2014; U.S. industry representative, email message to USITC staff, June 19, 2015; U.S. government official, interview by USITC staff, Washington, DC, May 29, 2015; government official, email message to USITC staff, July 20, 2015.

⁴³⁴ U.S. government official, email message to USITC staff, July 20, 2015; U.S. industry representative, email message to USITC staff, June 19, 2015. In addition, the FSSAI is considering introducing new mandatory India-unique standards for alcoholic beverages. FSSAI, "Scheme of Product Approvals," May 11, 2015. According to U.S. industry sources, these standards would create new standards of identity and other requirements for certain alcoholic beverages that would deviate from international practice. Although developments on this were ongoing as of mid-July 2015, U.S. industry and government officials expressed the concern that the introduction of new India-unique restrictions could lead to the exclusion of U.S. exports of certain alcoholic beverages to India. U.S. government official, interview by USITC staff, Washington, DC, May 29, 2015; U.S. industry representative, email message to USITC staff, June 18, 2015; U.S. government official, email message to USITC staff, July 20, 2015; *Business Today*, "FSSAI Plans to Bring Alcoholic Beverages on Its Radar," June 25, 2015; *Economic Times*, "Government Proposes to Introduce Standards for Alcoholic Beverages," July 31, 2015; *Hindu*, "Beer, Whiskey, Other Alcoholic Drinks," June 24, 2015.

⁴³⁵ India's cosmetics market reportedly is valued at \$5 billion and is growing by 15–20 percent annually, twice as fast as the U.S. and European markets. U.S. industry representative, email message to USITC staff, June 15, 2015; Beauty Packaging, "Top 20 Companies," n.d. (accessed June 30, 2015).

Ban on Imports of Animal-Tested Cosmetics

Beginning in November 2014, India banned imports of animal-tested cosmetics.⁴³⁶ India is the first South Asian country to implement such a measure.⁴³⁷ U.S. exporters have reportedly encountered difficulties complying with India’s ban on animal-tested cosmetics, as most other countries accept—and some require—animal testing to prove that cosmetics are safe for consumers. U.S. industry representatives assert that it is difficult to prove their products comply with the animal testing ban without receiving guidelines from the Indian government on how to do so.⁴³⁸

New Testing Requirements for Trace Heavy Metals

U.S. industry representatives report that in 2015 the Indian government began to expand enforcement of existing legislation that prohibits mercury in the manufacturing of cosmetics. The new enforcement approach serves to prohibit any trace of mercury in finished cosmetics products. According to U.S. industry representatives, cosmetics entering India are being rejected or subjected to additional testing for containing trace levels that have been scientifically proven safe in the United States.⁴³⁹ They describe such trace levels of mercury as “non-intended and technically unavoidable” due to the ubiquity of the metal.⁴⁴⁰ Industry representatives have expressed the concern that many U.S. products may be denied access to the Indian market because of this new interpretation.⁴⁴¹

⁴³⁶ This import ban came into effect as a result of rule 135-B of the Drug and Cosmetics (Fifth Amendment) Rules, 2014. Government of India, Central Drugs Standard Control Organization (HQ), Office of Drugs Controller General India, “Circular,” February 15, 2015. India had previously banned in-country cosmetic testing on animals in May 2014. Gazette of India, Ministry of Health and Family Welfare, “Notification,” May 21, 2014.

⁴³⁷ Zeldin, “India: No Import of Cosmetics Tested on Animals,” October 17, 2014; U.S. industry representative, telephone interview by USITC staff, June 16, 2015; Humane Society International; “HSI’s Be Cruelty-Free India Makes History,” October 14, 2014.

⁴³⁸ U.S. industry representative, telephone interview by USITC staff, June 16, 2015.

⁴³⁹ Although the Minamata Convention on Mercury allows up to a 1 part-per-million (ppm) trace level for cosmetic products, current Indian standards do not give allowable levels for trace contaminants. The Modi government interprets Indian standards as requiring that cosmetics have zero ppm of mercury when tested at the border. IBHA, submission to Indian Ministry of Health and Family Welfare, June 22, 2015; IBHA, submission to Indian Ministry of Health and Family Welfare, June 19, 2015; U.S. industry representative, telephone interview by USITC staff, June 16, 2015; U.S. industry representative, email message to USITC staff, June 15, 2015.

⁴⁴⁰ U.S. industry representative, email message to USITC staff, June 15, 2015; IBHA, submission to Indian Ministry of Health and Family Welfare, June 22, 2015; International Cooperation on Cosmetic Regulation, “Principles for the Handling of Traces,” April 11, 2013.

⁴⁴¹ U.S. industry representative, email message to USITC staff, June 24, 2015; U.S. industry representative, email message to USITC staff, July 2, 2015; U.S. industry representative, email message to USITC staff, July 10, 2015.

2015 Proposed Regulations for Cosmetics

U.S. cosmetics and personal care sector representatives have reported their concerns that the Modi government's draft amendments to the Drugs and Cosmetics (Amendment) Bill, 2015,⁴⁴² would create barriers to exports of cosmetics and personal care products to India. The draft bill would create new, India-unique BIS requirements for local testing of cosmetics, demand preapproval of clinical testing for cosmetics, and establish mandatory penalties for noncompliance.⁴⁴³ Moreover, the draft bill would redefine cosmetics by creating a category called "new cosmetics," which industry representatives believe could be used to include or exclude certain products from regulation.⁴⁴⁴

Improved Public-Private Cooperation and Outstanding Industry Concerns

Despite the concerns expressed in the three previous sections, U.S. sector representatives state that Indian regulatory authorities under the Modi government have been more willing to cooperate and that they have simplified required paperwork for imports of cosmetics and personal care products.⁴⁴⁵ In May 2015, the Drug Controller General of India launched a webpage that serves as a consolidated access point for cosmetics product approvals and import processes. The Modi government has also sought to address industry concerns about the challenges of meeting India-unique labeling requirements. However, industry representatives maintain that requiring these particular India-specific labels is still inconsistent with current global practices and increases costs.⁴⁴⁶

Medical Devices

India 2014 reported that the U.S. medical device industry faced several problems in India, including price controls and ambiguous regulations, which were believed to have discouraged

⁴⁴² This bill is further discussed in the context of implications for the pharmaceutical and medical devices industries in the case study on medical devices below.

⁴⁴³ Government of India, Central Drugs Standard Control Organization, "Draft Drugs and Cosmetics Amendment Bill 2015," January 2, 2015; U.S. industry representative, email message to USITC staff, June 15, 2015; U.S. industry representative, email message to USITC staff, June 15, 2015.

⁴⁴⁴ The draft bill would classify "new cosmetics" products containing ingredients that have not been established by Indian authorities as safe for use in cosmetics. U.S. industry representatives were particularly concerned that this could create inconsistent technical review criteria and inconsistent decisions regarding approval of products. Government of India, Central Drugs Standard Control Organization, "Draft Drugs and Cosmetics Amendment Bill 2015," January 2, 2015; U.S. industry representative, telephone interview by USITC staff, June 16, 2015; U.S. industry representative, email message to USITC staff, June 15, 2015.

⁴⁴⁵ U.S. industry representative, email message to USITC staff, June 15, 2015; U.S. industry representative, telephone interview by USITC staff, June 16, 2015; industry representative, email message to USITC staff, July 10, 2015.

⁴⁴⁶ U.S. industry representative, email message to USITC staff, June 16, 2015.

greater participation in the market by foreign firms.⁴⁴⁷ Additional concerns included India’s low per capita expenditure on medical devices and the absence of an industrial ecosystem that would make the production of high-value-added devices within the country a viable strategy.⁴⁴⁸ *India 2014* also found that the Indian government did not provide incentives for domestic manufacturing sufficient to counterbalance the import duties the government places on certain inputs for medical devices, which are higher than on finished goods.⁴⁴⁹ The failure of Indian regulations to distinguish between pharmaceuticals and medical devices was another prominent concern.⁴⁵⁰ For these reasons, the report found that even though demand for medical technology in India is rising rapidly, U.S. foreign direct investment (FDI) and export opportunities, as well as the growth of the domestic industry, had been limited.⁴⁵¹

Since *India 2014* was published, the Modi government has proposed draft policies that address some of these concerns. For example, India’s Health Ministry proposed a draft National Health Policy (Draft Health Policy) and introduced an amendment to the Drug and Cosmetics Act in 2015, both of which recognize the regulatory distinctions between pharmaceuticals and medical devices.⁴⁵² Further, in June 2015 the Department of Pharmaceuticals issued a draft National Medical Device policy, which aims to promote medical device manufacturing in India, among other goals. Industry representatives generally welcomed proposals to regulate medical devices separately from pharmaceuticals; to remove FDI barriers; and to rationalize the duty structure for various medical devices. Medical device and pharmaceutical producers, however, expressed concerns over India’s apparent intention to continue substantial price controls.⁴⁵³

Draft National Health Policy Addresses Medical Technology

In December 2014, India’s Health Ministry—an agency which oversees the regulation of drugs, cosmetics, and medical devices—introduced the Draft Health Policy.⁴⁵⁴ The proposal, which would update the previous policy from 2002, described national priorities in the country’s healthcare sector to provide guidance to policymakers. Notable priorities include, again, regulating medical devices separately from pharmaceuticals; promoting the local production of

⁴⁴⁷ USITC, *India 2014*, 2014, 259.

⁴⁴⁸ BCG, *Medical Technology*, August 2014.

⁴⁴⁹ USITC, *India 2014*, 2014, 259.

⁴⁵⁰ India currently regulates 14 categories of medical devices as pharmaceutical products. U.S. industry representatives, telephone interviews by USITC staff, March 15 and 26, 2015. See also Eucomed, “Medical Devices and Pharmaceuticals,” n.d. (accessed June 24, 2015).

⁴⁵¹ USITC, *India 2014*, 2014, 259; Deloitte and CII, “Medical Technology Industry in India,” 2010.

⁴⁵² In another amendment to the Drugs and Cosmetic Act under the Modi government, the Ministry of Health and Family Welfare issued a notice in late September 2014 to permit the relabeling or stickering of medical devices to satisfy India-specific labeling requirements. *Gazette of India*, “G.S.R. 690(E),” September 25, 2014.

⁴⁵³ Industry representatives, telephone interviews by USITC staff, March 15 and 26, 2015; USITC, hearing transcript, May 5, 2015, 44 (testimony of Vince H. Suneja, TwoFour Insight Group).

⁴⁵⁴ Ministry of Health and Family Welfare, *Draft National Health Policy 2015*, December 2014.

medical technologies, including by addressing FDI restrictions and the inverted duty structure; and ensuring access to vital medical technologies by making them affordable to Indian consumers.⁴⁵⁵

Regulating Medical Devices Separately from Pharmaceuticals

Recognizing the need to harmonize India’s medical device regulations with international best practices, in January 2015 the Health Ministry released the draft Drugs and Cosmetics (Amendment) Bill of 2015. This bill would amend the Drug and Cosmetics Act of 1940—the law regulating the sale of medical devices and pharmaceuticals—to include a separate chapter on regulation of medical devices.⁴⁵⁶

The amendment has been widely supported by U.S. industry representatives, some of whom have worked with the Health Ministry to help develop draft policies, particularly since medical devices often present unique regulatory issues.⁴⁵⁷

Removing Medical Device FDI Barriers

A central plank of the Draft Health Policy encourages in-country manufacturing within the life sciences industry, in accordance with the Make in India initiative.⁴⁵⁸ To that end, in February 2015, the Reserve Bank of India formalized a government decision to allow FDI for medical device manufacturers without prior approval (the “automatic route”).⁴⁵⁹ This is considered to be a more efficient and timely process than the previous requirement of seeking permission from the Foreign Investment Promotion Board.⁴⁶⁰

Industry representatives consider this decision significant because it reflects what they see as the Modi government’s intent to prioritize FDI in the medical device sector.⁴⁶¹ Industry representatives in the United States and India support this policy change.⁴⁶² One industry

⁴⁵⁵ Ministry of Health and Family Welfare, *Draft National Health Policy 2015*, December 2014.

⁴⁵⁶ *Ibid.*; USITC hearing transcript, May 5, 2015, 54 (testimony of Vince H. Suneja, TwoFour Insight Group).

⁴⁵⁷ Industry representatives, telephone interviews by USITC staff, March 15, 2015, and March 26, 2015; industry representative, interview by USITC staff, New Delhi, May 12, 2015; AdvaMed, “AdvaMed Welcomes U.S.-India,” January 28, 2015; USITC, *India 2014*, 2014, 259.

⁴⁵⁸ The Make in India initiative is described in chapter 2. See Mukherjee, “Medical Devices,” June 9, 2015; USITC hearing transcript, May 5, 2015, 224 (testimony of Mukesh Aghi, U.S.-India Business Council).

⁴⁵⁹ FDI policies in for other industries are described in chapter 3.

⁴⁶⁰ Unnikrishnan, “RBI Formalizes,” February 3, 2015.

⁴⁶¹ *Ibid.*

⁴⁶² Industry representatives, telephone interviews by USITC staff, March 15, 2015 and March 26, 2015; AdvaMed, “AdvaMed Welcomes U.S.-India,” January 28, 2015; industry representative, interview by USITC staff, New Delhi, May 12, 2015.

representative stated that the new FDI regulations “send a good signal” and will likely encourage the expansion of medical device manufacturing in India.⁴⁶³

Duty Reductions for Medical Device Inputs

As noted in chapter 4, in early 2015 the Modi government reduced import duties for certain medical technologies and associated inputs as part of India’s 2015–16 Union budget. Medical device manufacturers in India had long expressed concerns over India’s inverted duty structure, which made imported inputs costlier than imports of finished products. This disparity placed domestic producers at a disadvantage and made the Indian market heavily reliant on imports.⁴⁶⁴

The tariff changes in the 2015–16 budget have removed both the base tariff and the added duties that India commonly assesses (known as special additional duties)⁴⁶⁵ on raw materials used, for example, in producing pacemakers. Additional products affected by reductions in either these additional duties or in the basic customs duty include medical endoscopes and artificial hearts.⁴⁶⁶

Price Controls Remain a Concern for Medical Device Producers

In contrast to these favorable changes, the Draft Health Policy would maintain pricing discretion for medical devices with the Department of Pharmaceuticals, which has imposed price controls through the Drug Pricing Control Order (DPCO). Foreign medical device producers in India have described price controls as a substantial concern. *India 2014* stated, for example, that the Central Government Health Scheme had required manufacturers of cardiac stents—an implantable medical device placed within the arterial walls of the heart—to cut retail prices by up to 65 percent within the previous two years.⁴⁶⁷ The DPCO also applies to unpatented pharmaceuticals; concerns about price controls for pharmaceutical producers are described in box 6.3.

In June 2015, India’s Department of Pharmaceuticals issued a draft National Medical Device Policy, which advocated the creation of a National Medical Device Authority. Under the draft policy, this new body would be tasked with promoting the industry; establishing learning centers; forming partnerships with industry; and supporting the indigenous industry, among

⁴⁶³ Industry representative, interview by USITC staff, New Delhi, May 12, 2015.

⁴⁶⁴ IBNLive, “Indian Medical,” February 19, 2015.

⁴⁶⁵ More information on India’s tariffs is provided in chapter 4 of this report.

⁴⁶⁶ See How to Export Import.com, “Import Customs Duty Changes,” March 30, 2015.

⁴⁶⁷ USITC, *India 2014*, 2014, 260.

Box 6.3: Price Controls Also a Concern for Pharmaceutical Producers

The DPCO lists 348 drugs as “essential” and subject to price control.^a Moreover, the DPCO of 2013, which is currently in effect, exempts Indian companies, but not foreign companies, from price controls for five years under certain conditions. Under Article 32, drugs that include indigenous R&D, that represent an improvement by an Indian company on a process for making an existing drug, or that include a new delivery system based on Indian R&D may be exempt from price controls.^b

The DPCO also has raised U.S. industry concerns because the number of drugs subject to price controls has been in a state of flux since the Modi government took office. For example, in late May 2014, the National Pharmaceutical Pricing Authority (NPPA), which is responsible for implementing the DPCO, issued internal guidelines for bringing new drugs under price control. On July 10, 2014, the NPPA brought 108 formulations of HIV, AIDS, diabetes, and cardiovascular drugs under price control with the new guidelines.^c In September 2014, under pressure from the Solicitor General and others, the NPPA rescinded the internal guidelines and the plans to add 108 drugs to its price control list. The Supreme Court of India upheld the decision and did not interfere in the decision to decontrol the 108 drugs.^d

New drugs, however, came under price control in September and December 2014, including certain antibiotics, vaccines, diabetes, and cancer drugs.^e Industry representatives expect the list of drugs under price control to be completed in 2015, and they have expressed a concern that approximately 500 drugs ultimately will be subject to controls, with cancer drugs a major focus.^f Industry representatives further expect that these new price controls will discourage foreign investment in R&D and production of critical drugs in India.^g

^a Government of India, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, “Drug Price Control Order,” May 15, 2013; Quartz India, “India’s Drug Price Control Regime,” September 25, 2014.

^b Government of India, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, “Drug Price Control Order,” May 15, 2013; Vishwanathan, “Drug Price Control Order (DPCO) 2013,” May 24, 2013.

^c USITC, hearing transcript, May 5, 2014, 51 (testimony of Vince Suneja, TwoFour Insight Group).

^d USITC, hearing transcript, May 5, 2014, 51 (testimony of Vince Suneja, TwoFour Insight Group); Financial Times, “India Scraps Generic Drug Price Controls,” September 23, 2014.

^e First Post, “De-controlling Drug Prices: Supreme Court Refuses,” October 27, 2014.

^f *Times of India*, “52 New Drugs Come under Price Control,” December 12, 2014.

^g Industry representative, interview by USITC staff, New Delhi, May 12, 2015; Reuters, “Parliamentary Committee Recommends Price Caps,” April 22, 2015; McLain, “India’s New Drug-Price Controls: Unintended Consequences?” July 15, 2014.

other initiatives.⁴⁶⁸ Most notably, the draft policy states that price controls for particular medical devices (e.g., cardiac stents) are needed to make them more affordable.⁴⁶⁹ The policy also aims to support the local industry by raising the possibility of preferences in government procurement for locally produced devices, issuing subsidies to local producers, offering tax incentives and loans, and further reducing duties on imported medical device components.⁴⁷⁰ Although the draft policy is not final, U.S. industry representatives remain concerned over the

⁴⁶⁸ Government of India, Department of Pharmaceuticals, “Draft National Medical Policy,” June 3, 2015, 3.

⁴⁶⁹ *Ibid.*, 6.

⁴⁷⁰ *Ibid.*, 4–5.

proposed continuation of price controls on medical devices, stating that they may discourage FDI projects.⁴⁷¹

Clinical Trials

India 2014 described a lack of clear regulations, uncertain legal liabilities, and a burdensome operating environment as deterring clinical trials in India. It said that “while the regulations affecting clinical trials are not intended to discriminate against foreign firms, the regulations sometimes have that effect because they weigh most heavily on trials for new drugs.”⁴⁷² Clinical trials are an important step in evaluating the safety and effectiveness of new drugs before they are submitted to regulators for approval. Since May 2014, the Modi government has taken several steps to improve transparency, predictability, and accountability in the clinical trial environment, and U.S. industry representatives generally reported more opportunities to engage with the Indian government.

Changes to the Clinical Trial Regulatory Landscape

An important deterrent to clinical trials reported in *India 2014* was the legal liability issue, particularly the lack of clarity on compensation that trial holders might be required to provide to participants in case of injury. In December 2014, the Health Ministry made a first step toward clarification by issuing an official order setting out different mathematical formulas to determine the amount of compensation to be paid in case of a serious adverse event other than death in a clinical trial.⁴⁷³ The order, however, did not define a study-related injury or how it will be determined.⁴⁷⁴

More recently, in June 2015, the Indian government amended Rule 122 DAB of the Drugs and Cosmetics Rules to clarify the definition of a study-related injury. The definition includes (1) failure of the investigational product (i.e., the drug, device, or product being tested) to provide the intended therapeutic effect where standard care, though available, was not provided to the subject as per trial protocol; and (2) the use of placebo where the standard care, though

⁴⁷¹ Industry representative, interview by USITC staff, Delhi, India, May 12, 2015; industry representative, telephone interview by USITC staff, March 25, 2015; Siddiqui, “India Takes First Step,” June 12, 2015; HS, “Indian Government.” HIS, “Indian Government Publishes Draft Policy on Medical Devices,” June 6, 2015.

⁴⁷² For example, the U.S. National Institutes of Health suspended 40 clinical trials in India in July 2013, and Quintiles, a large contract research organization, closed its phase 1 research center due to the difficult and unpredictable business environment. USITC, *India 2014*, 2014, 275–76.

⁴⁷³ Government of India, Ministry of Health and Family Welfare, “File No: CT/SAE-ND-Compensation Formulae/2014,” December 15, 2014.

⁴⁷⁴ *Ibid.*

available, was not provided to the subject as per trial protocol.⁴⁷⁵ The amendment requires medical care to be provided until such time as it is established that an injury was not trial-related, and provides additional operationally relevant information (e.g., timelines for reporting serious adverse events).⁴⁷⁶

Moreover, according to U.S. industry representatives and consultants, there has been improved engagement on clinical trial issues under the Modi government.⁴⁷⁷ Government officials have held meetings with industry representatives and requested feedback about their concerns and suggestions for improvements in the short, medium, and long term.⁴⁷⁸ Government officials also reportedly have stated their interest in a more balanced approach to clinical trials.⁴⁷⁹ Industry representatives are cautiously optimistic that there will be future improvements in the clinical trial process, as authorizing committees are being streamlined for better efficiency and inspection processes are becoming more aligned with international requirements.⁴⁸⁰ Future improvements to the clinical trial process could lead U.S. and foreign industry to perform more clinical trials in India.⁴⁸¹

Proposed Changes to the Drugs and Cosmetics Act

In December 2014, the Modi government opened for public comment a draft bill to amend the Drugs and Cosmetics Act of 1940 to further address clinical trials and other regulatory issues.⁴⁸² The draft bill includes key changes to rules currently in place that broadly require payments to clinical trial participants for medical costs for any injury, regardless of whether it is related to the trial.⁴⁸³ The new bill aims to ensure sponsors that they will not be liable for injuries that are not caused by the clinical trial. Even under the draft bill, however, uncertainty reportedly

⁴⁷⁵ *Gazette of India*, “Government of India, Ministry of Health and Welfare Notification,” December 12, 2014; Institute of Good Manufacturing Practices India, Faculty of Clinical Research, “Amendment Made to 122 DAB—Recently Notified,” January 8, 2015.

⁴⁷⁶ *Ibid.*

⁴⁷⁷ USITC, hearing transcript, May 5, 2014, 47–50 (testimony of Vince Suneja, TwoFour Insight Group); U.S. industry representative, written communication with USITC staff, Washington DC, July 1, 2015.

⁴⁷⁸ Industry representative, interview by USITC staff, New Delhi, May 12, 2015.

⁴⁷⁹ *Ibid.*

⁴⁸⁰ USITC, hearing transcript, May 5, 2014, 49–50 (testimony of Vince Suneja, TwoFour Insight Group); industry representative, interview by USITC staff, New Delhi, May 12, 2015; John Lewis, Association of Clinical Research Organizations, “Current Environment for Clinical Trials in India,” email message to USITC staff, July 23, 2015.

⁴⁸¹ Industry representative, interview by USITC staff, Mumbai, April 22, 2015; industry representative, telephone interview by USITC staff, April 29, 2015.

⁴⁸² This draft bill also includes provisions related to medical devices, which are discussed below.

⁴⁸³ Government of India, Central Drugs Standard Control Organization, “Draft Drugs and Cosmetics Amendment Bill 2015,” January 2, 2015.

remains as to how causation will be determined and who may be required to provide compensation, as these issues are left to the regulator to decide.⁴⁸⁴

The draft bill also includes criminal penalty provisions that raise concerns among some clinical trial providers.⁴⁸⁵ The U.S. Pharmaceutical Research and Manufacturers of America (PhRMA) has stated that the bill defines criminally punishable conduct far too broadly.⁴⁸⁶ According to the Association of Clinical Research Organizations, it is likely that the uncertainty surrounding the applicability of the bill's penal provisions will continue to seriously discourage the conduct of clinical research in India.⁴⁸⁷ Regulatory uncertainty also persists with regard to clinical trials and the approval process for biosimilars, as discussed in box 6.4.

⁴⁸⁴ Barnes et al., "India's Proposed Amendments," 2015, 1; Pharmaceutical Research and Manufacturers of America (PhRMA), email message to USITC staff, July 1, 2015.

⁴⁸⁵ Barnes et al., "India's Proposed Amendments," 2015, 1; industry representative, e-mail message to USITC staff, Washington DC, July 1, 2015.

⁴⁸⁶ Pharmaceutical Research and Manufacturers of America (PhRMA), e-mail message to USITC staff, July 1, 2015.

⁴⁸⁷ John Lewis, Association of Clinical Research Organizations, "Current Environment for Clinical Trials in India," email message to USITC staff, July 23, 2015.

Box 6.4: Clinical Trials and Biosimilars

A biosimilar is a biological product (derived from a living organism) that is approved based on a showing that it is highly similar to an approved biological product, known as a reference product. The biosimilar also must have no clinically meaningful differences in terms of safety and effectiveness from the reference product.^a The global biosimilars market, valued at nearly \$2 billion in 2014, is expected to grow rapidly over the next five years.^b India presents a particularly active market. As of June 2015, there were about 20 biosimilars on the market. By comparison, the U.S. Food and Drug Administration approved its first biosimilar in March 2015.^c

In general, for a biosimilar to be approved, the applicant must demonstrate compliance with regulations and provide supporting data from clinical trials. In 2012, India enacted “Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India,” which lay out the regulatory standards and describe the clinical trial data that must be submitted.^d As companies aim to comply with these relatively new regulations and demonstrate the safety of their innovative processes and products, questions may arise as to whether the regulatory standards have been met.

India’s biosimilar regulatory guidelines were at issue in litigation in 2014. In *Roche Products (India) Private Limited v Drugs Controller General of India* (Delhi High Court; CS (OS) 355/2014), the Court ruled that companies must obtain requisite approvals before going to market, overturning the approval of a biosimilar by the regulatory agency.^e According to industry representatives, legal and regulatory uncertainty continues to surround the review and approval of biosimilars in India, raising concerns for the U.S. biotechnology industry.^f

^a U.S. Food and Drug Administration, “Biosimilars,” March 6, 2015.

^b PR Newswire, “Biosimilars: Global Markets,” June 15, 2015.

^c U.S. Food and Drug Administration, “Biosimilars,” March 6, 2015.

^d Government of India, Central Drugs Standard Control Organization, “Biosimilar Guideline.pdf,” July 20, 2012.

^e Mueller and Anand, “An Overview of Biosimilars,” May 21, 2014.

^f USITC, hearing transcript, May 5, 2015, 174 (testimony of Lila Feisee, BIO); industry representative, telephone interview by USITC staff, July 30, 2015.

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Chapter 7

Intellectual Property Rights

India 2014 described barriers related to intellectual property rights (IPR) in the areas of trade secrets, regulatory test data, patents, trademarks, and copyrights, but noted that industry representatives were guardedly optimistic that the Modi government would improve the IPR regime.⁴⁸⁸ In research to prepare this report during May 2014–July 2015, the Commission did not identify any new laws, policies, or regulations adopted by the Modi government to ameliorate the IPR barriers described in *India 2014*. Nevertheless, U.S. industry and government representatives reported that Modi government officials have engaged in productive discussions on IPR issues, particularly in the context of the December 2014 Draft National IPR Policy (Draft IPR Policy). Table 7.1 summarizes major IPR policies and practices and changes identified under the Modi government.

Table 7.1: Indian IPR policies and practices, May 2014–July 2015

Policy or practice	Description of problem pre-May 2014	Changes found under Modi government
Trade secret protection	India does not have a statute that prohibits trade secret misappropriation.	No new law. The December 2014 Draft IPR Policy acknowledges that a law may be needed.
Regulatory test data protection	To obtain approval of their products, generic companies can rely on test data and other information submitted by innovator companies.	No new law. The December 2014 Draft IPR Policy describes this as a possible subject for study.
Compulsory licensing of patents	Companies may be required to make their patented technologies available to competitors under a wide range of circumstances.	No legal changes and none proposed in the December 2014 Draft IPR Policy.
Patenting standards	Strict standards result in the denial or revocation of biopharmaceutical patents in particular.	No legal changes and none proposed in the December 2014 Draft IPR Policy.
Protections against trademark counterfeiting and copyright piracy	High rates of counterfeiting and piracy of a wide range of physical and digital goods.	No legal changes and none proposed in the December 2014 Draft IPR Policy.
Processing and enforcing of patents, trademarks, and copyrights	Administrative officials and courts reportedly are overburdened and ill-equipped to handle growing caseloads, creating long delays and weakening deterrence.	Some additional resources have been allocated to improve processing of applications. New measures are proposed in the December 2014 Draft IPR Policy.

Source: Compiled by the Commission.

⁴⁸⁸ USITC, *India 2014*, 2014, 135–39.

More Engagement on IPR Issues

U.S. and Indian industry representatives described some improved engagement and transparency on IPR policy issues during May 2014–July 2015.⁴⁸⁹ The Pharmaceutical Research and Manufacturers of America (PhRMA), for example, stated at the Commission’s May 2015 hearing that the Modi government has emphasized “predictable decision-making, implementation of political commitments, transparency, and good governance—all factors that are consistent with a rules-based government open to dialogue and problem-solving in partnership with stakeholders.”⁴⁹⁰ Similarly, the President of the U.S. India Business Council (USIBC) testified that his members have noticed an increased willingness of government officials “to meet companies, understand their investment impediments and try to identify win/win solutions.”⁴⁹¹

Moreover, this increased engagement has included giving interested parties the opportunity to submit formal comments for consideration before new policies are adopted. In December 2014, for example, an Indian government-appointed think tank opened for public comment the new Draft IPR Policy (see box 7.1).⁴⁹² Many foreign and domestic stakeholders—including industry representatives, academics, and nongovernmental organizations—submitted written comments and also met with government officials to share their perspectives.⁴⁹³ Similarly, U.S. industry representatives reported that they filed written comments on various draft patent guidelines during May 2014–July 2015.⁴⁹⁴ In some cases, their comments were addressed in final documents; the Biotechnology Industry Organization (BIO), for instance, stated that several of its comments on guidelines for the examination of pharmaceutical patents were incorporated into the final guidelines issued by the Indian Patent Office.⁴⁹⁵

⁴⁸⁹ Industry representatives, interviews by USITC staff, New Delhi, May 11, 12, 2015; industry representatives, interviews by USITC staff, Bangalore, April 21, 2015; industry representatives, interviews by USITC staff, Mumbai, April 22 and 23, 2015.

⁴⁹⁰ PhRMA, written submission to the USITC, April 23, 2015, 1.

⁴⁹¹ USITC, hearing transcript, May 5, 2015 (testimony of Mukesh Aghi, USIBC), 159; industry representatives, interviews by USITC staff, New Delhi, May 11 and 12, 2015.

⁴⁹² Government of India, MOCI, DIPP, “National IPR Policy (First Draft),” December 19, 2014.

⁴⁹³ Barooah, “More Submissions on the Draft IP Policy,” March 9, 2015.

⁴⁹⁴ For example, U.S. industry representatives submitted comments on draft guidelines on the patentability of computer programs, algorithms, and mathematical or business models. See, e.g., Semiconductor Industry Association (SIA), written submission to Controller General of Patents, Designs and Trademarks (CGPDT), March 25, 2015; BSA | The Software Alliance (BSA), written submission to CGPDT, March 25, 2015; and American Intellectual Property Law Association (AIPLA), written submission to CGPDT, May 15, 2015.

⁴⁹⁵ BIO is a nonprofit organization with a membership of more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States and a number of foreign countries. BIO, written submission to USTR, February 6, 2015, 4, 36.

Box 7.1: India's Draft IPR Policy

India's 29-page Draft IPR Policy is intended to nurture creativity and innovation and address all facets of the country's IPR system. The draft, which was released in December 2014, describes overarching objectives and also makes particular recommendations. Recommendations that relate to the IPR barriers identified in *India 2014* are described in the text of this report. The Draft IPR Policy's overarching objectives are:

1. **Intellectual property (IP) awareness and promotion:** create awareness in all sections of society about the benefits of IP for accelerating development, promoting entrepreneurship, expanding employment, and increasing competitiveness.
2. **IP creation:** stimulate the creation and growth of IP assets.
3. **IP legal framework:** have strong and effective laws that are consistent with national priorities and international obligations.
4. **IP administration and management:** modernize and strengthen IP administration with efficient, expeditious, and cost-effective services.
5. **IP commercialization:** augment IP commercialization, valuation, licensing, and technology transfer.
6. **IP enforcement and adjudication:** strengthen mechanisms for combating IP violations to facilitate effective and speedy outcomes.
7. **IP human capital development:** expand human resources and capacities for IP teaching, training, research, and skill building.

The Draft IPR Policy also explains that IP has an important role in Make in India^a and other government initiatives predicated on fostering innovation and creativity by generating, protecting, and using IP assets. The draft concludes by recommending the creation of a high-level body in the government to coordinate, guide, and oversee the implementation and future development of IP in India.

Reportedly, a final draft is circulating for interministerial consultation and is expected to be submitted to the Union Cabinet for final approval later in 2015.

Sources: Government of India, MOCI, DIPP, "National IPR Policy (First Draft)," December 19, 2014; Express Pharma, "India's IPR Policy," July 21, 2015.

^a Make in India is discussed in greater detail in chapter 2.

U.S. industry representatives, as well as trade associations representing Indian firms, also strongly supported increased bilateral engagement between the U.S. and Indian governments during May 2014–July 2015.⁴⁹⁶ In December 2014, an "out-of-cycle" review by the U.S. Trade Representative (USTR) of India's IPR environment noted the government's positive

⁴⁹⁶ USITC, hearing transcript, May 5, 2015, 171 (testimony of Lila Feisee, BIO); USITC, hearing transcript, May 5, 2015, 28 (testimony of Linda Dempsey, NAM); USITC, hearing transcript, May 5, 2015, 188 (testimony of Patrick Kilbride, GIPC); USITC, hearing transcript, May 5, 2015, 178 (testimony of Amiee Aloji, PhRMA). See also Confederation of Indian Industries (CII), written submission to USTR, October 30, 2014, 3; Federation of Indian Chambers of Commerce and Industry (FICCI), written submission to USTR, October 31, 2014, 4.

commitments to several promising steps. These included plans to institutionalize high-level engagement on IPR issues; pursue a specific IPR work program; and deepen cooperation and information exchange under the auspices of the U.S.-India Trade Policy Forum.⁴⁹⁷ In April 2015, USTR stated that the U.S.-India High-Level IPR Working Group was continuing its work to foster an environment that stimulates investment and innovation through IPR protection and enforcement.⁴⁹⁸ One example of the Indian government’s acknowledgement of the importance of IPR protection is found in its Make in India program, which includes a commitment to establish a vibrant IPR regime conducive to investment in Indian manufacturing.⁴⁹⁹

Many U.S. government and industry representatives expressed concern, however, that increased engagement and rhetoric have not led to concrete actions during May 2014–July 2015.⁵⁰⁰ According to PhRMA, for example, the industry has not seen “measurable and actionable policy change” in the form of new laws, new policies, or improved administration of existing law.⁵⁰¹ The Alliance for Fair Trade with India similarly stated that India has not yet made the “proactive policy changes that will create a better business environment for the long term.”⁵⁰² Even the Draft IPR Policy—viewed favorably by industry representatives because it recognizes the role of intellectual property in promoting innovation—does not set forth concrete initiatives or deadlines that would, for example, raise India’s ranking on the IPR legal protection index published by the Global Intellectual Property Center.⁵⁰³

Reportedly, the lack of a strong IPR climate in India has affected not only U.S. and other foreign firms during May 2014–July 2015 but also innovative Indian startups that are moving their intellectual property out of the country because of uncertain protections.⁵⁰⁴ According to the Intellectual Property Owners Association, persistent IPR barriers in India continue to put technology providers on the defensive. The situation is making them less likely to partner with

⁴⁹⁷ USTR, “Statement by USTR,” December 12, 2014.

⁴⁹⁸ USTR, “India,” 2015, 45.

⁴⁹⁹ Government of India, MOCI, DIPP, Make in India Website, “Intellectual Property Facts,” n.d. (accessed July 28, 2015); see also FICCI, written submission to USTR, October 31, 2014, 5. Make in India is discussed in chapter 2.

⁵⁰⁰ USTR, “India,” 2015, 46; USITC, hearing transcript, May 5, 2015, 165 (testimony of Brian Pomper, AFT); USITC, hearing transcript, May 5, 2015, 191 (testimony of Patrick Kilbride, GIPC). See also industry representatives, interviews by USITC staff, Hyderabad, April 16, 2015; industry representatives, interviews by USITC staff, Mumbai, April 22, 2015; and industry representatives, interviews by USITC staff, New Delhi, May 12, 13, 2015.

⁵⁰¹ USITC, hearing transcript, May 5, 2015, 199–200 (testimony of Amiee Aloji, PhRMA).

⁵⁰² USITC, hearing transcript, May 5, 2015, 234 (testimony of Brian Pomper, AFTI).

⁵⁰³ USITC, hearing transcript, May 5, 2015, 187, 240 (testimony of Patrick Kilbride, GIPC); USITC, hearing transcript, May 5, 2015, 30 (testimony of Linda Dempsey, NAM); USITC, hearing transcript, May 5, 2015, 172 (testimony of Lila Feisee, BIO).

⁵⁰⁴ USITC, hearing transcript, May 5, 2015, 32–33 (testimony of Linda Dempsey, NAM).

Indian firms and exchange the knowledge that would help India achieve its goal of becoming an innovation leader.⁵⁰⁵

No Major Changes to IPR Laws

As noted above, during the May 2014–July 2015 period, the Modi government did not enact, adopt, or implement new laws or regulations to address barriers described in *India 2014*. For example, India still lacks a statute protecting trade secrets, and it does not protect against unauthorized reliance by outside producers on test data and information that innovator companies submit to regulators.⁵⁰⁶ The law continues to authorize the compulsory licensing of patented technologies under a wide variety of circumstances;⁵⁰⁷ patent standards continue to be strictly applied to biopharmaceutical products; and industry representatives continue to report substantial counterfeiting and piracy problems. Industry representatives did, however, report some incremental improvements during May 2014–July 2015. For example, no new compulsory licenses have been issued. There have been some favorable administrative and judicial patent decisions, and some additional resources and improved procedures have been directed to the processing of IPR applications.

Statutory Protections for Trade Secrets and Regulatory Test Data Are Still Not Available

Some industry representatives have stated that the lack of a trade secret law continues to create uncertainty about the circumstances under which protection will be available, and deters companies from conducting research and development (R&D) or other knowledge-intensive activities in India.⁵⁰⁸ Others interviewed by Commission staff were less concerned

⁵⁰⁵ Intellectual Property Owners Association, written submission to the USITC, June 2, 2015, 2.

⁵⁰⁶ U.S. companies active in India rely on trade secrets to protect their valuable technical and proprietary information. Because trade secrets do not have to be registered with administrative agencies, they are particularly important to small and medium-sized enterprises and companies with limited resources. USITC, *India 2014*, 2014, 140, 144.

⁵⁰⁷ A compulsory license permits someone else to produce a patented product or use a patented process without the consent of the patent owner. Under section 84 of the India Patents Act, a compulsory license may be issued three years after a patent is granted when the reasonable requirements of the public have not been satisfied; the invention is not available at a reasonably affordable price; or the patent is not “worked” in India. Section 92 further permits the Indian government to obtain a compulsory license for a national emergency or noncommercial public use of the patented subject matter. USITC, *India 2014*, 2014, 150–51.

⁵⁰⁸ AFTI, written submission to USITC, May 12, 2015, 9; BSA, written submission to IPR Think Tank, January 2015, 3; industry representatives, interviews by USITC staff, Hyderabad, April 16 and 17, 2015.

because they do not hold their trade secrets in India or believe that they have sufficient contractual or other protections in place.⁵⁰⁹

India's Draft IPR Policy emphasizes the need to enact laws to "fill gaps" in India's protection regime, including in the area of trade secrets.⁵¹⁰ U.S. government and industry representatives stated that a trade secret law would be an important sign of an improvement in India's IPR policy environment and an inducement for firms to broaden their innovative activities.⁵¹¹ As FICCI, an association that represents Indian firms, stated: "A predictable and recognizable trade secret regime will improve investor confidence and create a facilitative environment for flow of information."⁵¹²

India also still lacks a statute that prohibits companies producing generic goods from making unauthorized use of test data and information submitted to regulators by innovator companies, as noted in *India 2014*. The Draft IPR Policy makes no commitments on this subject, noting only that the protection of undisclosed information is "an important area of study and research for future policy development."⁵¹³ While it appeared the Indian Parliament might consider protecting test data for agricultural chemicals in 2015 under the Pesticides (Amendment) Bill, no concrete actions had been taken as of mid-July 2015.⁵¹⁴ The U.S. government and industry representatives continue to urge legal change in this area.⁵¹⁵

A Cautious Approach to Compulsory Licenses

U.S. industry representatives described positive and negative patent-related developments during May 2014–July 2015. They considered it a positive development that no new compulsory

⁵⁰⁹ According to the Intellectual Property Owners Association, however, contract or tort laws may not be sufficient to protect against misappropriation when there is not an employment or other close relationship between the trade secret owner and bad actor. Intellectual Property Owners Association, written submission to the USITC, June 2, 2015, 4. See also industry representative, interview by USITC staff, Hyderabad, April 17, 2015, and industry representative, interview by USITC staff, Mumbai, April 23, 2015.

⁵¹⁰ Government of India, MOCI, DIPP, "National IPR Policy (First Draft)," December 19, 2014, 12.

⁵¹¹ Industry representatives, interviews by USITC staff, Hyderabad, April 16 and 17, 2015; industry representative, interview by USITC staff, Mumbai, April 23, 2015; industry representative, interview by USITC staff, New Delhi, May 11, 2015; AFTI, written submission to the USITC, May 12, 2015, 9; Pepsico, written submission to USTR, October 31, 2014; National Foreign Trade Council, written submission to USTR, February 6, 2015, 2; USTR, "India," 2015, 51; Kamphausen, "Innovate in India," 2015, 29.

⁵¹² FICCI, written submission to USTR, October 31, 2014, 25.

⁵¹³ Government of India, MOCI, DIPP, "National IPR Policy (First Draft)," December 19, 2014, 13 (specifically, the report identifies the "protection of undisclosed information not extending to data exclusivity" as an area of study).

⁵¹⁴ USTR, "India," 2015, 50.

⁵¹⁵ *Ibid.*; PhRMA, written submission to the USITC, May 5, 2015, 5; Intellectual Property Owners Association, written submission to the USITC, June 2, 2015, 3; USITC, hearing transcript, May 5, 2015, 168–69 (testimony of Brian Pomper, AFTI); USITC, hearing transcript, May 5, 2015, 245 (testimony of Patrick Kilbride, GIPC); industry representatives, interviews by USITC staff, New Delhi, May 11 and 13, 2015; industry representatives, interview by USITC staff, Mumbai, April 22, 2015.

licenses have been issued since the one for Bayer’s cancer drug, Nexavar, which was granted in 2012 and upheld by the Supreme Court of India in 2014.⁵¹⁶ At the Commission’s May 2015 hearing, PhRMA stated that the Modi government has taken a “measured and cautious approach” to compulsory license requests.⁵¹⁷ For example, in June 2014, the Department of Industrial Policy and Promotion (DIPP) rejected a compulsory license requested by the Ministry of Health and Family Welfare (Health Ministry) for the patented blood cancer drug, Dasatinib, on the grounds that the request was not sufficiently justified.⁵¹⁸ The Global Intellectual Property Center similarly noted that there has been an apparent retreat from a political bias in favor of compulsory licenses, and that a cabinet-level committee put in place by the previous government to foster compulsory license applications appears to have been dismantled.⁵¹⁹

Recent developments, however, may undermine industry optimism. In July 2015, the Ministry of Commerce and Industry reported that it was again considering a compulsory license request from the Health Ministry for Dasatinib.⁵²⁰ Moreover, other industry representatives, including the Semiconductor Industry Association (SIA), remain concerned that India will continue to use compulsory licensing as a way to accelerate the transfer of patented technologies in key areas.⁵²¹ For example, the December 2014 Draft IPR Policy endorses India’s National Manufacturing Policy and Technology Acquisition and Development Fund, both of which contain provisions promoting compulsory licensing.⁵²² To reduce uncertainty, some suggested that the Modi government consider announcing an official hiatus in the use of compulsory licenses, or at least provide greater clarity on how decisions would be made going forward.⁵²³

Mixed Decisions on Biopharmaceutical Patents

Judicial and administrative decisions on biopharmaceutical patents were mixed during May 2014–July 2015. U.S. government and industry representatives continue to raise concerns

⁵¹⁶ USITC hearing transcript, May 5, 2015, 172 (testimony of Lila Feisee, BIO).

⁵¹⁷ PhRMA, written statement to the USITC, May 5, 2015, 1–2.

⁵¹⁸ Similarly, in August 2015, the Indian Patent Office rejected a compulsory license request for an anti-diabetes drug on the grounds that the applicant did not meet the legal criteria. *Economic Times*, “India Rejects Lee Pharma’s Compulsory License Plea,” August 18, 2015; see also Sen, “Health Ministry’s New Bid for Cancer Drug,” June 18, 2014.

⁵¹⁹ USITC hearing transcript, May 5, 2015, 186 (testimony of Patrick Kilbride, GIPC).

⁵²⁰ *Economic Times*, “Commerce and Industry Ministry Considering Proposal,” July 24, 2015.

⁵²¹ Patent protection is particularly important to SIA members, who often hold large and valuable patent portfolios. SIA, written submission to USTR, February 5, 2015, 23. See also ITIF, written submission to the USITC, June 2, 2015, 6–7; Intellectual Property Owners Association, written submission to the USITC, June 2, 2015, 4.

⁵²² Government of India, MOCI, DIPP, National IPR Policy (First Draft), December 19, 2014, 19.

⁵²³ Kamphausen, *Innovate in India*, 2015, 28–29; USTR, “India,” 2015, 50.

about strict patentability requirements, including section 3(d) of the Patent Act of 2005,⁵²⁴ that make it particularly difficult to obtain patents for pharmaceutical and biotechnology inventions.⁵²⁵ There were, however, some decisions favorable to rights holders during May 2014–July 2015, according to the Indian Pharmaceutical Alliance (IPA) and nongovernmental organizations.⁵²⁶ The Modi government did not announce any anticipated changes in this area in the Draft IPR Policy.

Table 7.2 describes key judicial and administrative decisions in India during May 2014–July 2015 involving biopharmaceutical patents held or sought by multinational companies. Those that went against innovator companies typically found that patentability standards of novelty, inventive step and utility, and/or section 3(d) requirements had not been satisfied. According to some industry representatives, negative decisions often were inconsistent with decisions made in the United States and other jurisdictions.⁵²⁷ U.S. industry representatives also raised concerns about regulators in Indian states that grant marketing approval to generics without taking into account the patent status of the original drug, thereby requiring long and expensive court proceedings to get infringing drugs off the market.⁵²⁸ By contrast, IPA and others pointed to favorable judicial decisions for innovator companies during May 2014–July 2015, including multiple cases in which they obtained injunctions to prevent further infringement of their products (see table 7.2).⁵²⁹

⁵²⁴ Under section 3(d), derivatives of a known substance, such as salts, esters, ethers, and polymorphs, are presumed to be the same as the original chemical and not patentable, unless it can be shown that they differ significantly in therapeutic efficacy. Patents Act of 2005, section 3(d); USITC, *India 2014*, 2014, 148–50.

⁵²⁵ Industry representatives in the semiconductor and software sectors also have raised concerns about section 3(k) of the India Patents Act, which limits patents for computer programs, algorithms, and mathematical or business methods. See, e.g., SIA, written submission to CGPDT, March 25, 2015; BSA, written submission to CGPDT, March 25, 2015.

⁵²⁶ IPA, written submission to USTR, October 28, 2014, 7–8; Ragavan et al., written submission to USTR, October 2014, Annex 2.

⁵²⁷ USITC hearing transcript, May 5, 2015, 180 (testimony of Amiee Aloï, PhRMA); USITC hearing transcript, May 5, 2015, 172 (testimony of Lila Feisee, BIO); ITIF, written submission to the USITC, June 2, 2015, 6–7.

⁵²⁸ USITC hearing transcript, May 5, 2015, 179 (testimony of Amiee Aloï, PhRMA); ITIF, written submission to the USITC, June 2, 2015, 7; industry representative, interview by USITC staff, New Delhi, May 11, 2015.

⁵²⁹ IPA, written submission to USTR, October 28, 2014, 7–8; Ragavan et al., written submission to USTR, October 2014, Annex 2.

Table 7.2: Key rulings on biopharmaceutical product patents in India from May 2014–July 2015

Company/product name	Decision	Date	Treatment Area
Compulsory Licenses			
Bristol-Myers Squibb (BMS)/Dasatinib	Compulsory license denied	06/2014	Cancer
Bayer/Nexavar	Compulsory license upheld	12/2014	Cancer
Patent Applications			
Abraxis Biosciences/Abraxane	Patent denied	06/2014	Cancer
Pfizer/ Voriconazole	Patent granted	10/2014	Fungal infections
Gilead/Solvadi	Patent pending	01/2015	Hepatitis C
Novartis/Galvus	Patent denied	05/2015	Diabetes
Patent Revocations			
F. Hoffmann-LaRoche/Bonviva	Patent revoked	12/2014	Osteoporosis
AbbVie/Humira	Patent revoked	12/2014	Autoimmune disorders
Boehringer Ingelheim/Spiriva	Patent revoked	03/2015	Lung function
Injunctions			
BMS/Atazanavir	Injunction denied	12/2014	HIV
Novartis/Onbrez	Injunction granted	02/2015	Lung function
MSD/Januvia and Janumet	Injunction granted	03/2015	Diabetes
BMS/Dasatinib	Injunction granted	06/2015	Cancer

Sources: Sen, “Health Ministry’s New Bid,” June 18, 2014; ENS Economic Bureau, “SC Dismisses SLP Filed by Bayer,” December 13, 2014; Jayaraj, “Natco vs. Abraxis,” June 27, 2014; *Business Standard*, “Pfizer Wins Patent,” October 12, 2014; *Business Standard*, “Patent Refused to Novartis,” May 15, 2015; *Managing Intellectual Property*, “India Pharma Patentees Score Crucial Victories,” February 23, 2015; *Business Standard*, “Patent Office Revokes,” January 2, 2015; Helfand, “AbbVie’s Humira Competition,” December 9, 2014; Reuters, “Germany’s Boehringer Loses,” March 10, 2015; Wasserman, “Merck Scores Victory,” May 15, 2015; Jayaraj, “DHC Upholds Validity,” July 16, 2015.

A study by TwoFour Insight (which sent a witness to the Commission’s hearing) suggests some basis for both perspectives.⁵³⁰ The study found that the Indian Patent Office agreed with its counterparts in the United States or Europe in 53 percent of decisions involving the life sciences (pharmaceuticals, biotechnology and medical devices); disagreed in 16 percent of cases; and in the remainder of the cases, the U.S. or European Union patents offices had not yet made a decision. Where there was disagreement, the Indian Patent Office cited section 3(d) as a basis for patent denial in most of the cases. The study noted that while the dataset was small, consisting of only 58 decisions made in India in March 2015 that overlapped with decisions in

⁵³⁰ USITC hearing transcript, May 5, 2015, 56 (testimony of Vince Suneja, TwoFour Insight); TwoFour Insight Group, “Do Decisions by USPTO/EPO Influence?” March 30, 2015.

the United States and Europe, the somewhat high rate at which section 3(d) was a factor “warranted closer examination.”⁵³¹

Other observers noted that Indian companies often are the ones developing targeted improvements to drugs to meet local needs—such as the reformulation of vaccines to eliminate the need for cold chain storage and transport—and that these local companies and innovations are undermined by unduly strict patenting standards.⁵³² For this reason, the India Association of Biotechnology Led Enterprises (ABLE) has recommended that the government let the patent system work to encourage needed innovation. ABLE has urged the government to instead consider more direct solutions to India’s health problems, particularly increased investments in the health care system.⁵³³

In contrast to these industry views, Doctors Without Borders/Médecins Sans Frontières (MSF) and other nongovernmental organizations stated that India should continue to apply strict patentability standards and broad provisions for compulsory licensing to maintain its status as “pharmacy to the developing world.” They asserted that if India were to lose this status, it would be devastating for patients, treatment providers, and global health donors, including the U.S. government, who would pay much higher prices for essential drugs in their aid programs.⁵³⁴ To address the disincentives for R&D that may result from patent denials, MSF suggested new approaches that try to break the link between the cost of R&D and the high price of the end product.⁵³⁵

The Draft IPR Policy does not identify patenting standards as an area in need of reform.⁵³⁶ It does, however, recommend the protection of “small inventions” through a new law on utility models or petty patents. This step is intended to encourage greater commercialization of intellectual property assets by small and medium-sized enterprises.⁵³⁷ Although recognition of the value of small inventions would be consistent with a relaxation of section 3(d)’s strict standards for incremental biopharmaceutical inventions, the Draft IPR Policy does not draw this connection. For their part, industry representatives have expressed varying views on the

⁵³¹ TwoFour Insight Group, “Do Decisions by USPTO/EPO Influence?” March 30, 2015.

⁵³² Office of Pharmaceutical Producers of India (OPPI), letter to Minister Sinha, April 18, 2015, 3 (describing government-appointed committee finding that an overwhelming number of international patent applications filed by Indian entities are for subject matter that would not be patentable under section 3(d)); Burrill Media LLC, *Accelerating Growth*, 2014, 17–18.

⁵³³ Burrill Media LLC, *Accelerating Growth*, 2014, 17–18.

⁵³⁴ MSF, written submission to the USITC, June 2, 2015, 3; see also Union for Affordable Cancer Treatment, written submission to USTR, February 5, 2015, 2.

⁵³⁵ MSF, written submission to the USITC, June 2, 2015, 4.

⁵³⁶ Government of India, MOCI, DIPP, “National IPR Policy (First Draft),” December 19, 2014, 11–12.

⁵³⁷ *Ibid.*, 9–10.

advisability of implementing a new petty patent regime, particularly given the substantial resource challenges already facing the Indian patent office.⁵³⁸

Continued High Rates of Counterfeiting and Piracy

The U.S. government and industry representatives, particularly those in the content and media sector, noted continuing problems with high rates of counterfeiting (trademark infringement) and piracy (copyright infringement) in India. These problems reportedly are exacerbated by increasing Internet penetration, as well as laws that do not fully address online infringement. While the Draft IPR Policy recognizes that piracy and counterfeiting discourage creativity and innovation, it reportedly proposes few concrete solutions. U.S. government and industry representatives continue to seek new laws to address legal gaps, along with stronger administrative and legal enforcement. Concrete actions, however, did not occur during May 2014–July 2015.

According to witnesses at the Commission’s hearing and other industry representatives, the level of infringing goods on the market in India remained substantial during May 2014–July 2015.⁵³⁹ Physical markets throughout India (many of which were identified in the first report) continued to offer large quantities of infringing goods.⁵⁴⁰ The camcording of copyrighted U.S. and Indian films also continued to be a severe problem. For example, in 2014, 40 major U.S. motion pictures reportedly were camcordered from theaters in India, with global distribution of the camcordered copies.⁵⁴¹ Moreover, the music industry continued to experience substantial infringement. Industry representatives in India estimated that only 1–2 percent of music consumption comes from legal purchases while 98–99 percent is illegal, according to a 2015 study by FICCI and KPMG.⁵⁴² Industry representatives also described an environment where unauthorized copies are readily available online for free through direct download, torrent, social networking, and streaming sites.⁵⁴³

U.S. government and industry representatives have urged India to pass laws addressing substantial counterfeiting and piracy. These would include the enactment of anti-camcording

⁵³⁸ Intellectual Property Owners Association, written comments to the India National IPR Think Tank, January 29, 2015, 7–8; Leung, “Are Utility Models a Key Part?” October 9, 2014.

⁵³⁹ USITC hearing transcript, May 5, 2015, 23 (testimony of Michael Schlesinger, IIPA); USITC hearing transcript, May 5, 2015, 197 (testimony of Brian Pomper, AFTI); USITC hearing transcript, May 5, 2015, 122–23 (testimony of Richard Rossow, Center for Strategic and International Studies); ITIF, written submission to the USITC, June 2, 2015, 6–7; International AntiCounterfeiting Coalition (IACC), written submission to USTR, February 6, 2015, 12; industry representatives, interviews by USITC staff, Mumbai, April 22 and 23, 2015.

⁵⁴⁰ USITC, *India 2014*, 2014, 161–62; USTR, *2014 Out-of-Cycle Review*, March 5, 2015, 22.

⁵⁴¹ IIPA, “India,” April 2015, 29; industry representative, interview by USITC staff, Mumbai, April 23, 2015.

⁵⁴² FICCI-KPMG, *#shootingforthestars*, April 2015, 117.

⁵⁴³ IIPA, “India,” April 2015, 28; industry representative, interview by USITC staff, Mumbai, April 22, 2015.

legislation; additional rules against circumventing technological protections for films, music, and other content; and effective measures to counter online piracy, including appropriate notice-and-takedown and other mechanisms to address websites hosting illegal content.⁵⁴⁴ These measures are not recommended in the Draft IPR Policy; whether changes will nonetheless occur remains to be seen.⁵⁴⁵

Ongoing Challenges to IPR Processing and Enforcement

India 2014 described a “clear consensus” among Indian and U.S. industry representatives that the Indian government needs a stronger focus on IPR processing and enforcement. Under the Modi government, U.S. and Indian industry representatives continued to agree that backlogs in administrative agencies and the courts substantially undermine IPR value in India. Although the Modi government has recognized the need to strengthen enforcement mechanisms and has taken some positive steps, industry representatives did not report substantial improvements during May 2014–July 2015. The World Bank’s recent finding that India continues to rank 186th out of 189 economies on the ease of resolving commercial disputes in the courts confirms that much remains to be done.⁵⁴⁶

New Measures to Address Delays in IPR Processing

U.S. and Indian industry representatives described backlogs and long delays in processing IPR applications as substantial concerns in *India 2014*. These concerns continued during May 2014–July 2015.⁵⁴⁷ The Modi government has, however, implemented some new measures to address these problems, including hiring additional personnel in trademark and patent offices, upgrading electronic filing and payment systems, increasing training, and introducing a new “Stock and Flow” utility tool, which provides a real-time snapshot of the status of trademark and patent applications.⁵⁴⁸

The Draft IPR Policy also contains proposals to improve patent, trademark, and copyright processing. For example, in the area of copyrights, it suggests new measures to modernize the copyright office, digitize records, and increase staffing. Industry representatives suggested

⁵⁴⁴ USTR, “India,” 2015, 47; IIPA, “India,” April 2015, 32–34.

⁵⁴⁵ National anti-camcording legislation, for example, was not introduced in the Parliament during May 2014–July 2015. USTR, “India,” 2015, 47; industry representative, interview by USITC staff, Mumbai, April 23, 2015.

⁵⁴⁶ The World Bank’s ease of doing business rankings also are discussed in chapter 2.

⁵⁴⁷ Trademark Working Group, written submission to USTR, October 31, 2014, 2; SIA, written submission to USTR, February 5, 2015, 25. See also USITC, *India 2014*, 2014, 147.

⁵⁴⁸ Intellectual Property Owners Association, written submission to the USITC, June 2, 2015, 1; FICCI, written submission to USTR, October 31, 2014, 7–9; IPA, “2014 Special 301 Out-of-Cycle Review,” October 28, 2014, 3–4; Pepsico, written submission to USTR, October 31, 2014, 2.

additional ways to strengthen IP administration, including greater transparency, the use of state-of-the-art technology, and more predictable timeframes.⁵⁴⁹

Moreover, a court case challenging long delays in the patent system appears to have spurred some reforms during May 2014–July 2015. In October 2014, the Delhi High Court issued an opinion in *Nitto Denko v. Union of India*, finding that long delays violated patent rules. Based on the court’s opinion and suggestions from a government-appointed committee, the Modi government committed to spending about \$50 million for new examiners and other improvements.⁵⁵⁰

The Delhi High Court also required the government to establish a committee to examine additional measures, including whether patent terms should be extended to compensate for delays and whether certain patents could receive expedited treatment. In February 2015, the committee issued its report and rejected the extension of patent terms. Instead, it suggested that the law be amended to allow for expedited examination in cases where the patent applicant commits to manufacture the invention in India.⁵⁵¹ This recommendation had not moved forward as of mid-July 2015. One of the most controversial aspects of the Bayer/Nexavar compulsory license was its reliance on the fact that the patented product was not locally manufactured.⁵⁵² Other localization requirements and incentives of concern to U.S. industry representatives are described in chapter 5.

New Proposals to Improve IPR Enforcement and Reduce Judicial Delays

The Draft IPR Policy contains several proposals to strengthen IPR enforcement and reduce judicial delays. These proposals include launching a task force to coordinate the efforts of the multiple central government agencies with IPR jurisdiction; working closely with state governments to include IPR crimes under state laws and police enforcement efforts; and facilitating dispute resolution through new specialized IPR tribunals.⁵⁵³

⁵⁴⁹ Government of India, MOCI, DIPP, “National IPR Policy (First Draft),” December 19, 2014, 15–16; International Trademark Association (INTA), written submission to the IPR Think Tank, January 29, 2015, 3–5.

⁵⁵⁰ Anand and Anand, “Nitto Denko v Union of India—Committee Report,” April 2015.

⁵⁵¹ *Ibid.*

⁵⁵² The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), whose obligations apply to all WTO members, requires patents and their associated rights to be available “without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” Intellectual Property Owners Association, written submission to the USITC, June 2, 2015, 3.

⁵⁵³ Government of India, MOCI, DIPP, “National IPR Policy (First Draft),” December 19, 2014, 21–22.

While U.S. government and industry representatives generally supported these proposals, they also raised the concern that they do not go far enough.⁵⁵⁴ For example, the Business Action to Stop Counterfeiting and Piracy (BASCAP), part of the International Chamber of Commerce, recommended that the Draft IPR Policy address the vital role of national customs authorities in monitoring the supply chain and preventing fakes from entering the territory. BASCAP also urged that the Draft IPR Policy highlight the need for the government to give customs agencies enough funding, training, and authority to carry out their role.⁵⁵⁵

Industry representatives did not, however, describe major improvements in the enforcement environment during May 2014–July 2015. According to the Trademark Working Group, for example, infringers know that an administrative proceeding or a court case will take a long time to resolve. They therefore generally refuse to negotiate or settle, preferring to continue their infringing activities unobstructed for years. The SIA similarly noted that the lack of near-term consequences means that the threat of filing a legal action has little deterrent effect on infringers.⁵⁵⁶

In the copyright area, IIPA stated that while courts in some jurisdictions (including the High Courts in Delhi, Mumbai, Chennai, and Kolkata) did a creditable job of issuing preliminary injunctions and other court orders, these positive examples generally were not emulated in other states.⁵⁵⁷ Experiences in other locations, including Gujarat, reportedly were more negative, with endemic problems such as monetary awards that are too small to deter illegal activity, clogged dockets, archaic procedures, and multiple opportunities to delay proceedings.⁵⁵⁸ Other organizations that represent rights holders similarly stated that obtaining timely and deterrent injunctive and monetary relief continues to present substantial challenges.⁵⁵⁹

The World Bank’s 2015 Doing Business report corroborates this negative anecdotal evidence.⁵⁶⁰ The World Bank’s “enforcing contracts” indicator measures how long it takes to resolve a standard commercial dispute in a nation’s courts. Globally, India ranks 186 of 189 economies on the ease of enforcing contracts. This ranking is based on a review of the relevant civil

⁵⁵⁴ USTR, “India,” 2015, 46; IIPA, written submission to USTR, February 6, 2015, 26–27.

⁵⁵⁵ International Chamber of Commerce, BASCAP, written submission to IPR Think Tank, January 30, 2015.

⁵⁵⁶ Trademark Working Group, written submission to USTR, October 31, 2014, 2; SIA, written submission to USTR, February 5, 2015, 25.

⁵⁵⁷ IIPA, written submission to USTR, February 7, 2015, 30; USITC hearing transcript, May 5, 2015, 119–21 (testimony of Michael Schlesinger, IIPA).

⁵⁵⁸ Ibid.

⁵⁵⁹ BSA, written submission to USTR, February 2015, 24 (this states that while the courts have been reasonably prompt in granting injunctions, obtaining deterrent damages continues to be a challenge); industry representatives, interviews by USITC staff, Mumbai, April 22, 2015.

⁵⁶⁰ The World Bank’s 2015 Doing Business report is described in more detail in the section “Improving the Ease of Doing Business” in chapter 2.

procedures that would apply to a basic contract dispute between two domestic businesses, combined with a survey of local lawyers.⁵⁶¹ In India, it takes 1,420 days (almost four years) to resolve a basic civil case, compared to 453 days in China, 389 days in Mexico, 267 days in Russia, and 41 days in the United States. India’s ranking on this indicator in 2015 remained unchanged from the previous year.⁵⁶²

⁵⁶¹ Complex IPR disputes involving foreign parties take longer. According to the Trademark Working Group, for example, it takes five to seven years to resolve a trademark dispute in most courts in India. Trademark Working Group, written submission to USTR, October 31, 2014, 2.

⁵⁶² World Bank Group, *Doing Business 2015*, 2015, “India,” 14.

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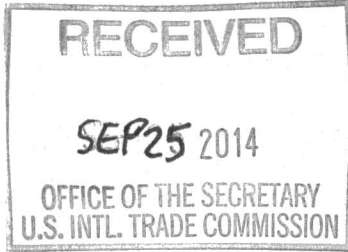
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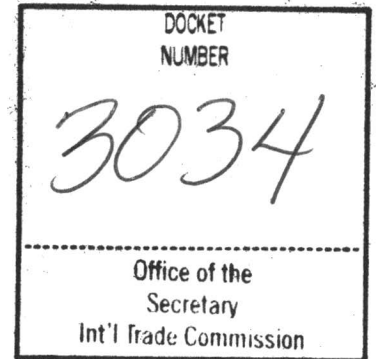
Appendix A

Request Letter

Congress of the United States
Washington, DC 20515



September 24, 2014



The Honorable Meredith Broadbent
Chairman
U.S. International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

Dear Chairman Broadbent:

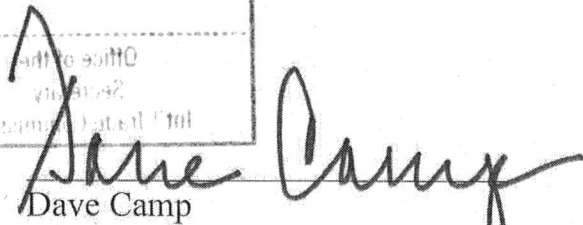
We are writing concerning the ongoing International Trade Commission investigation requested on August 2, 2013, under section 332(g) of the Tariff Act of 1930 (19 U.S.C. § 1332(g)) regarding India's industrial policies that discriminate against U.S. trade and investment. We look forward to receiving this report, which is to focus on India's policies during the period from 2003 through mid-2014, by the December 15, 2014, deadline.

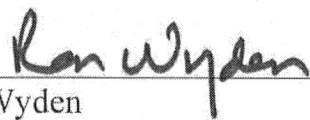
Given the recent national elections in India and the formation of a new Bharatiya Janata Party-led government, and our interest in receiving the most comprehensive and up-to-date information possible, we now request under section 332(g) of the Tariff Act of 1930 ((19 U.S.C. § 1332(g)) that the Commission conduct a second investigation concerning India's industrial policies that discriminate against U.S. trade and investment since the first ITC investigation. In particular, we request that you include information about any significant changes by the new Indian government to the trade and investment policies identified in the ITC's first report. The investigation should also include any new relevant trade and investment policies and practices, focusing on the period from mid-2014. We expect that this new investigation will allow the Commission to meet with relevant Indian government officials in the new Bharatiya Janata Party-led government and seek additional information from U.S. firms on any developments in India relevant to the scope of matters identified in our original August 2013 request.

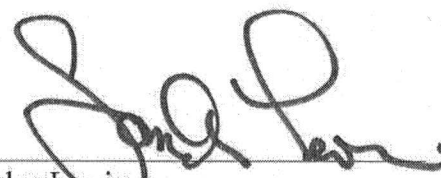
We request that the Commission deliver this second report to us by September 24, 2015. As was the case with our earlier request, we do not expect the Commission to make findings regarding the legal merits of any Indian laws or policies. In

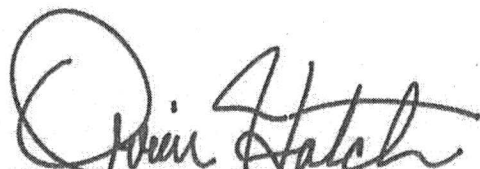
addition, because we intend to make the report available to the public, we request that the Commission not include confidential business information.

Sincerely,


Dave Camp
Chairman
House Committee on Ways and Means


Ron Wyden
Chairman
Senate Committee on Finance


Sander Levin
Ranking Member
House Committee on Ways and Means


Orrin Hatch
Ranking Member
Senate Committee on Finance

Appendix B

Federal Register Notice

respondent. The Commission Office of Unfair Import Investigations is a party to this investigation. The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain vision-based driver assistance system cameras and components thereof by reason of infringement of certain claims of U.S. Patent No. 6,807,287.

On January 26, 2015, complainant TRW moved to terminate the investigation in its entirety based on a withdrawal of the complaint. On January 27, 2015, respondent Magna Electronics Inc. (“Magna”) submitted a response to the motion, indicating that it “does not oppose TRW’s motion to withdraw its complaint and to terminate this investigation.” Magna Resp. at 1. On January 28, 2015, the Commission investigative staff filed a response supporting the motion.

On February 3, 2015, the ALJ issued the subject ID (Order No. 20) granting complainant’s motion to terminate. No party petitioned for review of the subject ID. The Commission has determined not to review the subject ID.

The authority for the Commission’s determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission’s Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: February 23, 2015.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2015–03980 Filed 2–25–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–550]

Trade and Investment Policies in India, 2014–2015

AGENCY: United States International Trade Commission.

ACTION: Rescheduling of public hearing.

SUMMARY: The Commission has rescheduled the public hearing in this investigation from April 7, 2015 to May 5, 2015, in order to allow interested parties to access more recent information in preparing their testimony and pre-hearing briefs and statements.

DATES:

April 21, 2015: Deadline for filing requests to appear at the public hearing.

April 23, 2015: Deadline for filing pre-hearing briefs and statements.

May 5, 2015: Public hearing.

May 12, 2015: Deadline for filing post-hearing briefs and statements.

June 2, 2015: Deadline for filing all other written submissions.

September 24, 2015: Transmittal of Commission report to the Committees.

ADDRESSES: All Commission offices, including the Commission’s hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <http://www.usitc.gov/secretary/edis.htm>.

FOR FURTHER INFORMATION CONTACT:

Project Leaders James Stamps (202–205–3227 or james.stamps@usitc.gov) or Deputy Project Leader Jeff Okun-Kozlowicki (202–205–5991 or jeff.okun.kozlowicki@usitc.gov) for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission’s Office of the General Counsel (202–205–3091 or william.gearhart@usitc.gov). The media should contact Margaret O’Laughlin, Office of External Relations (202–205–1819 or margaret.olaughlin@usitc.gov). Hearing-impaired individuals may obtain information on this matter by contacting the Commission’s TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Public Hearing: As announced in the notice of institution of the investigation published in the **Federal Register** on October 31, 2014 (79 FR 64834), the hearing will be held at the U.S. International Trade Commission building, 500 E Street SW., Washington, DC; it will begin at 9:30 a.m. In addition to the hearing date, the deadline dates for filing of requests to appear and pre-hearing and post-hearing briefs and statements have been changed: The deadline for filing requests to appear at the hearing has been changed to April 21, 2015; the deadline for filing pre-

hearing briefs and statements has been changed to April 23, 2015; and the deadline for filing post-hearing briefs and statements has been changed to May 12, 2015. All other requirements and procedures set out in the October 31, 2014, notice continue to apply. In the event that, as of the close of business on April 21, 2015, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant may call the Secretary to the Commission (202–205–2000) after April 21, 2015 for information concerning whether the hearing will be held.

By order of the Commission.

Issued: February 19, 2015.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2015–03853 Filed 2–25–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1190–0009]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension With Change, of a Previously Approved Collection Americans With Disabilities Act Discrimination Complaint Form

AGENCY: Civil Rights Division, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Civil Rights Division, Disability Rights Section, has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 27, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Rebecca Bond, Chief, Disability Rights Section, Civil Rights Division, by calling (800) 514–0301 or (800) 514–0383 (TTY) (the Division’s Information Line), or write her at the Department of Justice, Civil Rights Division, Disability Rights Section—NYA, 950 Pennsylvania Avenue NW., Washington, DC 20530.

above individual. The FIRS is available 24 hours a day, seven days a week. Replies are provided during normal business hours.

Authority: 43 CFR 1784.4–1.

Jenna Whitlock,

Associate State Director.

[FR Doc. 2014–25916 Filed 10–30–14; 8:45 am]

BILLING CODE 4310–DQ–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–550]

Trade and Investment Policies in India, 2014–2015

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

SUMMARY: Following receipt on September 25, 2014, of a joint request from the House Committee on Ways and Means and the Senate Committee on Finance (Committees) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission (USITC, or Commission) instituted investigation No. 332–550, *Trade and Investment Policies in India, 2014–2015*.

DATES:

March 24, 2015: Deadline for filing request to appear at the public hearing.

March 26, 2015: Deadline for filing pre-hearing briefs and statements.

April 7, 2015: Public hearing.

April 14, 2015: Deadline for filing post-hearing briefs and statements.

June 2, 2015: Deadline for filing all other written submissions.

September 24, 2015: Transmittal of Commission report to the Committees.

ADDRESSES: All Commission offices, including the Commission’s hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <http://www.usitc.gov/secretary/edis.htm>.

FOR FURTHER INFORMATION CONTACT:

Project Leaders James Stamps (202–205–3227 or james.stamps@usitc.gov) or Deputy Project Leader Jeff Okun-Kozłowski (202–205–5991 or jeff.okun.kozlowicki@usitc.gov) for information specific to this

investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission’s Office of the General Counsel (202–205–3091 or william.gearhart@usitc.gov). The media should contact Margaret O’Laughlin, Office of External Relations (202–205–1819 or margaret.olaughlin@usitc.gov). Hearing-impaired individuals may obtain information on this matter by contacting the Commission’s TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: In their request letter the Committees noted that the Commission is in the process of completing an investigation and report on India’s trade, investment, and industrial policies covering the period 2003 through mid-2014 (Commission investigation No. 332–543, *Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy*). The Committees also noted the recent national elections in India and the formation of a new Bharatiya Janata Party-led government.

As stated in the letter, in light of the new government and the Committees’ interest in receiving the most comprehensive and up-to-date information possible, the Committees asked the Commission to conduct a second investigation concerning any significant changes since the first USITC investigation to India’s industrial policies that discriminate against U.S. trade and investment. As requested by the Committees, the Commission will include in its report for the second investigation:

- Information about any significant changes by the new Indian government to the trade and investment policies identified in the Commission’s first report (which is to be delivered to the Committees by December 15, 2014); and
- Information on any new relevant trade and investment policies and practices in India, focusing on the period from mid-2014. The Committees asked that the Commission deliver its second report by September 24, 2015. The Committees also noted that they intend to make the Commission’s report available to the public and asked that the report not contain any confidential business information.

Public Hearing: A public hearing in connection with this investigation will be held at the U.S. International Trade

Commission Building, 500 E Street SW., Washington, DC, beginning at 9:30 a.m. on April 7, 2015. Requests to appear at the public hearing should be filed with the Secretary, no later than 5:15 p.m., March 24, 2015, in accordance with the requirements in the “Submissions” section below. All pre-hearing briefs and statements should be filed not later than 5:15 p.m., March 26, 2015; and all post-hearing briefs and statements should be filed not later than 5:15 p.m., April 14, 2015. In the event that, as of the close of business on March 24, 2015, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at 202–205–2000 after March 24, 2015, for information concerning whether the hearing will be held.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., June 2, 2015. All written submissions must conform with the provisions of section 201.8 of the *Commission’s Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 and the Commission’s Handbook on Filing Procedures require that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12:00 p.m. eastern time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

The Commission intends to publish summaries of the positions of interested persons in an appendix to its report. Persons wishing to have a summary of their position included in the appendix should include a summary with their written submission. The summary may not exceed 500 words, should be in MSWord format or a format that can be easily converted to MSWord, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. In the appendix the Commission will

identify the name of the organization furnishing the summary, and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found. Any submissions that contain confidential business information (CBI) must also conform with the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties. In its request letter, the Committees stated that they intend to make the Commission's report available to the public, and asked that the Commission not include any confidential business information in the report that it sends to the Committees. Any confidential business information received by the Commission in this investigation and used in preparing this report will not be published in a manner that would reveal the operations of the firm supplying the information.

Issued: October 28, 2014.

By order of the Commission.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2014-25926 Filed 10-30-14; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

[OMB Number 1125-0010]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Notice of Appeal to the Board of Immigration Appeals From a Decision of a DHS Officer

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review (EOIR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the *Federal Register* at

Volume 79, Number 168, page 51607, on August 29, 2014, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until December 1, 2014.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jeff Rosenblum, General Counsel, Executive Office for Immigration Review, U.S. Department of Justice, Suite 2600, 5107 Leesburg Pike, Falls Church, Virginia 20530; telephone: (703) 305-0470. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or send to OIRA_submissions@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and/or
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Notice of Appeal to the Board of Immigration Appeals from a Decision of a DHS Officer—Form EOIR-29.

3. *The agency form number:* Form EOIR-29.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: A party who appeals a decision of a DHS Officer to the Board of Immigration Appeals (Board).

Other: None.

Abstract: A party affected by a decision of a DHS Officer may appeal that decision to the Board, provided that the Board has jurisdiction pursuant to 8 CFR 1003.1(b). The party must complete the Form EOIR-29 and submit it to the DHS office having administrative control over the record of proceeding in order to exercise the regulatory right to appeal.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that there are 6,569 respondents, 6,569 annual responses, and that each response takes 30 minutes to complete.

6. *An estimate of the total public burden (in hours) associated with the collection:* 3,284.5 annual burden hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: October 28, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014-25917 Filed 10-30-14; 8:45 am]

BILLING CODE 4410-30-P

DEPARTMENT OF JUSTICE

Notice of Availability of an Environmental Assessment on a Proposal To Award a Contract for New Low Security Beds to One Private Contractor To House Approximately 2,000 Federal, Low-Security, Adult Male, Non-U.S. Citizen, Criminal Aliens at a Contractor-Owned, Contractor-Operated Correctional Facility Under the CAR 15, Requirement B Initiative

AGENCY: Federal Bureau of Prisons, U.S. Department of Justice.

ACTION: Environmental Assessment.

SUMMARY: The U.S. Department of Justice, Federal Bureau of Prisons (BOP) announces the availability of the Criminal Alien Requirement 15, Requirement B Environmental Assessment (EA) for the proposal to award one contract to house up to 2,000

Appendix C

Calendar of Hearing

Appendix C: Calendar of Hearing

CALENDAR OF PUBLIC HEARING

Those listed below are scheduled to appear as witnesses at the United States International Trade Commission’s hearing:

Subject: Trade and Investment Policies in India, 2014-2015

Inv. No.: 332-550

Dates and Time: May 5, 2015 – 9:30 a.m.

Sessions will be held in connection with this investigation in the Main Hearing Room (room 101), 500 E Street, S.W., Washington, DC.

PANEL 1

ORGANIZATION AND WITNESS:

Center for Strategic & International Studies (“CSIS”)
Washington, DC

Richard Rossow, Senior Fellow and Wadhvani Chair in
U.S.-Policy Studies

International Intellectual Property Alliance (“IIPA”)
Washington, DC

Michael Schlesinger, Of Counsel

National Association of Manufacturers (“NAM”)
Washington, DC

Linda M. Dempsey, Vice President

American Insurance Association (“AIA”)
Washington, DC

Stephen Simchak, Director, International Affairs

TwoFour Insight Group, LLC
McMurray, PA

Vince H. Suneja, Chief Executive Officer

Information Technology and Innovation Foundation (“ITIF”)
Washington, DC

Dr. Robert D. Atkinson, President

PANEL 2

ORGANIZATION AND WITNESS:

U.S. India Business Council (“USIBC”)
Washington, DC

Dr. Mukesh Aghi, President

Alliance for Fair Trade with India (“AFTI”)
Washington, DC

Brian Pomper, Executive Director

Biotechnology Industry Organization (“BIO”)
Washington, DC

Lila Feisee, Vice President, International Affairs

Pharmaceutical Research and Manufacturers of America (“PhRMA”)
Washington, DC

Amiee A. Aloï, Associate Vice President, International

U.S. Chamber of Commerce (“USCC”)
Global Intellectual Property Center
Washington, DC

Patrick Kilbride, Executive Director, International IP

-END-

Appendix D

Written Submissions

Appendix D: Written Submissions

Written Submissions

Interested parties had the opportunity to file written submissions to the Commission in the course of this investigation. Interested parties were asked to provide along with their written submission a summary of the position in written submissions. This appendix contains such written summaries, provided that they meet certain requirements set out in the notice of investigation. The Commission has not edited these summaries. This appendix also contains the names of other interested parties who filed written submissions during investigation but did not provide written summaries. For each written submission, a full copy of each written submission is available in the Commission's Electronic Docket Information System (EDIS).⁵⁶³ The full text of the transcript of the Commission's May 5, 2015, hearing is also available on EDIS.

Alliance for Fair Trade with India

No written summary provided. Please see EDIS for full submission.

American Insurance Association

No written summary provided. Please see EDIS for full submission.

Confederation of Indian Industry

No written summary provided. Please see EDIS for full submission.

Médecins Sans Frontières/Doctors Without Borders

No written summary provided. Please see EDIS for full submission.

Information Technology & Innovation Foundation

No written summary provided. Please see EDIS for full submission.

⁵⁶³ Available online on <http://edis.usitc.gov>.

Intellectual Property Owners Association

No written summary provided. Please see EDIS for full submission.

International Intellectual Property Alliance

No written summary provided. Please see EDIS for full submission.

National Association of Manufacturers

No written summary provided. Please see EDIS for full submission.

National Pork Producers Council

No written summary provided. Please see EDIS for full submission.

Pharmaceutical Research and Manufacturers of America

PhRMA welcomes the opportunity to provide input in support of the important work of the International Trade Commission to examine the progress made by the Indian government to address the trade and investment barriers identified in the Commission's first report. We are encouraged by the ongoing efforts of the U.S. Government to seek high-level engagement with the Modi Government on intellectual property (IP) issues. In particular, the commitment to an ongoing technical work plan as part of the High-Level IP Working Group offers opportunities to secure concrete commitments that demonstrate India's genuine intention of fostering innovation and improving patient access to new medicines. Further, India's draft National IPR Policy recognizes the economic and socio-cultural benefits that a strong IP regime can bring to India through economic growth and a vibrant R&D environment. PhRMA also acknowledges the measured approach taken by the Government in responding to recent requests for compulsory licenses⁵⁶⁴ and the successes some companies have had in enforcing their patents in India at the preliminary injunction stage.

⁵⁶⁴ See Live Mint, "DIPP seeks details on blood cancer drug for issuance of CL," Oct. 19, 2014, available at: http://www.livemint.com/Industry/zC10tFm18dmz4E6pyGyjyM/DIPP-seeks-details-on-blood-cancer-drug-for-issuance-of-CL.html?utm_source=copy (last visited Apr. 23, 2015).

However, despite these potentially positive signs, PhRMA and its member companies remain negatively impacted by India’s failure to respect IP rights. There remains significant unpredictability in IP protection and enforcement in India as new examples of products facing negative IP decisions have emerged and there have been no meaningful policy changes to address the IP challenges faced by innovative companies or in tackling the true barriers to access to medicines:

- States in India continue to be able to grant marketing authorization to generic versions of a medicine four years after the original product was first approved, regardless of the patent status of the original medicine, forcing companies to seek lengthy redress in India’s court system.
- Pharmaceutical patents, which have been granted in dozens of other countries, continue to be revoked in India using “hindsight” analyses made during post-grant oppositions and pre-grant oppositions citing a lack of inventiveness.
- Patent applications for innovative medicines continue to be denied on the impermissible basis that the applicant has failed to demonstrate that their new form of a known substance has “enhanced efficacy” under Section 3(d) of the Indian Patents Act.
- Other examples of India’s inconsistent approach to implementation of a strong IP regime include the lack of protection provided for clinical test and other data that innovative pharmaceutical manufacturers are required to submit during the marketing approval process.

Despite the Indian Government’s desire to attract increased R&D investment, such practices do little to reassure potential investors that the technology and IP they bring to India will be protected.

Notwithstanding our member companies’ best efforts to engage in a productive dialogue with the Indian Government about the critical link between innovation and patient health, the innovative biopharmaceutical industry continues to face significant challenges in the market. In short, more work is needed to improve confidence and reliability in India’s IP environment.

TwoFour Insight Group, LLC

No written summary provided. Please see EDIS for full submission.

U.S.-India Business Council

No written summary provided. Please see EDIS for full submission.

Appendix D: Written Submissions

Appendix E

Laws, Policies, and Practices Timeline

Key Trade and Investment-Related Laws, Policies, and Practices Introduced from May 2014 to August 2015

May 2014

- May 26: Narendra Modi inaugurated prime minister (PM).

August 2014

- August 20: Cabinet approves Digital India initiative.⁵⁶⁵
- August 26: India approves FDI up to 100 percent in railway transportation.⁵⁶⁶
- August 26: Cabinet approves increase in FDI cap in defense industry from 26 percent to 49 percent.⁵⁶⁷

September 2014

- September 25: PM Modi announces Make in India initiative.⁵⁶⁸
- September 30: PM Modi and President Obama issue joint statement at end of visit the United States by PM Modi. The statement notes commitments in several areas, including:
 - To work through the Trade Policy Forum (see November 2014) to promote the development of a business environment that encourages investment and manufacturing in both countries;
 - To establish a high-level intellectual property working group that meets annually as part of the Trade Policy Forum with the goal of promoting innovation that fosters economic growth and job creation;

⁵⁶⁵ Government of India, “Digital India—A Programme to Transform India,” August 20, 2014.

⁵⁶⁶ *Economic Times*, “Cabinet approves raising FDI cap in defence to 49 percent, opens up railways,” August 7, 2014. PRS Legislative Research, “Monthly Policy Review, August 2014,” September 1, 2014.

⁵⁶⁷ *Economic Times*, “Cabinet approves raising FDI cap in defence to 49 percent, opens up railways,” August 7, 2014.

⁵⁶⁸ Government of India, MOCI, “Prime Minister to Launch ‘Make in India,’” September 24, 2014.

- To work to strengthen U.S-India trade and investment relations in the IT industry and the IT-enabled service industry;
- To hold public-private discussions during 2015 on new areas of cooperation, including innovation in advanced manufacturing, harmonization of standards, and other initiatives to facilitate cross-border trade and investment; and
- To conclude a memorandum of understanding between the two countries to promote U.S. investment in Indian clean energy projects.⁵⁶⁹

October 2014

- October 1: Ministry of Communications and Information Technology (MCIT) adds 3 new products to the list of domestically produced products to which the Indian government is expected to give preference in procurement under the Preferential Market Access policy: biometric iris sensors, biometric access control/authentication devices, and biometric fingerprint sensors.⁵⁷⁰
- October 14: USTR begins Special 301 out-of-cycle review of India. Report to take stock of progress on U.S. bilateral engagement with India on intellectual property rights issues.⁵⁷¹
- October 21: Indian government issues Coal Mines (Special Provisions) Ordinance, 2014, allowing online auctions to allocate coal mining blocks and allowing private domestic and foreign companies to bid for mining operations through online auctions.⁵⁷²
- October 29: Cabinet authorizes FDI of up to 100 percent in India's construction development sector.⁵⁷³

November 2014

- November 7: MCIT announces expansion of Compulsory Registration Order (CRO II). CRO II adds 15 information and communications technology (ICT) products to the list of products requiring mandatory registration and testing.⁵⁷⁴

⁵⁶⁹ White House, "U.S.-India Joint Statement," September 30, 2014.

⁵⁷⁰ Government of India, MCIT, "Notification: Policy for Preference," October 1, 2014.

⁵⁷¹ USTR, "USTR Begins Special 301 Report Out-of-Cycle Review," October 14, 2014.

⁵⁷² PRS Legislative Research, "Monthly Policy Review, October 2014," November 3, 2014; *Gazette of India*, "The Coal Mines (Special Provisions) Ordinance," November 3, 2014.

⁵⁷³ Government of India, Cabinet, "Review of Foreign Direct Investment Policy," October 29, 2014.

⁵⁷⁴ Government of India, Ministry of Communications and Information Technology (MCIT), "Notification," November 7, 2014.

- November 7: State of Rajasthan implements labor law changes relating to the Industrial Disputes Act, the Contract Labour Act, and the Factories Act. Among other things, new measures aim to give employers greater flexibility in hiring and firing workers.⁵⁷⁵
- November 18: United States and India release memorandum of understanding (MOU) on clean energy. The MOU between U.S. Export-Import Bank and Indian Renewable Energy Development Agency makes available up to \$1 billion in financing to facilitate U.S. private sector investment in Indian clean energy projects.⁵⁷⁶
- November 24–25: U.S.-India Trade Policy Forum, eighth meeting (New Delhi). The two countries exchanged views on a range of trade and investment issues, in particular concerning agriculture, including sanitary and phytosanitary standards; services and investment; services liberalization in the ICT sector; promoting investment in manufacturing; and intellectual property.⁵⁷⁷

December 2014

- December 3: DIPP announces plans to explore ways to fast-track investment proposals from the United States and to address issues related to bottlenecks faced by U.S. investors in the implementation of their investment proposals.⁵⁷⁸
- December 10: Select Committee issues report on Insurance Laws (Amendment) Bill (introduced in Parliament in 2008). Bill would increase foreign equity cap in Indian insurance companies from 26 percent to 49 percent.⁵⁷⁹
- December 10: Coal Mines (Special Provisions) Bill, 2014, introduced in lower house (see October 21). Passed by lower house on December 12, 2014.
- December 12: USTR concludes Special 301 out-of-cycle review of India and acknowledges India's recent commitments regarding intellectual property.⁵⁸⁰
- December 19: Constitution (122nd Amendment) Bill introduced in Parliament (lower house). Bill would establish a national goods and service tax (GST).⁵⁸¹

⁵⁷⁵ *Business Standard*, "President Okays Rajasthan Labour Reforms," November 8, 2014.

⁵⁷⁶ White House, "U.S. and India Climate and Clean Energy Cooperation," January 25, 2015.

⁵⁷⁷ USTR, "India and United States Joint Statement," November 25, 2014.

⁵⁷⁸ Government of India, "Inter-Ministerial Committee to Fast-track Investment Proposals," December 3, 2014.

⁵⁷⁹ PRS Legislative Research, "Monthly Policy Review, December 2014," January 2, 2015, 5.

⁵⁸⁰ USTR, "Statement by the Office of the U.S. Trade Representative," December 12, 2014.

⁵⁸¹ PRS Legislative Research, "Monthly Policy Review, December 2014," January 2, 2015, 5.

- December 23: Parliament session ends. Bills presented in Parliament but left unpassed by both houses include Insurance Laws (Amendment) Bill (passed in lower house but not taken up by upper house); Coal Mines (Special Provisions) Bill (passed in lower house but not taken up by upper house); and Constitution (122nd Amendment) Bill (was not voted on by either house).⁵⁸²
- December 24: Cabinet approves 100 percent FDI under automatic route for medical device sector.⁵⁸³
- December 24: DIPP posts draft National Intellectual Property Rights Policy for public comment.⁵⁸⁴
- December 26: Ordinance (re-issue of ordinance of October 21, 2014) liberalizes India's coal mining sector, to give effect to the Coal Mines (Special Provisions) Bill. Bill passed in March 2015.
- December 27: Ordinance liberalizes FDI in India's insurance sector, raising the foreign equity cap in Indian insurance companies from 26 percent to 49 percent, to give effect to the Insurance Laws (Amendment) Bill.⁵⁸⁵ Bill passed in March 2015.
- December 31: Ordinance relaxes India's land acquisition laws by amending Land Acquisition Act, 2013, pertaining to land acquisition and fair compensation for certain categories of land use.⁵⁸⁶

January 2015

- January 12: Ordinance opens mining concessions and leases in India to auction and other measures to promote transparency and encourage investment.⁵⁸⁷ Bill passed in March 2015.
- January 13: The United States and India sign framework bilateral investment initiative.
- January 23: United States and India sign joint declaration of intent to advance implementation of Digital India initiative and further bilateral commercial ICT cooperation.⁵⁸⁸

⁵⁸² Ibid., 2.

⁵⁸³ Government of India, Cabinet, "Review of the Policy on Foreign Direct Investment," December 24, 2014.

⁵⁸⁴ PRS Legislative Research, "Monthly Policy Review, December 2014," January 2, 2015, 20.

⁵⁸⁵ Ibid., 5–6.

⁵⁸⁶ Ibid., 2–3.

⁵⁸⁷ PRS Legislative Research, "Monthly Policy Review, January 2015," February 2, 2015, 4.

⁵⁸⁸ White House, "U.S.-India Joint Statement—Shared Effort; Progress," January 25, 2015.

- January 23: United States and India announce an agreement on transfer pricing, under which both parties agree to respect bilateral advance pricing arrangements.⁵⁸⁹
- January 25: United States and India issue joint statement on continued bilateral collaboration with increased opportunities for investment, improved bilateral trade, and stronger investment ties. The two countries agreed to cooperate on India’s efforts to establish a defense industrial base in India through the Make in India initiative.⁵⁹⁰ The two countries also reached an agreement addressing longstanding U.S. concerns about liability of civil nuclear suppliers in India.⁵⁹¹

February 2015

- February 2: Reserve Bank of India formalizes rule allowing 100 percent FDI in medical devices sector.⁵⁹²
- February 24: Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement (Amendment) Bill introduced in Parliament. Bill designed to replace ordinance issued December 31, 2014.⁵⁹³
- February 24: Mines and Minerals (Development and Regulation) Amendment Bill introduced in Parliament. Bill to replace ordinance issued January 12, 2015.⁵⁹⁴
- February 28: Government of India releases 2015–16 Union Budget.⁵⁹⁵

March 2015

- March 12: Parliament passes Insurance Laws (Amendment) Bill, replacing ordinance of December 27, 2014.⁵⁹⁶
- March 20: Parliament passes Coal Mines (Special Provisions) Bill, replacing ordinance of October 21, 2014 (reissued December 26, 2014).⁵⁹⁷

⁵⁸⁹ *Economic Times*, “Obama in India: India and US Finalise Framework,” January 22, 2015. For U.S. rules on the bilateral advanced pricing agreement program, see U.S. Department of the Treasury, Internal Revenue Service, “Acceptance of Pre-filing Conference Requests for U.S.-India Bilateral APAs,” <http://www.irs.gov/Businesses/Corporations/Acceptance-of-Pre-filing-Conference-Requests-for-U-S-India-Bilateral-APAs>.

⁵⁹⁰ White House, “U.S.-India Joint Statement—Shared Effort; Progress for All,” January 25, 2015.

⁵⁹¹ PRS Legislative Research, “Monthly Policy Review, January 2015,” February 2, 2015, 3.

⁵⁹² RBI, “Foreign Direct Investment in Pharmaceuticals Sector—Clarification,” February 2, 2015.

⁵⁹³ PRS Legislative Research, “Monthly Policy Review, February 2015,” March 2, 2015, 7.

⁵⁹⁴ *Ibid.*

⁵⁹⁵ Government of India, Ministry of Finance, “Budget Speech by Hon’ble Finance Minister,” February 28, 2015.

⁵⁹⁶ PRS Legislative Research, “Monthly Policy Review, March 2015,” April 1, 2015, 3.

⁵⁹⁷ *Ibid.*, 5–6.

- March 20: Parliament passes Mines and Minerals (Development and Regulation) Amendment Bill, replacing ordinance issued January 12, 2015.⁵⁹⁸
- March 20: Parliament session ends.
- March 25: India releases a draft model bilateral investment treaty (BIT) for public comments.⁵⁹⁹

April 2015

- April 1: India releases 2015–20 Foreign Trade Policy Statement.⁶⁰⁰
- April 3: Ordinance (reissue of ordinance of December 31, 2014) on land acquisition to give effect to the Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement (Amendment) Bill.⁶⁰¹

May 2015

- May 6: Constitution (122nd Amendment) Bill passed by lower house of parliament. Bill would establish the GST.⁶⁰²
- May 11: The Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement (Second Amendment) Bill, 2015, introduced into Parliament.
- May 12: MCIT releases the National Telecom Machine-to-Machine (M2M) Roadmap (Roadmap). Among other things, the Roadmap provides guidelines proposing certain local-content and localization measures.⁶⁰³

June 2015

- June 3: Department of Pharmaceuticals issues a draft National Medical Device Policy for public comment.⁶⁰⁴

⁵⁹⁸ Ibid., 5.

⁵⁹⁹ Government of India, Ministry of Finance, Department of Economic Affairs, “Indian Model Text of Bilateral Investment Promotion,” n.d. (accessed April 15, 2015).

⁶⁰⁰ Government of India, MOCI, “Foreign Trade Policy, 1 April 2015–31 March, 2020,” April 1, 2015; PRS Legislative Research, “Monthly Policy Review, April 2015,” May 1, 2015, 2.

⁶⁰¹ *Gazette of India*, “The Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement (Amendment) Ordinance, 2015,” April 7, 2015.

⁶⁰² PRS Legislative Research, “Monthly Policy Review, May 2015,” June 1, 2015, 2.

⁶⁰³ Government of India, MCIT, “Roadmap,” May 12, 2015.

⁶⁰⁴ Government of India,, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, “Draft National Medical Policy,” June 3, 2015, 3; PRS Legislative Research, “Monthly Policy Review, June 2015,” July 1, 2015, 6.

- June 17: Finance minister approves formation of two committees to facilitate implementation of the GST by April 1, 2016.⁶⁰⁵
- June 17: Cabinet approves Bureau of Indian Standards (BIS) Bill, 2015, for introduction into Parliament. Among other things, bill would include goods and services under the ambit of the BIS.⁶⁰⁶

July 2015

- July 22: One of the committees constituted in June 2015 submits its report to the upper house of Parliament with recommendations for changes to the GST bill.⁶⁰⁷

August 2015

- August 13: Monsoon session (July 21–August 13, 2015) of Parliament ends. No land acquisition bill or GST bill was passed during this session.⁶⁰⁸
- August 19: India’s Supreme Court upholds a 2014 ruling against the food product approval (PA) process of India’s Food Safety and Standards Authority (FSSAI). As a result, the FSSAI published notices that it would no longer continue the food PA process (August 26) and that it will seek legal assistance to formulate new food PA regulations (August 31).

⁶⁰⁵ PRS Legislative Research, “Monthly Policy Review, June 2015,” July 1, 2015, 2.

⁶⁰⁶ *Ibid.*, 6.

⁶⁰⁷ PRS Legislative Research, “Monthly Policy Review, July 2015,” August 3, 2015, 2.

⁶⁰⁸ PRS Legislative Research, “Monthly Policy Review, August 2015,” September 1, 2015, 2, 5.

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<http://www.dot.gov.in/sites/default/files/u10/National%20Telecom%20M2M%20Roadmap.pdf>.
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Appendix F

Financial Inclusion Initiative

Final Inclusion Initiative

The Modi government’s efforts to bring millions of rural Indians into the formal banking sector through Pradhan Mantri Jan-Dhan Yojana, a financial inclusion initiative, will create substantial changes in the Indian banking industry that may have repercussions for the way foreign banks operate in India. The Modi government has aggressively pushed to expand “financial inclusion”—increasing the availability and affordability of formal financial services—in rural India, setting a goal of 100 million new bank accounts.⁶⁰⁹ To facilitate this, the Reserve Bank of India, India’s central banking institution, approved separate license provisions for microfinance-oriented Indian banks.⁶¹⁰ Other firms have begun to set up the infrastructure required to digitize rural banking in India, seen as a way to expand rural residents’ access to banking services at low costs.⁶¹¹

The Modi government is also altering a number of social policies to increase the likelihood of rural adoption of formal banking services. For instance, in 2015 it was announced that many state benefits, like food assistance and other direct payments, will be deposited into bank accounts associated with debit cards.⁶¹² Furthermore, the central government is offering subsidized interest rates for savings accounts that serve a social function, such as an account opened in the name of a female child.⁶¹³ Such efforts to drastically increase the number of banking customers in India may make the Indian market more appealing to foreign banking and financial service providers, thereby potentially mitigating the effects of some of the barriers identified in *India 2014*.⁶¹⁴

The financial inclusion effort could also increase the growth of private banks in India, thus reducing government involvement. For example, one Indian banker forecasts that private banks will “easily” control “more than 50 percent of the [banking] sector’s assets in ten years’ time,” as opposed to the 25 percent that is privately controlled today.⁶¹⁵ It remains unclear how much foreign banks will benefit from the predicted rise of the private banking sector.

⁶⁰⁹ Flood, “India Is the Jewel,” May 31, 2015.

⁶¹⁰ RBI, “RBI Releases Guidelines for Licensing,” November 27, 2014; Crabtree, “New Lenders to Transform India’s Banking Scene,” May 10, 2015; *Times of India*, “Bandhan Financial Services to Launch Bank,” June 17, 2015.

⁶¹¹ Crabtree, “New Lenders to Transform India’s Banking Scene,” May 10, 2015; *Statesman* (India), “Mobile Banking Goes to Rural India,” June 10, 2015; *Times of India*, “Bandhan Financial Services to Launch Bank,” June 17, 2015.

⁶¹² Jaitley, “Tax Reforms in India,” April 16, 2015.

⁶¹³ *Ibid.*

⁶¹⁴ USITC, *India 2014*, 2014, 217–220.

⁶¹⁵ Crabtree, “New Lenders to Transform India’s Banking Scene,” May 10, 2015.

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Appendix G

Standards and Technical Regulations

This appendix gives additional information about India’s standards and technical regulations. It supplements the information presented in chapter 6.

Overview of India’s Standards and Technical Regulations

India’s standards-setting system can create significant burdens for U.S. exporters. First, U.S. exporters face multiple India-unique mandatory standards and technical requirements. Moreover, they report that they are often excluded from taking a genuine, active role in the Indian process for the development of standards and technical regulations because they are given too little time to review and comment on draft proposals. Finally, they state that once requirements are finalized, they are often given too little time to implement new regulations. The following paragraphs provide an overview of India’s standards and technical regulatory system, highlighting key aspects.

Standards in India are created based on the provisions of the Bureau of Indian Standards (BIS) Act 1986 and the BIS Rule 1987. The BIS is a member of the International Organization for Standardization (ISO) and participates in ISO technical and policy-making committees.⁶¹⁶ BIS creates both voluntary and mandatory standards, many of which, as noted above, are India-unique. Responsibility for formulating technical regulations belongs to the agency in charge of the respective area, as shown in figure G.1. Final regulations are published in the official *Gazette of India*.

The BIS is also the national body for certifying assessments that products conform to Indian standards. Conformity assessment procedures are regulated by the BIS Act 1986, the BIS Rules 1987, and BIS (Certification) Regulations 1988. The central government tells the public via *Gazette* notification which articles or processes should conform to an Indian standard and should bear the BIS certification mark under a license from BIS.⁶¹⁷ According to Indian authorities, the requirements for the use of the BIS certification mark are the same for domestic and imported products.

⁶¹⁶ WTO, Secretariat, *India: Trade Policy Review*, 2015, 59. The BIS is described in more detail below.

⁶¹⁷ This process differs for products covered by a new set of rules stipulating a compulsory registration scheme for 30 electronic and ICT goods (which is discussed in chapter 6), whereas the BIS certification is required for 92 other products. See BIS online information at <http://www.bis.org.in/cert/ProdUnManCert.asp>.

Foreign producers must obtain a license from the BIS to bring into India any products that are subject to mandatory certification.⁶¹⁸ Foreign manufacturers must set up a liaison or branch office in India to obtain a license if the BIS has not signed a memorandum of understanding with the country where the manufactured goods originate.⁶¹⁹ Otherwise, foreign manufacturers may name an authorized representative in India responsible for checking compliance with the provisions of the BIS Act 1986 and its rules and regulations. Licenses are initially valid for one year and can be renewed for one to two years upon application.

Before products are licensed, BIS laboratories and BIS-accredited laboratories test them to ensure that they conform to Indian standards.⁶²⁰ Laboratories seeking accreditation from BIS must comply with the relevant standards of accreditation as well as with specific requirements of the National Accreditation Board for Testing and Calibration Laboratories (NABL).⁶²¹ There are currently no non-Indian laboratories accredited to test and certify products, though Underwriters Laboratories does have a laboratory in India.⁶²²

India's labeling requirements are also considered problematic by many U.S. exporters. The Legal Metrology Act 2009, the Legal Metrology (Packaged Commodities) (Amendment) Rules, 2015, and Food Safety and Standards (Packaging and Labelling) (Amendment) Regulations, 2015 regulate labeling requirements in India.⁶²³ Labeling requirements are described in chapter 6; standards will be discussed further below.

Indian Government Approach to Standards

U.S. industry and government representatives assert that under both the Singh and the Modi governments, Indian regulatory and standards development authorities have used the flexibility offered by two World Trade Organization (WTO) agreements (box G.1) to create numerous India-unique mandatory standards without clear justification.⁶²⁴ Industry representatives contend that the requirement for U.S. exporters to meet these standards is a significant obstacle to trading with the Indian market, and has even kept some U.S. exporters out of the

⁶¹⁸ Procedures for Grant and Operation of BIS License under Foreign Manufacturers Certification Scheme (FMCS), BIS online information, <http://www.bis.org.in/cert/fm.htm>.

⁶¹⁹ WTO, Secretariat, *India: Trade Policy Review*, 2015, 60–61.

⁶²⁰ *Ibid.*, 31.

⁶²¹ *Ibid.*, 61.

⁶²² Information about UL India is available at <http://india.ul.com>.

⁶²³ WTO, Secretariat, *India: Trade Policy Review*, 2015, 62; USDA, FAS, *India: FSSAI Publishes Packaging and Labeling Amendment Regulations*, April 14, 2015.

⁶²⁴ Government official, interview by USITC staff, Washington, DC, May 29, 2015.

Indian market altogether.⁶²⁵ Moreover, they state that there is a lack of transparency on how decisions are being made.⁶²⁶

Box G.1: WTO Commitments on Technical Regulations, Sanitary and Phytosanitary Measures, and Standards

As a member of the WTO, India has committed to complying with the WTO Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). Enshrined within these agreements is a country's right to regulate its own industries, provided it follows key guidelines when doing so.

In addition to individual countries' regulations, several international standardizing bodies also prepare international standards for a wide range of products. If there are products for which a member country has adopted, or expects to adopt, technical regulations, the country is required by the TBT and SPS agreements to fully participate in this preparation, within the limits of its resources. This requirement seeks to ensure that there is as little need as possible for deviation from international standards and that technical regulations across the globe will be harmonized as much as possible.

However, the TBT and SPS agreements also leave a degree of flexibility for WTO member countries. A member country may (1) modify an existing international standard, if the international standards would be ineffective or inappropriate for fulfilling a legitimate national objective; or (2) create a country-unique standard to fulfill a legitimate objective when an international standard does not already exist, providing the member follows certain guidelines. The WTO system therefore offers member countries some leeway in meeting their WTO commitments while adapting to domestic circumstances.

Source: WTO, "Agreement on Technical Barriers to Trade," https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm (accessed July 28, 2015); WTO, "Agreement on the Application of Sanitary and Phytosanitary Measures," https://www.wto.org/english/docs_e/legal_e/15-sps_e.htm (accessed July 28, 2015).

For example, in addition to mandatory testing and customs sampling (including for packaging and labeling) of imported products, India requires pre-market product approvals (PAs).⁶²⁷ According to U.S. government and industry representatives, India's PAs often go beyond international practice in evaluating products' safety and efficacy, and create additional costs, paperwork, and time burden.⁶²⁸ For its part, the Indian government asserts that its technical regulations and mandatory standards play a key role in protecting Indian consumers.⁶²⁹

⁶²⁵ Government official, interview by USITC staff, Washington, DC, May 29, 2015; industry representative, telephone interview by USITC staff, June 16, 2015.

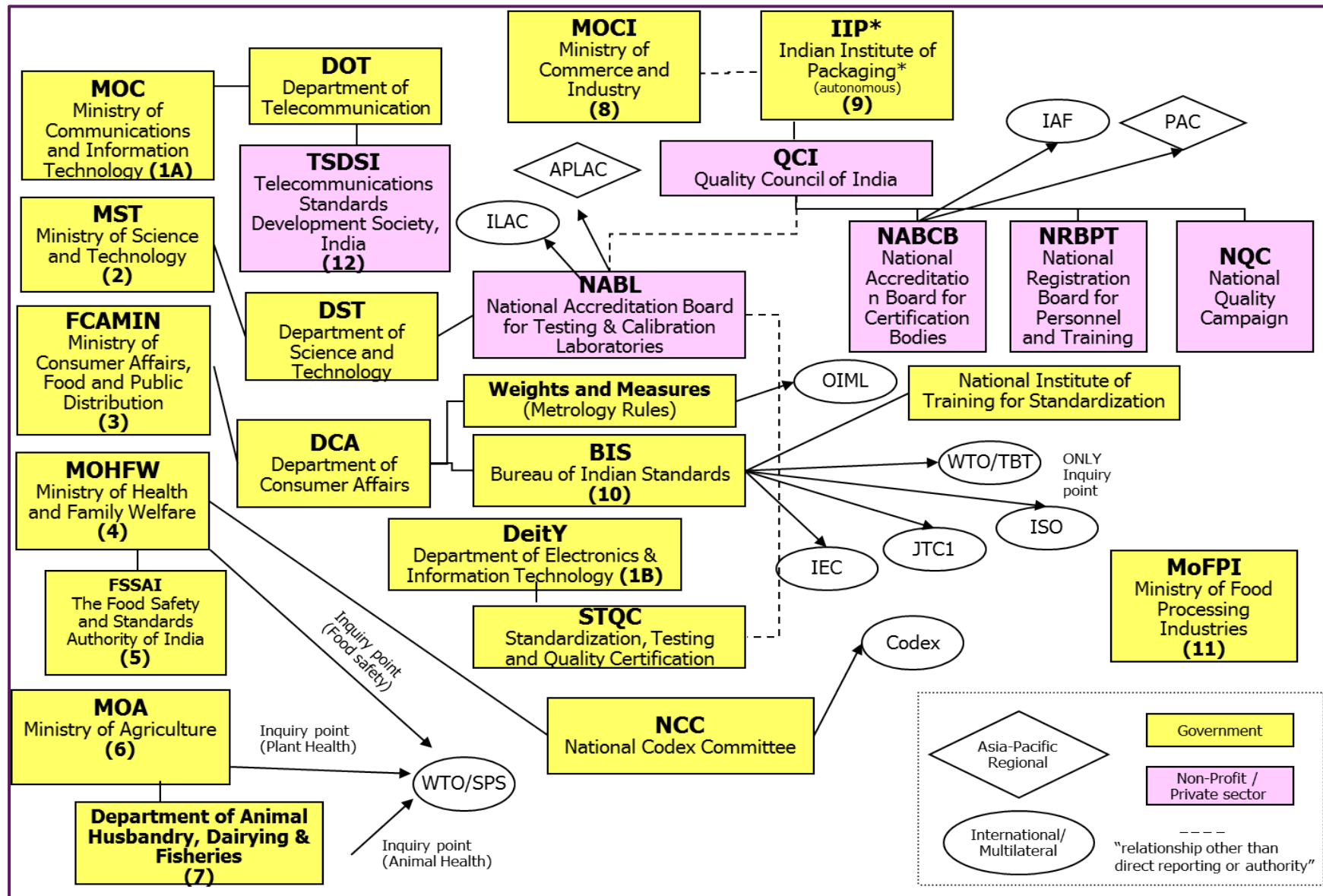
⁶²⁶ Government official, telephone interview by USITC staff, June 11, 2015.

⁶²⁷ In August 2015, the FSSAI published a notice that it would no longer continue the food PA process. Government of India, FSSAI, "F.No.P-15025/SCJ/2015-PA/FSSAI," August 26, 2015.

⁶²⁸ Government officials, telephone interviews by USITC staff, June 1 and June 20, 2015; government official, interview by USITC staff, Washington, DC, May 29, 2015; industry representative, telephone interview by USITC staff, June 16, 2015; government official, telephone interview by USITC staff, July 20, 2015; industry representative, email to USITC staff, July 20 and 21, 2015.

⁶²⁹ FSSAI, "Scheme of Product Approvals," May 11, 2015; government official, interview by USITC staff, Washington, DC, June 9, 2015.

Figure G.1: Regulatory, Standards, and Conformity Assessment Bodies in India



Source: Adapted from material provided by the American National Standards Institute.

1. **The Ministry of Communications and Information Technology (MOC) (1A)** contains three departments: the Department of Technology, the Department of Posts, and the Department of Electronics and Information Technology (DeitY) (1B).⁶³⁰
2. **The Ministry of Science and Technology** is responsible for the formulation of policies relating to science and technology, futurology, and matters concerning domestic technology.
3. **The Ministry of Consumer Affairs, Food, and Public Distribution** oversees two departments: the Department of Consumer Affairs and the Department of Food and Public Distribution. The Department of Consumer Affairs is responsible for internal trade, regulation of packaged commodities, training in legal metrology (weights and measures issues), and the implementation of standards of weights and measures. The ministry also oversees the implementation of the Bureau of Indian Standards Act, 1986.⁶³¹
4. **The Ministry of Health and Family Welfare** oversees two departments: the Department of Health and Family Welfare and the Department of Health Research. This ministry administers the implementation of the Food Safety and Standards Authority of India. It is also one of India’s inquiry points for WTO sanitary and phytosanitary (SPS) matters—food safety in particular.
5. **The Food Safety and Standards Authority of India (FSSAI)** was created under the Food Safety and Standards Act, 2006, to serve as a single reference point for all matters relating to food safety and standards.⁶³² The FSSAI is responsible for framing regulations, mandatory standards, and guidelines, and contributing to the development of international technical standards for food, including SPS measures. It also gives scientific advice and technical support to the central government and state governments in framing food policy, but does not have direct authority over state-level enforcement.
6. **The Ministry of Agriculture** is the apex body for formulating and administering rules, regulations, and laws relating to agriculture in India.⁶³³ The Ministry oversees the Department of Animal Husbandry, Dairying, and Fisheries, described below. It also serves as an inquiry point for WTO SPS matters on plant health.

⁶³⁰ Government of India, DeitY, July 28, 2015, <http://deity.gov.in/>. Due to space constraints in figure G.1, the link of DeitY’s direct reporting authority to the MOC is broken and shown separately, though the relationship remains direct.

⁶³¹ Government of India, Department of Consumer Affairs, “About Us,” June 15, 2015, <http://consumeraffairs.nic.in/forms/contentpage.aspx?lid=37>.

⁶³² Government of India, FSSAI, “Introduction,” 2011.

⁶³³ WTO, Secretariat, *Trade Policy Review: India*, 2015, 99.

7. **The Department of Animal Husbandry, Dairying and Fisheries (DAHDF)** is responsible for matters relating to livestock production, preservation, and protection from disease. It is also responsible for the improvement of stocks and dairy development and all matters pertaining to fishing and fisheries, inland and marine. The department is the inquiry point for WTO SPS matters—specifically, animal health.⁶³⁴
8. **The Ministry of Commerce and Industry** formulates and carries out policies to develop and promote India’s international trade and commerce. The ministry has seven autonomous bodies, including the India Institute of Packaging.⁶³⁵
9. **India Institute of Packaging** is responsible for improving the standards of packaging needed for the promotion of Indian exports. It is also tasked with creating infrastructural facilities for overall packaging improvement in India.
10. **The Bureau of India Standards (BIS)**, created in 1986, is India’s national standards body. The BIS is in charge of the formulation of standards (both voluntary and mandatory), compliance certification, the registration scheme, testing and calibration services, the sale of Indian standards, and international activities. It is also responsible for developing a national strategy for recognizing international standards and integrating them with production and exports in a way that encourages their growth and development.
11. **The Ministry of Food Processing Industries** has two main functions: policy and development. First, it formulates and implements policies for the food processing sector, and works to support the sector’s healthy growth in line with overall national priorities. It also sets up analytical and testing laboratories, actively participates in laying down food standards, and works to harmonize them with international standards.⁶³⁶ Although the ministry is no longer a regulatory body, it remains active in the standards development process and continues to influence food regulations, standards, and processes.⁶³⁷

⁶³⁴ Government of India, DAHDF, “About Us,” 2014, <http://dahd.nic.in/dahd/about-us.aspx>.

⁶³⁵ Government of India, Ministry of Commerce and Industry, “Autonomous Bodies, Commodity Boards,” 2014, http://commerce.nic.in/MOC/commodity_boards.asp.

⁶³⁶ Government of India, Ministry of Food Processing Industries, “Goals and Roles,” June 8, 2015, <http://www.mofpi.nic.in/ContentPage.aspx?KYEwmOL+HGpVlo8u9GICo3ITjUiz7go4/j8IKjJFpxPJf9Sv+Fbzm/7JgUq2xS4wi/O+6DL2h8=>.

⁶³⁷ WTO, Secretariat, *Trade Policy Review: India*, 2015, 99.

12. **The Telecommunications Standards Development Society, India (TSDSI)** is a nonprofit legal entity formed as a public-private partnership.⁶³⁸ The TSDSI is responsible for developing and promoting India-specific telecommunications requirements; standardizing solutions for meeting these requirements (and contributing these to international standards); and contributing to global standardization. The TSDSI also maintains its technical standards and other deliverables, safeguards related intellectual property rights, and helps create manufacturing expertise in India. In addition, it seeks to provide leadership to other developing countries in terms of telecommunications standardization.⁶³⁹

⁶³⁸ Telecommunications Standards Development Society, India, “About Us,” <http://www.tsdsi.org/main/about-us/> (accessed July 15, 2015).

⁶³⁹ Cellular Operators Association of India, “Key Topics,” 2015. <http://www.coai.com/indian-telecom-infocentre/tsdsi>.

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Appendix H

Land Acquisition

Land Acquisition

Many sources report that it is difficult to acquire land for business purposes in India. A variety of U.S. industry representatives doing or planning to do business in India indicate that, in addition to investment laws, India’s existing land acquisition laws and zoning regulations are important impediments to foreign direct investment (FDI) in the country.⁶⁴⁰ Problems acquiring land have led to delays and cancellations of key industrial development projects in India.⁶⁴¹ For example, India’s largest infrastructure project to date, the New Delhi-Mumbai Industrial Corridor, has encountered substantial delays due to land acquisition difficulties.⁶⁴² This industrial corridor, part of the Make in India initiative, is a key element of the Indian government’s plans to improve the country’s economic base and develop globally competitive industries along an area spanning six Indian states (Uttar Pradesh, Haryana, Rajasthan, Madhya Pradesh, Gujarat, and Maharashtra).⁶⁴³ In *India 2014*, some U.S. businesses reported that land acquisition challenges prevented them from setting up their facilities in their preferred locations in India. In the agriculture and food sector, 29.4 percent of responding U.S. companies said they had faced challenges in buying or using land.⁶⁴⁴

The term “land acquisition” in India refers to “the process by which land owned by private persons is compulsorily acquired . . . where the land owner has no choice over parting with the land, and is forced to relinquish his property.”⁶⁴⁵ For nearly 120 years, the basic law governing this process was the colonial-era (1894) Land Acquisition Act, albeit with periodic amendments. Growing clashes between farmers and private companies trying to acquire land for development projects prompted the previous Indian government to offer new legislation

⁶⁴⁰ India’s investment policies are described in chapter 3. USITC, *India 2014*, 2014, 208, 270–1; USITC, hearing transcript, May 5, 2015, 20 (testimony of Richard Rossow, Center for Strategic & International Studies); USITC, hearing transcript, May 5, 2015, 195 (testimony of Mukesh Agha, U.S.-India Business Council); industry representatives, interviews by USITC staff, Bangalore, April 21, 2015; industry representatives, interviews by USITC staff, Mumbai, April 22, 2015; industry and academic representatives, interviews by USITC staff, New Delhi, May 12, 2015; industry representatives, interviews by USITC staff, New Delhi, May 14, 2015; EY, *EY’s Attractiveness Survey: India 2014*, 2014, 49; WTO, *Trade Policy Review: India*, 2015, 8, 14. An OECD report also links trade and investment policy changes in India with the need for institutional changes in India’s labor regulations (“complex and strict labor regulations imply large compliance costs and discourage formal job creation”) as well as problems with education and training, infrastructure bottlenecks, land acquisition, and taxation (“the complexity and uncertainty surrounding the tax system discourage investment”). OECD, *OECD Economic Surveys: India 2014*, 2014, 71–91.

⁶⁴¹ *Economist*, “This Land Is Whose Land?” September 7, 2013; EY, *EY’s Attractiveness Survey: India 2014*, 2014, 49.

⁶⁴² *Business Standard*, “Mumbai-Delhi Industrial Corridor Stuck in Limbo,” August 15, 2013.

⁶⁴³ The Make in India initiative is described in chapter 2.

⁶⁴⁴ USITC, *India 2014*, 2014, 208–210, 226–228, 271.

⁶⁴⁵ PRS Legislative Research, “Legislative Brief,” July 17, 2015, 2. This source goes on to say, “Therefore, the process of acquisition overrides the property rights of the private land owner. This can be justified only if a case can be made for greater public benefit in taking away someone’s land ownership rights.”

repealing the act. The new law, officially titled the Right to Fair Compensation in Land Acquisition, Rehabilitation and Resettlement Act, 2013 (hereafter LARR 2013), entered into force on January 1, 2014.

2013 Changes Take Steps to Improve Land Acquisition

LARR 2013 included many provisions to strike a balance between the interests of landowners and the Indian government's stated goal of making land available for industrialization, infrastructure development, and urban expansion.⁶⁴⁶ Its provisions required:

- prior consent of at least 80 percent of affected landowners before land can be acquired for private projects, and of at least 70 percent of affected landowners for land acquired for public-private partnerships, or PPPs (“consent clause”);
- a social impact assessment to determine if the proposed acquisition would serve a public purpose, calculate the social impact, and see if the land taken would be the “bare minimum” size needed for the project; and
- compensation (“resettlement and rehabilitation awards”) for “affected families” (including tenants and sharecroppers); amendments clarified it includes “laborers” too.⁶⁴⁷

LARR 2013 has been criticized for being too complex and difficult to implement, and for increasing the cost and duration of projects.⁶⁴⁸ According to the government’s Project Monitoring Group, many projects aimed at spurring economic growth have stalled under LARR 2013. The group estimated that over \$390 billion of projects—power plants, factories, and other development projects—were waiting for approval as of March 2015.⁶⁴⁹

Modi Government Proposes New Land Bill in 2015

The Modi government has taken several steps to further change India’s land acquisition legislation. The Ministry of Rural Development held a conference of state-level revenue

⁶⁴⁶ PRS Legislative Research, “Legislative Brief,” July 17, 2015, 2; Roy, “India Cabinet to Extend Land Ordinance Again,” May 30, 2015.

⁶⁴⁷ *Gazette of India*, “Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement Act, 2013,” September 27, 2013.

⁶⁴⁸ *Economist*, “This Land Is Whose Land?” September 7, 2013; Singh, “India’s Controversial Land Acquisition Laws,” March 2015.

⁶⁴⁹ Pradhan, “Gandhi Returns to India to Lead Fight,” April 19, 2015.

ministers in New Delhi on June 27, 2014, to solicit ways to simplify the land acquisition process. On December 29, 2014, the Union Cabinet approved a proposal to promulgate an ordinance⁶⁵⁰ to amend LARR 2013. The ordinance went into effect on January 1, 2015.⁶⁵¹ To make permanent changes to LARR 2013, the Modi government introduced a land acquisition bill—*The Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement (Amendment) Bill, 2015*, or LARR 2015—in the lower house of Parliament on February 24, 2015.⁶⁵²

Objectives and Key Provisions of LARR 2015

LARR 2015 proposes to streamline the land acquisition process for industrial development, particularly in rural areas. According to the Modi government, the bill would make it possible to launch a series of new projects aimed at rejuvenating India’s disintegrating urban infrastructure, constructing sustainable smart cities and industrial corridors, and building superhighways and urban mass transit systems.⁶⁵³ LARR 2015 is also intended to jump-start stalled infrastructure development projects.⁶⁵⁴

LARR 2015 would create five special land use categories: defense and national security, rural infrastructure (including electrification), affordable housing and housing for the poor, industrial corridors, and infrastructure projects (including PPP projects) where the government owns the land. The bill also included certain exemptions; for example, it would exempt projects under these categories from the consent clause, the requirement to conduct a social impact assessment, and restrictions on acquiring irrigated multi-cropped land and other agricultural land.⁶⁵⁵

Legislation Remains in Parliament

The lower house of Parliament, which is controlled by Modi’s BJP, made several changes to LARR 2015 and passed it on March 10, 2015. The changes moderate some of the measures in

⁶⁵⁰ *Gazette of India*, “Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement Act (Amendment) Ordinance, 2014, December 31, 2014. Ordinances are discussed in more detail in chapter 2.

⁶⁵¹ *Ibid.*

⁶⁵² *Ibid.*

⁶⁵³ Rai, “Modi’s Economic Reforms Agenda in India,” April 22, 2015; *Gazette of India*, “Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement Act (Ordinance), 2015,” April 3, 2015.

⁶⁵⁴ Subramanian, “In India, Modi’s Land Acquisition Bill,” April 20, 2015; Singh, “India’s Modi Faces Opposition from Farmers,” March 22, 2015.

⁶⁵⁵ PRS, “The Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement (Amendment) Bill: Amendments,” March 10, 2015.

LARR 2015, but do not significantly alter the key provisions described.⁶⁵⁶ Despite the changes, the bill has not been passed in the upper house of Parliament amid substantial resistance from farmers' unions, civil society groups, and several Indian political parties.⁶⁵⁷

As Parliament was unable to pass LARR 2015, the President of India promulgated a second ordinance on April 3, 2015. The Modi government added the lower house of Parliament's changes to LARR 2015 and reintroduced it on May 11, 2015, as *The Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement (Second Amendment) Bill, 2015* (or Amended LARR 2015). On May 13, 2015, the government agreed to refer the bill to a Joint Parliamentary Committee of both houses to solicit input from stakeholders on the Amended LARR 2015.⁶⁵⁸ The President of India promulgated the ordinance again on May 30, 2015, since the second ordinance was set to expire June 4, 2015.⁶⁵⁹

⁶⁵⁶ NDTV, "9 Amendments, 2 Clauses in the Reworked Land Bill," March 11, 2015; Ghose, "Bill Summary," February 24, 2015; Kala and Mishra, "Legislative Brief," July 17, 2015.

⁶⁵⁷ Subramanian, "In India, Modi's Land Acquisition Bill," April 20, 2015; *Times of India*, "Farmers Denounce Land Acquisition Bill," May 14, 2015; *Indian Express*, "Joint Parliamentary Committee: Land Bill Provisions 'Alarming,'" June 10, 2015.

⁶⁵⁸ NDTV, "First Meeting of Joint Parliamentary Panel," May 29, 2015.

⁶⁵⁹ PRS Legislative Research (PRS). "Land Acquisition (Second Amendment) Bill, 2015," June 1, 2015, 5. Prime Minister Modi announced that the government would not reissue the ordinance in August 2015. Government of India, "English Rendering of PM's 'Mann Ki Baat,'" August 30, 2015.

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