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I. Anti-Corruption Developments

India is witnessing a sea of change in its approach to the issue of corruption. In 2011, a number of high-profile corruption scandals galvanized the anti-corruption movement into action, resulting in wide-spread protest, increased enforcement activity, and legislative proposals in Parliament.[1]

Two major corruption scandals in quick succession, revelations about the Commonwealth Games followed by the 2G spectrum allocation scam, brought to the fore provocative allegations of corruption in the Indian system of governance. Several criminal cases were registered against those accused, including companies and government employees. Ministers were taken into judicial custody and currently await trial. Both stories occupied pivotal space in newspapers and social media for several months.[2]

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* This article reviews legal developments in India during 2011. The committee editors were Hanishi T. Ali, Vice-Chair, ABA Section of International Law India Committee, and Managing Partner at Mithras Law Group (Westborough, Massachusetts) and Ajay Verma, Vice-Chair, ABA Section of International Law India Committee, and Attorney-at-Law/Advocate at Ajay Verma & Associates (New Delhi). Section I was authored by James Parkinson, Partner at Buckley Sandler LLP (Washington, D.C. and Los Angeles) and Priyanka Sharma Partner at Dua Associates (New Delhi); Section II was authored by Fernan Rodriguez, Colombian Attorney and Foreign Legal Consultant and Timothy D. Richards, Managing Partner and Alonso Sanchez, Associate all at The Richards Group (Miami, Florida); Section III was authored by H. Jayesh, Founder Partner at Juris Corp (Mumbai, India) assisted by Supriyo Bose (Sr. Associate), Aditi Manchanda (Associate) and Manali Gogate (Associate); Section IV was authored by Amer Raja, JD Candidate at American University, (Washington, D.C.); Section V was authored by Dipak Rao, Senior Partner and Sandeep Mohanty, Associate at Singhania & Partners LLP (Delhi, India). For developments in India during 2010, *see* Vandana Shroff et al., *India*, 45 INT'L LAW. 521 (2011). For developments in during 2009, *see* James Grandolfo et al., *India*, 44 INT'L LAW. 663 (2010).

1. For other developments in anti-corruption during 2011, *see* Leslie A. Benton et al., *Anti-Corruption*, 46 INT'L LAW. ___ (2012).

2. *Commonwealth Games Scam*, EKAKIZUNJ.COM, http://www.ekakizunj.com/Commonwealth_games_scam (last updated Jan. 19, 2012); *Kalmadi, Two Others Arrested in Commonwealth Games Scam*, BUSINESS STANDARD (Apr. 26, 2011), http://www.business-standard.com/india/news/kalmadi-two-others-arrested-in-commonwealth-games-scam/433564/; *2G Spectrum Scam*, TIMES OF INDIA, http://timesofindia.indiatimes.com/2g-spectrum-scam/specialcoverage/6940688.cms (last updated Feb. 4, 2012); *What is the 2G Spectrum*

The reaction was unprecedented: public displeasure about the level of corruption was alarming, and the government of India responded with a flurry of legislative proposals. The anti-corruption movement, initiated by veteran social activist Anna Hazare, led to widespread protests by citizens across India, forcing the government to constitute a ten-member Joint Committee of Ministers and civil society activists to draft an effective Jan Lokpal (Ombudsman) Bill.[3] The government is considering many other legal reforms.

While anti-corruption legislation has been in place since the pre-Independence era, many have critiqued the existing framework, specifically the Prevention of Corruption Act,[4] as insufficient. Having ratified the United Nations Convention against Corruption in May 2011,[5] and given the current climate, the Indian government is looking to overhaul its anti-corruption framework. Multiple administrative legal reforms are on the anvil. The Delhi (Right of Citizen to Time Bound) Delivery of Services Act, enacted in September 2011, seeks to end corrupt practices by making timely delivery of basic services a statutory right.[6] The government is examining the protection of whistleblowers, eliminating corruption relating to bribery of foreign officials, and creating a strong Lokpal. The purpose of the Jan Lokpal Bill is to create an effective and autonomous anti-corruption agency independent of the government.

The impact of this activity for U.S.-based lawyers and businesses interacting with India is multifaceted. The U.S. Foreign Corrupt Practices Act has long barred the kinds of corrupt practices that are the focus of the current attention.[7] The addition of the U.K. Bribery Act in July 2011 also added an important dynamic to the anti-corruption mix.[8] Many multi-national companies operating in India may find themselves subject to both the U.S. and U.K. anti-corruption legal regimes, in addition to the Indian law.

Companies that have developed strong compliance programs integrating both U.S. and Indian law, and that have properly trained employees and third parties acting on behalf of those companies, should find themselves on sound footing under both the U.S. and Indian legal regimes. But in view of the close attention now being given by Indian and U.S. enforcement authorities, and with the addition of a popular anti-corruption movement involving many India-based non-governmental organizations (NGOs), now is an opportune moment for companies and the lawyers advising them to re-examine their existing compliance programs and to confirm that the conduct of Indian-based operations meets the ever-tightening standards of Indian law as well as the U.S. law.

Scam About?, DECCAN HERALD (Nov. 15, 2011), http://www.deccanherald.com/content/112984/what-2g-spectrum-scam-about.html.

3. *Drafting of Lokpal Bill Requires Legal Expertise*, ANDHRA HEADLINES (Apr. 10, 2011), http://www.andhraheadlines.com/national/drafting-of-lokpal-bill-requires-legal-expertise-3-81900.html.

4. The Prevention of Corruption Act, No. 49 of 1988, INDIA CODE (1988), vol. 4, *available at* http://cbi.nic.in/rt_infoact/pcact.pdf.

5. United Nations Convention against Corruption, G.A. Res. 58/4, U.N. Doc. A/RES/58/4 (Oct. 31, 2003), *available at* http://www.unodc.org/documents/treaties/UNCAC/Publications/Convention/08-50026_E.pdf; *India Ratifies UN Convention Against Corruption*, THE TIMES OF INDIA (May 13, 2011), http://articles.timesofindia.indiatimes.com/2011-05-13/india/29539746_1_convention-fight-corruption-assets.

6. The Delhi (Right of Citizen to Time Bound Delivery of Services) Act, No. 07 of 2011, INDIA CODE (2011), vol. 4, *available at* http://www.delhi.gov.in/wps/wcm/connect/8e0b1a8046929ac58a8fde0956274163/ESLA-ACT.pdf?MOD=AJPERES&lmod=1567745503; *see* Bribery Act, 2010, 59 Eliz. 2, c. 32 (U.K.), *available at* http://www.legislation.gov.uk/ukpga/2010/23/pdfs/ukpga_20100023_en.pdf.

7. Foreign Corrupt Trade Practices Act, 15 U.S.C.A. §§ 78dd-1, dd-2, dd-3 (West 2009).

8. *See* Bribery Act, c. 32.

No one can predict with certainty the ultimate result of the current anti-corruption sentiment and activity in India, and some observers suggest that this is a movement that will pass. But it is clear that there is unprecedented attention being given to fighting corruption on both the supply and demand sides of the equation. Until the final Indian legal regime is settled, and very likely once it is settled, the key to steering clear of corruption-related trouble is to know the risk, develop appropriate compliance controls, train employees and agents, and remain diligent about applying the program.

II. New Treaties Between India and Colombia

A. New Bilateral Investment Treaty Between India and Colombia

On June 12, 2011, India and Colombia entered into a bilateral investment protection treaty (the India-Colombia BIT) to encourage foreign investment by nationals of the contracting parties.[9] The India-Colombia BIT provides protection to investors of a contracting party against arbitrary or confiscatory government measures. The protections are enforceable by independent international arbitration. The India-Colombia BIT is typical of most investment treaties in its framework and substantive protections. The following are the salient provisions of the India-Colombia BIT:

- Fair and Equitable Treatment: the India-Colombia BIT affords a foreign investor protection against arbitrary and unfair or inequitable treatment by the government under standards of international law.[10]
- Non Discrimination: the India-Colombia BIT assures national treatment and most favored nation status to investors of each state.[11] This means that foreign investors cannot be treated less favorably than investors from the host country or from a third party country.
- Anti-Expropriation: the India-Colombia BIT guarantees that government expropriation of investments, including actions tantamount to expropriation, are prohibited except under due process of law and accompanied by full compensation.[12]
- Dispute Settlement: under the India-Colombia BIT a state must submit a foreign investor's claim of a treaty violation to arbitration.[13] The arbitration must be conducted by an independent ad hoc tribunal and the tribunal's award will be binding.[14]

1. *Covered Investors and Investments under the India-Colombia BIT*

Perhaps the most significant provisions within the India-Colombia BIT are those related to the definitions of the terms "investor" and "investments." Read together, these definitions delimit which parties may benefit from treaty protection.

9. Acuerdo para la Promoción y Protección de Inversiones [Agreement for the Promotion and Protection of Investments], L. 1449/2011, junio 14, 2011, Diario Oficial [D.O.] No. 48.100 (Colom.).
10. *See id.* art. 3(4)
11. *See id.* art. 4.
12. *Id.* art. 6.
13. *Id.* art. 9.
14. *Id.*

2. *Investment*

The India-Colombia BIT defines investments to mean: "every type of asset that has been established or acquired by investors of a contracting party in the territory of the other contracting party . . . ."[15] Similar to many investment agreements, the India-Colombia BIT subsequently provides a non-exclusive list of permitted investments, and specifically states that the minimum characteristics of an investment under the treaty must include: (i) the commitment of capital or other resources, (ii) the expectation of gain or profit, and (iii) the assumption of risk for the investor.[16] Hence, an investment, for purposes of the India-Colombia BIT, includes a broad spectrum of current and future potential arrangements within each member country.

3. *Investor*

The India-Colombia BIT defines "investor" as "any physical or natural person or an entity of one of the Contracting parties that has made investments in the territory of the other Contracting party in accordance with its national legislation."[17] The India-Colombia BIT further defines the terms "natural persons" to mean individuals who are nationals of either Colombia or India and "entities" as organizations incorporated or constituted under the laws of such state and that carry out substantial business within that state.[18]

The India-Colombia BIT is representative of various Latin American investment treaties in that it requires corporate investors to carry out substantial business in the relevant state. This provision is included to prevent treaty shopping, i.e., when individuals from third party jurisdictions create a new company, or shell company, simply to benefit from the provisions of a particular investment treaty. Importantly, the India-Colombia BIT does not expressly include within its definition of "investor" treaty protection for investments made by nationals of a contracting state through intermediary corporations located in third-party jurisdictions. It would have been preferable to have seen this language incorporated into the India-Colombia BIT and not leave it open to argument of whether indirectly controlled investments are covered by the treaty protection.

B. New Tax Treaty Signed Between India and Colombia

On May 13, 2011, India and Colombia signed a Double Taxation Avoidance Agreement (DTAA).[19] The DTAA is a comprehensive tax treaty designed to prevent double taxation of income earned in one country by a resident of the other country. The DTAA will also include provisions for the exchange of information for tax purposes.

The DTAA has yet to be ratified by the contracting parties and entered into force. But if ratified, the DTAA will set maximum rates for withholding taxes imposed on dividends, interest, and royalties. While dividends, interest, and royalties will be subject to tax in

15. *Id.* art. 1(2).
16. *Id.* art. 1(2.3).
17. *Id.* art. 1(1.1).
18. *Id.* art. 1(1.1)(a)-(b).
19. Ministry of Finance, *India Signs DTAA with Republic of Colombia for Avoidance of Double Taxation and for Prevention of Fiscal Evasion with Respect to Taxes on Income*, PRESS INFO. BUREAU, GOV'T OF INDIA (May 13, 2011), http://pib.nic.in/newsite/erelease.aspx?relid=72125 (press e-release by the Ministry of Finance).

both India and Colombia, the maximum withholding tax will not exceed five percent in the case of dividends and ten percent in the case of interest and royalties.[20] The DTAA provides that business profits from a permanent establishment will be taxable in the source State. Furthermore, profits derived from construction, assembly, or installation projects lasting at least six months will be taxed in the source state. Capital gains from the sale of shares will be taxable in the country of source. Finally, the DTAA incorporates a limitation on benefits provisions, in order to prevent tax treaty abuse and treaty shopping, as well as comprehensive measures for the exchange of information and assistance in tax collection between tax authorities of the two countries.

III. Capital Markets Developments

India boasts of one of the oldest capital markets in Asia, and is home to its first stock exchange. This section focuses primarily on two key developments in the equity and debt capital markets in India during 2011.

A. Equity Capital Markets: New Takeover Code

After considerable deliberations with market participants, the Securities and Exchange Board of India (SEBI) issued regulations to govern substantial acquisitions of shares and takeovers.[21] The "New Takeover Code" replaces the 1997 Takeover Code and makes the following key changes:

i) increases the trigger point for open offers to twenty-five percent of the voting rights in the target company (fifteen percent under the Old Takeover Code);[22]
ii) increases the minimum offer size to twenty-six percent (twenty percent earlier) of the total shares of the target company;[23]
iii) introduces the concept of "voluntary open offer;" and
iv) extends disclosures to be made by promoters in relation to "pledges" over their holding, to all types of "encumbrances."

Significant revisions have been made regarding timelines to complete an acquisition, as well as an open offer price. The provision of paying a higher price for the promoter shares in the form of non-compete fees has not found a place in the New Takeover Code.

In relation to public offerings, SEBI has recently taken steps to simplify the process, including reducing the time from opening of the issue to subscription to actual listing. The New Takeover Code has also resulted in certain consequential amendments to the SEBI (Issue of Capital and Disclosure Requirements) Regulations, 2009.

20. *Id.*

21. Securities and Exchange Board of India (Substantial Acquisition of Shares and Takeovers) Regulations, 2011, Gazette of India, section III(4) (Sept. 23, 2011), *available at* http://www.sebi.gov.in/cms/sebi_data/attachdocs/1316778211380.pdf.

22. *Id.* ch. 2(3)(1).

23. *Id.* ch. 2(7).

B. Debt Capital Markets

The debt capital market in the past few years has witnessed rapid strides in financial innovation through launch of structured notes. In the Indian market these are issued as debentures or bonds, returns linked to equity, equity indices, commodities, and commodity indices. Although structured products have been around in the Indian market for some time, there was no formal recognition of them. This has now been achieved with the introduction of "Guidelines for Issue and Listing of Structured Products/Market Linked Debentures."[24] The Guidelines have (i) brought some certainty to issuance of even non-principal protected structures, (ii) crystallized on whom lies the onus of suitability and appropriateness, and (iii) clarified SEBI's stance on what the regulator views as a minimum 'acceptable' level of disclosure.

The Guidelines embody SEBI's thinking on hybrid securities that combine features of plain vanilla debt and exchange-traded derivatives that were being issued through private placements and being listed on stock exchanges. The Guidelines prescribe additional compliances and disclosure requirements to be met with by issuers of such structured products, in addition to those mandated under the SEBI (Issue and Listing of Debt Securities) Regulations, 2008.

The Guidelines set out minimum net worth requirements for issuers of such structured products and require additional disclosures regarding credit risk and model risk in relation to the structured notes. Further, there is a minimum ticket size of INR one million.[25] Issuers must set out a scenario analysis in their offering document that represents the value of the debt securities under rising, stable, and falling market conditions. Another key requirement placed on the issuer is to appoint a "valuation agent" that will provide valuations of the structured products at least once a calendar week. Although the objective is laudable, the risk is that investors will misconstrue the valuation to be a price at which they may sell the market-linked debentures. Realistically, although the product may be listed, there is virtually no secondary market for such products.

Following the sub-prime crisis, after a lull in the market, the market for market-linked debentures is on the rise. The products in this space include index-linked products with a few stock-linked and commodity-linked (primarily gold) products. Non-principal protected market-linked debentures still form a small portion of the market, which comprises some very sophisticated players, and it is a matter of time before certain innovative structures are offered to select investors.

C. Other Updates

As a result of the inter-agency spat between SEBI and the Insurance Regulatory and Development Authority (IRDA) over the issue of regulation of Unit-Linked Insurance Policies, the Financial Stability Development Council (FSDC) was incorporated in December 2010 "to institutionalise and strengthen the mechanism for maintaining financial

24. Circular from Maninder Cheema, Deputy Gen. Manager of the Sec. & Exch. Bd. of India to All Registered Merchant Bankers, All Recognized Stock Exchanges, and All Registered Credit Rating Agencies (Sept. 28, 2011), *available at* http://www.sebi.gov.in/cms/sebi_data/attachdocs/1317205112545.pdf (regarding Guidelines for Issue and Listing of Structured Products/ Market Linked Debentures).

25. *Id.*

stability, financial sector development and inter-regulatory coordination."[26] The FSDC is chaired by the Union Minister of Finance and the members include RBI, IRDA, SEBI, and the Pension Fund Regulatory and Development Authority, with the RBI Governor as the ex-officio deputy chairman.[27]

A key part of the Competition Act (2002), empowering the Competition Commission of India to scrutinize and approve or reject acquisitions, mergers, or amalgamations involving Indian entities or impacting India, finally came into effect as of June 1, 2011.[28]

To facilitate the development of the bond market, the RBI issued directions to allow eligible participants to undertake repurchase trades (Repos) on corporate bonds (before this, Repos were permitted only in government securities). Key stipulations are that the bonds should be rated at least 'AA' and held in the dematerialized account of the seller of the securities. Eligible participants consist of banks, financial institutions, mutual funds, and primary dealers.[29]

In a far-reaching move, the Indian government finally allowed foreign investors to invest in the Indian capital market by investing through Indian mutual funds. This is subject to the stipulations contained in the norms that were notified in August.[30]

In sum, the year 2011 witnessed substantial regulatory activity in capital markets in India. Although enhanced disclosure norms should bring more transparency in transactions, one can also expect further amendments in the securities law regime to address the concerns of a complex and innovative securities market.

IV. Pharmaceutical Rights and Compulsory Licensing in India

In 2011, generic drug makers in India leaped towards securing greater access to patented medicines in the Indian market. Two industry leaders, NATCO and Cipla, decided to take on large pharmaceutical companies such as Bayer and Pfizer in an attempt to produce patented medicines at lower costs.[31] Although they initially petitioned these companies for voluntary licenses, NATCO and Cipla subsequently embarked on the first compulsory licensing proceedings in India since the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement).[32] NATCO's

26. *Budget Announcements Pertaining to Capital Markets Division*, GOV'T OF INDIA: DEP'T OF ECON. AFFAIRS, http://finmin.nic.in/the_ministry/dept_eco_affairs/capital_market_div/Budget%20Announcements.asp (last visited Feb. 11, 2012).

27. *RBI Chief to Head FSDC Sub-Panel*, THE HINDU (Oct. 13, 2010), http://www.thehindu.com/business/Industry/article827186.ece.

28. Ministry of Corporate Affairs Notification, 2011, Gazette of India, section II(3) subsection ii (Mar. 4, 2011), *available at* http://www.sebi.gov.in/cms/sebi_data/attachdocs/1316778211380.pdf.

29. Notification from H.R. Kahn, Exec. Dir. of the Reserve Bank of India to All Market Participants (Jan. 8, 2010), *available at* www.rbi.org.in; http://www.rbi.org.in/scripts/NotificationUser.aspx?Id=5456&Mode=0#A.

30. Circular from Asha Shetty, Deputy Gen. Manager of the Sec. & Exch. Bd. of India to All SEBI Registered Mutual Funds/Approved Asset Management Companies (AMCs)/Depository Participants/Custodians (Aug. 9, 2011), *available at* http://www.sebi.gov.in/cms/sebi_data/attachdocs/1312859496065.pdf (regarding Investment by Foreign Investors in Mutual Fund Schemes).

31. Khomba Singh, *Natco Pharma Files India's First Compulsory License Plea*, THE ECONOMIC TIMES (Aug. 2, 2011), http://articles.economictimes.indiatimes.com/2011-08-02/news/29842834_1_compulsory-licence-sorafenib-tosylate-natco-pharma.

32. *See id.*

challenge, in particular, was a "test case" for India's compulsory licensing law and may indicate a larger trend towards generic companies asserting a stronger role in the Indian pharmaceutical market.[33]

A compulsory license is a grant of right by the government to a generic manufacturer to produce and sell a patented drug.[34] The Indian compulsory licensing provision has been deeply ingrained in the Indian Patents Act and reflects the pre-TRIPS regime in which public policies were more favorable to generic drug retailers.[35] Compulsory licensing provisions are included in the Indian Patents Act in sections 84, 86, 89, 92 and 93.[36] These provisions have remained largely unchanged throughout the years and outline both the substantive and procedural requirements in obtaining a compulsory license.[37]

In academic circles, the Indian compulsory licensing provision has often been characterized as a "safety valve" and as a tool to "bridge the gap" between individual health needs and patent owner rights.[38] But there is an "inherent tension" between the rights of patent owners (who claim the need for incentives for innovation) and patients (who claim access to necessary medications).[39]

The Indian compulsory licensing provisions are also largely in line with international obligations in many regards. The TRIPS agreement, signed during the Paraguay Round of World Trade Organization negotiations, also includes an article discussing compulsory licensing provisions.[40] Under Article 31 of the TRIPS agreement, countries may grant a right to manufacture and sell a patented product if certain requirements are met.[41] The requirements are: (1) the petition must be considered on its individual merits, (2) a petition for a voluntary license must be sought within a reasonable period of time and be unsuccessful, (3) the scope must be limited with regards to time and purpose, (4) the supply must be for the domestic market, and (5) the right holder must receive adequate remuneration.[42] The TRIPS agreement, however, does not refer to Article 31 as a compulsory licensing provision, but rather as "use without the authorization of the patent holder."[43]

Similar requirements arise under the Indian Patents Act. Under section 84 of the Indian Patents Act, a compulsory license may only be granted if: (1) there is authorization

33. *See id.*

34. Jamie Feldman, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT'L BUS. L. 137, 139 (2009).

35. Sarah Beth Myers, *A Healthy Solution for Patients and Patents: How India's Legal Victory Against a Pharmaceutical Giant Reconciles Human Rights With Intellectual Property Rights*, 10 VAND. J. ENT. & TECH. L. 763, 766 (2007-2008).

36. Radhika Bhattacharya, *Are Developing Countries Going Too Far on TRIPS? A Closer Look at the New Laws in India*, 34 AM. J.L. & MED. 395, 408 (2008).

37. *Id.* at 408, 414, 418.

38. *See id.* at 398.

39. *See, e.g.*, Katharine W. Sands, *Prescription Drugs: India Values Their Compulsory Licensing Provision—Should the United States Follow in India's Footsteps?*, 29 HOUS. J. INT'L L. 191, 194–95 (2006); *see also* Feldman, *supra* note 34, at 140.

40. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter Agreement].

41. *Id.* art. 31.

42. *Id.*

43. *Id.* art. 70.

on the individual merits, (2) the license is granted under reasonable commercial terms, (3) at least three years must elapse from the grant of the patent, and (4) the public need is not being adequately met due to cost or availability constraints.[44] India's apparent compliance with TRIPS provisions will likely make it a difficult for a foreign pharmaceutical company to petition a state to file for a World Trade Organization (WTO) dispute settlement procedure. The procedural requirements outlined in TRIPS and the Patents Act also seem analogous on many grounds; however, the implementation of such provisions by the Controller may call into question the interpretation of the compulsory licensing exceptions.

In 2011, Indian drug manufacturers incorporated an active approach to securing low-cost patented medicines that are purportedly being inadequately produced and distributed.[45] NATCO, a Hyderabad based generic drug producer, is leading the charge in attempting to obtain a compulsory license.[46] The application for a compulsory license was characterized as a test case particularly because of the high stakes involved for both patients and patent holders.[47] To maximize its potential for winning the compulsory licensing bid, NATCO has alleged a number of facts in its application. NATCO asserts that Bayer's drug *sorafenib tosylate* (Nexavar),[48] has not been made available to the Indian public since its patent grant in 2008.[49] Nexavar is a cancer drug used to treat Hepatic Cell Carcinoma (HCC) and Renal Cell Carcinoma (RCC).[50] The application alleges that in 2008, there were 20,144 reported cases of HCC and 8,900 cases of RCC; of those, an estimated 18,043 HCC patients and 5,733 RCC patients died.[51] NATCO further claims that ninety-nine percent of HCC and RCC patients do not receive Nexavar because of the probative costs and restricted availability (only in metropolitan hospitals).[52] The estimated cost for a HCC or RCC patient is Rs. 280,000, which translates to roughly US $5,800.[53] Because Indians pay for pharmaceuticals themselves and not under complex insurance regimes, only a select few can afford Nexavar.[54] Therefore, NATCO also alleges that the "practice adopted by the Patentee of exorbitantly pricing its patented life-saving product is abuse of its monopolistic rights."[55]

In addition to filing the application, NATCO has tried to ensure that all the procedural requirements under the Patents Act and TRIPS agreement are satisfied. NATCO petitioned for a voluntary license in December 2010, which was subsequently rejected by Bayer without justification. NATCO also waited three years after the Indian government

44. The Patents Act, No. 39 of 1970, INDIA CODE (1970), *available at* http://www.wipo.int/wipolex/en/text.jsp?file_id=128092.

45. *See generally Cipla in the News*, CIPLA (Feb. 10, 2012), *available at* http://www.cipla.com/whatsnew/news.htm.

46. Singh, *supra* note 31.

47. *See id.*

48. *Publication U/S. 87(1): The Compulsory License Application No. C.L.A. No. 1 of 2011 from M/S. Natco Pharma Ltd. in Patent No. 215718*, 32 OFFICIAL J. OF THE PATENT OFFICE 13344 (2011), *available at* https://docs.google.com/viewer?a=v&pid=sites&srcid=ZGVmYXVsdGRvbWFpbnxzcGljeWlwZmlsZXN8Z3g6NDFlNjAxZDIyOTY0MjMyMg [hereinafter NATCO Compulsory License Application].

49. *See id.* at 13354.

50. *Id.* at 13351.

51. *Id.* at 13347–48.

52. *Id.* at 13352.

53. *Id.* at 13346.

54. *See id.* at 13354.

55. *Id.* at 13361; *see generally* Singh, *supra* note 31.

originally granted the patent to Bayer in 2008 before filing its application.[56] Furthermore, NATCO has included as part of its application its willingness to: provide Nexavar for Rs. 8,800,[57] limit territory of manufacture and sale to India, provide the generic medication to only HCC and RCC patients, pay a royalty as determined by the Controller, and offer the drug free of cost to the needy.[58] NATCO may well obtain India's first compulsory license. The only adverse factor before the Controller in the NATCO compulsory license request has been the civil suit filed by Bayer for infringement.[59] But NATCO indicates as part of the application that the compulsory license claim was filed without prejudice to its "rights, contentions, and liberties."[60]

NATCO's decision to seek compulsory licensing in India is, therefore, indicative of the overall trend in India towards limiting the exclusivity of patent rights when significant health concerns arise. Since the compulsory license application in August, 2011, NATCO has been joined by Cipla in considering additional compulsory license filings.[61] The outcomes of these three compulsory license filings, however, remain largely a mystery in spite of most of the statutory requirements being satisfied. Patent right owners do require substantial protection in developing markets, primarily because of the threat to monopoly rights and recuperation of expenditures in research and development. While these contentions may be accurate, the NATCO approach seeks to limit the monopolistic rights in developing countries like India, primarily because it views the present regime as abusive. On a practical level, compulsory licensing provisions should never need to be employed as private agreements, and ordering can provide a means through which large pharmaceuticals and generics can adequately serve the market while still recuperating costs. But because no such agreement was made possible or even discussed, if NATCO's bid is successful, it will lead to many more claims in the future. Looking ahead, 2012 should prove to be a challenging year for pharmaceuticals in India because these first three claims will likely open the floodgates of compulsory licensing applications.

V. Prevention Of Money Laundering Act

Money laundering poses a threat to the integrity and the financial system of a country. India made efforts in 2011 to combat money laundering by enforcing the 2003 Prevention of Money Laundering Act (PLMA), a statute that came into force in 2005. Section 3 of the PLMA defines the offence of money laundering as "[w]hosoever directly or indirectly attempts to indulge or knowingly is a party or is actually involved in any process or activity connected with the proceeds of crime and projecting it as untainted property shall be guilty of [the] offence of money laundering."[62]

In 2011 one enforcement case was registered by the Enforcement Directorate against the chairman of Satyam, Ramalinga Raju. He was accused of diverting funds of Satyam

56. NATCO Compulsory License Application, *supra* note 48, at 13354.
57. *Id.* at 13357.
58. *Id.* at 13361–62.
59. *See id.* at 13362.
60. *Id.*
61. *See generally id.*
62. The Prevention of Money-Laundering Act, No. 15 of 2003, INDIA CODE (2002), section 3, *available at* http://fiuindia.gov.in/pmla-section3.htm.

for the purposes of purchasing nearly fifty plots in Medchal and Qutbullahpur, near Hyderabad. An order for attachment of his properties was passed by the Deputy Director of Enforcement. On March 4, 2011, the High Court upheld the judgment of the lower court. The Supreme Court, however, granted bail on November 4, 2011.[63]

By enacting the PMLA, India has shown its resolve against money laundering, but compared to other countries much more needs to be done.[64] The list of statutes under which money laundering as an offense can be invoked (as provided for in the schedules to the Act)[65] is rather restricted. Surprisingly, it still does not cover offenses under the Income Tax Act and the Central Excise Act, which leaves certain offenses, such as tax evasion, outside the purview of money laundering. A new money laundering bill has been proposed to address some of the lacunae.

63. *Bail for Ramalinga Raju, Brother and Another*, THE HINDU (Nov. 4, 2011), http://www.thehindu.com/news/national/article2597752.ece.

64. For other developments in anti-money laundering during 2011, *see* Mikhail Reider-Gordon et al., *Anti-Money Laundering*, 46 INT'L LAW. ___ (2012).

65. The Prevention of Money-Laundering Act, *supra* note 62.