Selected Essays in Pharmaceutical Industry

A Cyril Amarchand Mangaldas Thought Leadership Initiative
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We are pleased to present before you this select compilation of essays on the Pharmaceutical Industry.

With over 10,500 manufacturing units and over 3,000 pharmaceutical companies, the pharmaceutical industry in India is bustling with activity and has gone a long way in making India’s presence felt as a significant player in the world markets. Over the years, the pharmaceutical industry in India has grown manifold by following both organic and inorganic growth strategies. Projections indicate that pharmaceutical exports from India are likely to reach USD 27 billion by 2016-17. With the “Make in India” initiative of the Government of India to promote indigenous manufacturing units, the pharmaceutical industry is gaining momentum in an effort to consolidate its existing position and record unprecedented growth.

The pharmaceutical industry also happens to be one of the closely followed industries of the economy owing to the nature of business undertaken by it and the effect it has on the lives of the general public. The element of general public health and interest attached to the pharmaceutical industry subjects it to intensive public scrutiny and a plethora of rules and regulations, some of which plague the industry with an element of uncertainty. However, as the pharmaceutical industry attracts a large amount of domestic and foreign investments and has reaped immense returns for India in the past, the Government and the Indian judiciary have taken active efforts to balance public health concerns with the commercial realities of the industry. Additionally, adoption of international standards by India in the pharmaceutical space has also helped in instilling investor confidence in the industry.

We have compiled a few selected essays pertaining to the pharmaceutical industry and the allied medical devices sector with a view to provide an understanding, from a
regulatory perspective of the industry and the various nuances related to it. We have started by giving a broad overview of the industry and have encapsulated the extant legislative and regulatory framework governing the industry. We have thereafter sought to provide an insight into the policy perspective which enshrouds foreign investment in the pharmaceutical industry. We have also discussed the intellectual property laws which apply to the pharmaceuticals industry which on the one hand permit pharmaceutical companies to protect their intellectual capital and reap economic benefits from their inventions and innovations and on the other permit compulsory licensing with a view to address public welfare needs. In this context we have also included an analysis of the Supreme Court’s decision in the *Glivec case*. This compilation also includes an essay on clinical trials, which, ironically for an industry which thrives on research and innovation, has been a subject of numerous oppositions and controversies. While the pharmaceutical industry has assumed the centre stage of attention in the healthcare space – at least from a regulatory perspective, the medical devices sector of India is also a fast growing industry, albeit its nascent stage of evolution, deserving of specific and relevant laws and regulations – from that perspective, we have endeavoured to provide a brief insight into the legislative framework that governs the medical devices sector in India. An essay on competition laws that have a bearing on the industry and its activities is also part of this compilation. As domestic legislations play an integral part in running the activities of any industry, we have also attempted to provide the reader with a flavour of the labour legislations in India which would typically apply to this industry.

This is a small tribute from our firm to the Pharmaceutical Industry in India as part of our Thought Leadership series. Wish you a happy read!

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Contents

The Legislative & Regulatory Framework – An Overview 07
FDI in the Pharmaceutical Industry – A Policy Perspective 13
Competition Law Issues in the Pharmaceutical Industry 23
Clinical Trials – Changing Regulatory Framework 29
Medical Devices in India 47
The Indian Pharmaceutical Industry and Patents 53
The Glivec Judgement – A case against Patent Ever-Greening 67
The Indian Pharmaceutical Industry – Labour & Employment Issues 75

*Disclaimer: These articles are not intended to serve as legal advice and the position of law expressed in these articles are only valid as on the date of publication of such article.*
## The Legislative & Regulatory Framework – An Overview

### Snapshot of Sector Specific Governing Laws

<table>
<thead>
<tr>
<th>Core Sector Legislations (Manufacturing, Sales, Marketing, Import, Export)</th>
<th>Price Control Legislations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Intellectual Property Laws

### Guidance Documents/ Self-Regulatory Codes

### Governing Laws

## I. Core Industry Legislations

<table>
<thead>
<tr>
<th></th>
<th>Core Industry Legislations</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Drugs and Cosmetics Act, 1940&lt;br&gt;Drugs and Cosmetics Rules, 1945</td>
<td>Regulates approval, manufacturing, import, distribution, and sale of drugs, medical devices and cosmetics.</td>
</tr>
<tr>
<td>2.</td>
<td>Narcotic Drugs and Psychotropic Substances Act, 1985</td>
<td>Regulates production, manufacture, cultivation, possession, sale, purchase, transport, storage and consumption of any narcotic drug or psychotropic substances identified under the Act.</td>
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<td></td>
<td>Act/Order/Regulation</td>
<td>Description</td>
</tr>
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<td>--------------------------------------------------------------</td>
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</tr>
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<td>4</td>
<td>Pharmacy Act, 1948</td>
<td>Regulates pharmacy education, profession and practice of pharmacy in India.</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>II. Price Control Legislations/Regulations</strong></td>
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<tr>
<td>1.</td>
<td>Essential Commodities Act, 1955</td>
<td>Regulates the delivery of commodities or products such as foodstuff, drugs, fuel (petroleum products) etc. Establishes control measures that check obstructionist activities such as hoarding or black-marketing.</td>
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<td>2.</td>
<td>National List of Essential Medicines of India (NLEM)</td>
<td>Published by the Ministry of Health and Family Welfare. The primary purpose of NLEM is to promote rational use of medicines considering three important aspects, i.e., cost, safety and efficacy. Furthermore, it promotes prescription by generic names. Published as a list of about 350 medicines (revised from time to time) that are deemed essential and are required to be made available at affordable prices. Contains data from the Indian Pharmacopoeia and National Formulary of India.</td>
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<tr>
<td>3.</td>
<td>Drugs Price Control Order, 2013</td>
<td>Regulates prices of controlled bulk drugs and formulations.</td>
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<td></td>
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<td></td>
<td><strong>III. Intellectual Property Laws</strong></td>
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<tr>
<td>1.</td>
<td>Patents Act, 1970</td>
<td>Primary legislation governing the issue of patents in India. Product and process patent grants (term: 20 years). Special sections applicable to the pharmaceutical industry, especially with respect to ever-greening of patents (restricted under Section 3(d) and compulsory licensing of patents (Section 84)).</td>
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|   | 2. Trade Marks Act, 1999 | • Provides a mechanism for registration, protection of trademarks and prevention of fraudulent trademarks.  
• Also, provides for rights acquired by registration of trademarks, modes of transfer and assignment of trademark rights, nature of infringements, penalties for such infringement and remedies available to the owner in case of infringement.  
• Right to use is provided with respect to specific classes of goods and services in the territory of India.  
• Regulates protection of sensitive personal data and information.  
• Provides for implementation and maintenance of security and procedures for safe keeping of sensitive data such as medical history of patients, records, personal information and information relating to health conditions.  
• Establishes liability & penalties in cases of wrongful disclosure of personal data without proper authorization.  
|   | 3. Information Technology Act, 2000 (IT Act) | • Provides for protection of sensitive personal data, information, personal and sensitive medical records, patient histories and such other personal medical and/or health related information.  
• Obligation to protect sensitive personal information is placed on recipients. Such obligation arises when such data is collected, stored, used or transferred.  
• Obligation to publish data protection policies on public portals.  
• Penalties prescribed.  
|   | 4. Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 |
### IV. Guidance Documents/Self-Regulatory Codes

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<td>2.</td>
<td>Good Clinical Practice Guidelines (Clinical Practices)</td>
<td>- Regulates professional conduct of registered medical practitioners in India. Establishes regulations relating to the professional conduct, etiquette and ethics for registered medical practitioners.</td>
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| 3. | Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (MCI Code) | - Sets out restrictions on acceptance of gifts or other forms of gratification from industry representatives acting in furtherance of marketing activities.  
- Sets out disciplinary and penal punishments for acts of professional misconduct. |
| 4. | Uniform Code for Pharmaceutical Marketing Practices (UCPMP) | - This is a voluntary code adopted by the industry – a self regulating mechanism.  
- Establishes guidelines for good marketing practices to be employed by pharmaceutical companies.  
- Prohibits giving of cash or monetary incentives to healthcare professionals.  
- Restricts pharmaceutical companies from providing free samples of drugs to any person not qualified to prescribe such products. |
Regulatory Agencies

1. Central Drug Standard Control Organisation (CDSCO)
   - The Central Drug Authority (under the aegis of the Ministry of Health and Family Welfare, Government of India) for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act, 1940.
   - CDSCO has 6 zonal offices, 4 sub-zonal offices, 13 port offices and 7 laboratories under its control.
   - Key functions include regulatory control over import of drugs, approval of new drugs, regulatory control over clinical trials, issuance of manufacturing, testing, sale and export licenses.
   - Oversees functioning of the Drugs Technical Advisory Board (DTAB) and the Drugs Consultative Committee (DCC).

2. Drug Controller General of India (DCGI)
   - Statutory authority established under the Drugs and Cosmetics Act, 1940 for discharging functions thereunder.
   - Heads the CDSCO and is responsible for approval of licenses and other general functions of the CDSCO as prescribed under the said Act.

3. State Drug Standard Control Organisation
   - Established at the state level under the Drugs and Cosmetics Act, 1940.
   - Responsible for monitoring drug quality and regulatory compliances at the state level.

4. National Pharmaceuticals Pricing Authority (NPPA)
   - An organization under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, Government of India, established to set the ceiling price of certain bulk drugs and formulations and to enforce prices and availability of certain medicines in the country.
   - Has the power to implement and enforce provisions of the Drugs (Prices Control) Order, 2013.
FDI in the Pharmaceutical Industry – A Policy Perspective

Foreign direct investment ("FDI") has traditionally been seen as an indispensable tool for constructing the pathway to growth and development for a country. Since the initiation of the liberalisation of the Indian economy in 1991, FDI has been a driver of growth and development of India. FDI not only helps in pumping money into an economy but also has (or at least is expected to have) a spill over or trickledown effect – bringing in new technology, greater innovation, efficient management and economies of scale. Even though the benefits of FDI are manifold, it is interesting to observe that every sector reacts differently to infusion of foreign investment. For instance, a sector which thrives primarily on indigenous industries typically resists FDI, as foreign investment in such a sector may adversely affect the domestic production. This explains why FDI in sectors where the social landscape and/or indigenous industries have a larger role to play, has conventionally been more regulated than other sectors.

Healthcare: Need for Availability, Accessibility and Affordability

The pharmaceutical ("pharma") industry helps in running the lifeline of a country thereby making it a firmly regulated industry. A peculiar characteristic of this industry, perhaps worldwide and in particular in India, is that although it strives to make profits and promote growth like any other commercial enterprise, it is also expected to cater to society at large and operate with the primary objective of alleviating the needs of the people by providing them with quality healthcare. In a welfare economy such as India’s, pharma companies are not looked at solely as profit generating enterprises but as the saviour of the people which need to operate for the benefit of society at large by providing efficient healthcare at affordable prices. Therefore, with a view to balancing commercial vis-a-vis public interests, social benefits emanating from the pharma industry have been the most important drivers while formulating India’s FDI policy governing this industry.

India: A land of change – From generic to branded medicines

While pre-independent India saw a primarily unorganised pharma industry, post-independent India witnessed a growth in the pharma industry which can be attributed to a number of factors including policy changes and infusion of FDI in the industry. The policy governing FDI in pharma has witnessed some important milestones which have steered the pharma industry in India to the present stage.
Pre-liberalisation era

The Indian pharma industry was largely controlled by multinational companies before 1990. While 85% of the drugs were manufactured/supplied by multinational companies, domestic units only produced the remaining 15%. This situation was reversed in 1990 with the domestic industries capturing 85% of the market. This change was due to a number of underlying factors including: (a) sectoral reservations for the public sector and the small scale sector in order to build up self-sufficiency; (b) the patent regime refusing “product patent” and allowing only “process patent”; and (c) the introduction of the Foreign Exchange Regulation Act, 1974 (“FERA”) which then required all multinational companies to dilute their shareholdings to 40% in order to continue in India.¹

Liberalisation era

The liberalisation era coupled with the amendment to the Patents Act, 1970 went a long way in bringing about a remarkable transition in the pharma industry.

- 1986 – Drug Policy

The Drug Policy of 1986 started the process of liberalisation of the pharma industry by making FERA-companies (then Indian companies in which non-resident interest exceeded 40%) eligible for entry in areas where their entry was desirable from the objective of better health care. Accordingly, the list of bulk drugs open to all investors was revised to include certain drugs such as Penicillin, Polio Vaccine and any new drug for which the company conducted clinical trials and obtained the approval of the Drug Controller. FERA-companies were made eligible for licenses mainly in respect of certain bulk drugs (complete list set out in Annexure I to the Drug Policy of 1986) by including them in Appendix I of the Industrial Licensing Policy, subject to a phased manufacturing programme (specifying indigenisation to be achieved annually as a percentage of the value of production), and related formulations in order to encourage higher bulk drug production.

- 1991 – Opening up of the pharma industry to FDI

  (i) Amidst the period of liberalisation of the Indian economy, the drug and pharma industry was opened to 51% FDI. Infusion of FDI was allowed under the automatic approval route in the manufacture of drugs, medicines and allied products.

  (ii) However, foreign investors were still plagued with concerns regarding the intellectual property rights regime that India offered. The Patents Act, 1970 permitted patents only for “processes” and the term of such patents was restricted to 5 years. This allowed a number of manufacturers to develop alternative processes (typically ‘reverse-engineering’) for the same product thereby providing a generic variety of the drug at lower prices. Even though this regime could have been said to be useful for the Indian drug

manufacturers, it disincentivised foreign participation in the Indian pharma industry.

- **1994/95 – Signing and ratification of the TRIPS Agreement**
  (i) India signed the Trade Related Aspects of Intellectual Property Rights agreement (“TRIPS”) of the General Agreement on Tariffs and Trade on April 15, 1994 and ratified it in the year 1995.
  (ii) One of the foremost objectives of TRIPS was to provide a minimum level of patent protection in order to promote international trade and investment in an increasingly interdependent global market.²
  (iii) India had a **transitional period of 10 years** to harmonise its intellectual property law in accordance with the TRIPS (Articles 65 and 66 of TRIPS).
  (iv) Signing and ratification of TRIPS meant that there were imminent changes to the intellectual property rights framework in India. This increased the confidence of the foreign investors in the Indian pharma market.

- **2000 – Further liberalisation**
  Press Note No. 2 (2000 Series) dated February 11, 2000 further liberalised the pharma industry by allowing:
  (i) FDI up to **74%** under the **automatic route** in the case of **bulk drugs**, their intermediates and for formulations (except those produced by the use of recombinant DNA technology).
  (ii) FDI **above 74%** under the **approval route** (on consideration by the Government on a case to case basis) for manufacturing of **bulk drugs** from basic stages and their intermediates and bulk drugs produced by the use of recombinant DNA technology as well as the specific cell/tissue targeted formulations provided it involves manufacturing from a basic stage.

- **2001 – Full liberalisation**
  (i) Press Note No. 4 (2001 Series) dated May 21, 2001 modified the Press Note No. 2 (2000 Series) and permitted up to **100% FDI** for manufacture of **drugs and pharmaceuticals** under the **automatic route**, provided the activity did not attract compulsory licensing or involved use of recombinant DNA technology, and specific cell/tissue targeted formulations.
  (ii) However, **Government approval** was still required for FDI in the manufacture of **licensable drugs, pharmaceuticals and bulk drugs** produced by **recombinant DNA technology and specific cell/tissue targeted formulations**.

- **2005 – Dispensation of compulsory licensing for Drugs and Pharma**
  (i) The Department of Industrial Policy and Promotion (“DIPP”), vide notification S.O. 1386(E) dated September 23, 2005, **removed “Drugs and**

Pharma” from the list of industries in respect of which industrial licensing was compulsory.

(ii) Pursuant to this, FDI in the pharma industry up to 100% fell within the purview of the automatic approval route (Press Note No. 4 (2006 Series) dated February 10, 2006).

(iii) The Government also adopted a minimal interference policy towards FDI in India and decided that the best regulator of what is being brought into the country and its outcome would be market force itself.\(^3\)

- **2005 – Amendment to the Patents Act, 1970 in accordance with TRIPS**
  
  The amendment to the Patents Act, 1970 in 2005 introduced the concept of “product patents” in India which could be granted for a period of 20 years for the new product. This was a major setback to India’s generic drug manufacturing industry, which had thrived on developing new processes for manufacturing an already known product or for a new product. However, this meant that the standards of patent protection being adopted by India were now at par with the international standards, thereby increasing confidence of foreign investors in India.

- **2011 – Distinction between Brownfield and Greenfield investments**
  
  (i) In October 2011, the Prime Minister of India chaired a high level meeting to discuss the FDI policy in the drugs and pharma industry, during which the report of the Arun Maira Committee (which was formed, on the heels of a spate of foreign acquisitions in this industry, to study the trend and impact of the mergers and acquisitions in the pharma industry) was accepted and the following decisions were taken:\(^4\)

  (a) **100% FDI** will be allowed under the automatic route for Greenfield investments in the pharma industry as this will facilitate addition of manufacturing capacities, technology acquisition and development.

  (b) For Brownfield investments in the pharma industry, FDI will be allowed, subject to the approval of (for an interim period of 6 months) the Foreign Investment Promotion Board (“FIPB”) (during the said period of 6 months, the Competition Commission of India will lay down enabling regulations for effectively overseeing mergers and acquisitions in the pharma industry).

  The policy decision to differentiate between Greenfield and Brownfield investments was done to ensure there was a balance between commercial objectives of permitting FDI in the pharma industry and the public health concerns. The aforesaid changes essentially came about as a result of the

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\(^3\) Secretariat for Industrial Assistance, Destination India, Department of Industrial Policy and Promotion, New Delhi, Issue No. 2 (2004).

\(^4\) Press Release dated October 10, 2011, India will continue to allow 100% FDI in Greenfield Pharma - CCI to develop necessary enabling regulations for Brownfield FDI in six months - PM chairs high level meeting, Ministry of Commerce & Industry, Press Information Bureau, Government of India.
reaction to the spate of takeovers of domestic industries and sector concerns regarding the availability of essential medicines, research and development considerations, and the availability of technology.5

(ii) Consequently, Press Note No. 3 (2011 Series) dated November 8, 2011 revised the FDI policy and drew a distinction between FDI for Greenfield and Brownfield (investments in existing companies) investments. Based on the decision of the high level meeting in October 2011, while FDI up to 100% under the automatic route was allowed for Greenfield investments, FDI for Brownfield investments was routed through the approval of the FIPB. The press note also stated that the policy will be reviewed after a period of 6 months.

(iii) The Review 2011-13 published by the FIPB set out the following conditions which were being imposed by the FIPB while recommending approval for Brownfield investments in the pharma industry (as suggested by the Special Group headed by the Additional Secretary, Ministry of Economic Affairs)6 to combat the risk posed by these investments:

(a) For the next 5 years, the company receiving foreign investment will have to maintain the production of medicines under the National List of Essential Medicines at a level which would be the highest quantity of production in the preceding 3 years from the grant of approval.

(b) For the next 5 years, the company receiving foreign investment will have to maintain its expenditure on research and development at a level which would be the maximum level incurred in 3 years prior to the grant of the approval.

(c) Complete information relating to any transfer of technology along with induction of foreign investment into the investee company will have to be provided to the administrative ministry and the FIPB secretariat.

(d) Submission of a quarterly compliance report by the company in respect of the conditions contained in the letter of approval, duly certified by the auditors of the company, to the FIPB secretariat, the Ministry of Corporate Affairs and the DIPP.

These conditions now form a part of the conditions on which FIPB approves Brownfield investments in the pharma industry.

- August, 2013 – Parliamentary Committee Report

The following key recommendations pertaining to FDI in the pharma industry were made by the Parliamentary Standing Committee on Commerce:7

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6 Ibid.
7 Supra note 1.
(i) The committee noted that it was unhappy with the flurry of mergers/acquisitions/takeover of domestic pharma companies since the real danger of 100% FDI and the selling/takeover of Indian companies is the decimation of competition as well as of indigenous capabilities.

(ii) The committee asked the Government to take concrete steps to attract and ensure that substantial amounts of investments are brought in the research and development space of the pharma industry with a special focus on tropical diseases.

(iii) The committee noted that FDI flow into Brownfield projects did not add any fresh capacity in terms of production, distribution network or asset creation to the desired level but has encroached upon our generic base and adversely affected the pharma industry.

(iv) The committee was of the considered opinion that the Government must impose a blanket ban on any FDI in Brownfield pharma projects. It strongly recommended that the DIPP take all measures to stop any further takeover/acquisition of domestic pharma units as the pharma industry is one of those industries of the economy which has to be dictated by motivations of public good rather than foreign investments, profit and revenue.

(v) The committee agreed with the present FDI policy on Greenfield pharma projects permitting up to 100% FDI under the automatic route and recommended DIPP to create favourable conditions to promote Greenfield investments in the pharma industry. However, it was also of the view that FDI in Greenfield pharma projects may be automatic but subject to some conditions, failure to comply with which would attract a penalty including cancellation of registration.

No changes were made to the FDI policy governing investments in Brownfield projects in the pharma industry pursuant to this report and the FIPB continued to monitor such investments by imposing conditions at the time of granting the approval for the investment.

- **2014 – Clarification with respect to “non-compete” clauses**

  (i) Amidst speculation of banning FDI in the Brownfield pharma industry, Press Note No. 1 (2014 Series) dated January 8, 2014 added a further condition that a non-compete clause in any of the inter se agreements, would only be allowed in special circumstances with the approval of the FIPB.

  (ii) The said press note, however, did not clarify whether the said condition is applicable only to FDI in Brownfield projects in the industry and not to Greenfield investments.

- **2015 – Carve out created for Medical Devices**

  (i) The DIPP has, with effect from January 21, 2015, permitted 100% FDI under the automatic route for manufacturing of medical devices vide Press Note No. 2 (2015 Series) dated January 6, 2015 to allow the following:
(a) FDI in manufacturing of medical devices under the automatic route (for both Greenfield and Brownfield projects for manufacturing of medical devices).

(b) Defining the term ‘medical device’ subject to the amendment in the Drugs and Cosmetics Act, 1940.

(c) Dispensing with the general conditions applicable to FDI in the pharma industry including approval of the FIPB for non-compete clauses and submission of a certificate by the prospective investor and investee for FDI in manufacturing of medical devices.

Under the erstwhile FDI policy, the position on medical devices was not clear because it referred only to the pharma industry. In addition, under the Drugs and Cosmetics Act, 1940, the definition of medical devices only includes certain notified medical devices (not all medical devices) which are subsumed within the definition of “drugs”. Hence, there was lack of clarity on whether ‘pharmaceuticals’ included ‘medical devices’ or not. Therefore, circumspect investors, out of abundant caution, adopted the approval route.

The clarity brought about by the aforesaid 2015 press note has been welcomed by the stakeholders and is expected to benefit the cash starved medical devices industry.8

- **Amendment to the Drugs and Cosmetics Act, 1940**

  (i) A draft of the Drugs and Cosmetics (Amendment) Bill, 2015 was put in the public domain on December 31, 2014 by the Department of Health and Family Welfare inviting comments from the stakeholders at large.

  (ii) The said amendment introduces new definitions (including that of medical devices), new provisions governing medical devices and conduct of clinical trials, sets up new authorities and proposes centralised licensing for categories of very critical drugs.

  (iii) Transparent laws and better regulatory framework governing the drugs and pharma industry will further boost investor confidence in the industry.

- **2016 – FDI in Brownfield Pharma relaxed – up to 74% under Automatic Route**

  (i) The Narendra Modi Government, in its endeavor to relax the FDI policy for foreign investors, through its Press Release dated June 20, 2016 (“2016 Press Release”), has, *inter alia*, relaxed the FDI approval requirements into a Brown field pharmaceutical entity by allowing FDI up to 74% under the automatic route.

  (ii) Investment above 74% into a Brown field pharmaceutical entity would continue to be under the government route.

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This and other liberalisation measures have been announced in order to further facilitate ease of doing business in India, provide a major impetus to employment and job creation, incentivize industrialization and attract greater influx of FDI into India.

FDI in Pharma: Still a long road ahead?

Research indicates that if India moves to a stronger intellectual property regime, with rights and protections comparable to China or even the United States, it will generate very large benefits for the economy and people. FDI flows to India’s pharma industry would increase sharply as would its research and development activities. This increase in pharma FDI and research and development would expand the industry’s output and employment, India’s access to the world’s most advanced pharmaceuticals would increase, improving the health of the Indian populace.\(^9\)

The Government has recently approved the National Pharmaceutical Pricing Policy-2012 and has put in place a regulatory framework for pricing of drugs that would ensure availability of essential medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, employment and shared economic well-being for all.\(^10\)

The protectionist measures which formed the pivot of the FDI policy governing the pharma industry have given way to proactive measures calling for infusion of more foreign investment in the industry.

As can be seen, India has gone through immense transformation with respect to its foreign investment policies in the pharma industry. India being so uniquely and strategically placed in this field, as one of the leaders in the production of generic drugs globally, must sustain and continue its focus on streamlining policy and adapting to the various technological, technical and trade related changes occurring internationally.

From all of this we can safely conclude that despite India having made moves in the right direction, there is still a lot that can and needs to be done to make India a leader rather than just one of the big players in the industry today. By adopting progressive and long-term approaches, India’s potential and success can increase manifold. Distancing itself from imminent fiscal and populist considerations and looking at the bigger picture could go a long way in streamlining policies and perspectives.

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10 Press Release dated March 17, 2015, *Various measures taken to realize the dream of ‘Make in India’ in pharmaceutical sector*, Ministry of Chemicals and Fertilizers, Press Information Bureau, Government of India.
The Indian pharmaceuticals market is the third largest in the world in terms of volume and thirteenth largest in terms of value and it is expected to grow to USD 85 billion by 2020. The pharmaceutical industry in India consists of both originator drug companies and generic companies of varied scales; however, branded generics constitute a major portion of the Indian pharmaceutical industry. Effective competition regulation of the pharmaceutical markets is considered an important method to ensure that consumers consistently have access to good quality medicines at a reasonable price. The major provisions under the Competition Act, 2002 (“Competition Act”) came into effect in 2009 and since then the Competition Commission of India (“CCI”) has adopted a consistently proactive stance concerning anti-competitive practices in the pharmaceutical industry.

Enforcement by CCI: The Story so far

CCI has been mandated under the Competition Act to regulate competition in India by scrutinizing and restricting:

1) Anti-competitive agreements (Section 3);
2) Practices amounting to abuse of dominance (Section 4); and
3) Anti-competitive mergers/acquisitions/amalgamations (Section 5 & 6).

In the pharmaceutical space, CCI has evinced a clear interest in tackling anti-competitive conduct by companies in public procurement (prohibited under Section 3 of the Competition Act) as evident from a recent case where CCI has imposed a penalty of Rs. 640 million (USD 9.5 million) on 2 major global pharmaceutical players, for entering into a cartel in a government tender for procurement of QMMV - an anti-meningitis vaccine.

CCI has been also inquiring into alleged anti-competitive practices prevailing in the pharmaceutical supply/distribution chain with focus on trade associations of chemists and druggists. Various parties have challenged these orders passed by CCI before the Competition Appellate Tribunal ("COMPAT") or a High Court. While some of the orders have been upheld (albeit modified), some orders have been set aside or remitted for re-consideration and some legal challenges are yet to be

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2 M/s Bio-Med Pvt Ltd v. Union of India & Ors., [Case No. 26/2013], decided on: June 4, 2015 [Penalty imposed on GlaxoSmithKline & Sanofi].
3 Varca Chemist and Druggist & Ors. v. Chemists & Druggists Association, Goa, [Case No. MRTP C-127/2009/DGIR4/28], decided on: June 11, 2012; Vedant Bio Sciences v. Chemist & Druggists Association of Baroda, [Case No. C-87/2009/DGIR], decided on: September 5, 2012; M/s Santuka Associates Pvt. Ltd. v. All India Organization of Chemists and Druggists & Ors., [Case No. 20/2011], decided on: February 19, 2013; M/s Sandhya Drug Agency vs Assam Drug Dealers Association and Ors., [Case No. 63/2011], decided on December 9, 2013; M/s Peeveear Medical Agencies, Kerala vs All India Organization of Chemists and Druggists and Ors., [Case No. 41/2011], decided on December 9, 2013; M/s Arora Medical Hall, Ferozepur vs Chemists & Druggists Association, Ferozepur & Ors., [Case No. 30/2012], decided on: February 5, 2014; In Re: Bengal Chemist and Druggist Association [Suo moto Case No. 02 of 2012 and Ref: Case No. 01 of 2013], decided on March 11, 2014; In Re: Collective boycott/refusal to deal by the Chemists & Druggists Association, Goa (CDAG) M/s Glenmark Company and, M/s Wockhardt Ltd [Suo Moto Case No. 05/2013], decided on October 27, 2014; M/s Robit Medical Stores Madurai Pharmaceutical Limited & Ors. [Case No.78/2012], decided on 29 January 2015.
decided. It may also be noted that although CCI has recently penalized a pharmaceutical manufacturer for acceding to the diktats of a trade association but the COMPAT has set aside the same on appeal.

CCI started its merger control functions on June 1, 2011 and has since scrutinized and approved various combinations. Most of these pre-merger notifications which involved companies engaged in the pharmaceutical space were approved by the CCI within a period of 30 days in Phase-I itself.

However, in a recent combination matter, CCI granted approval for the combination subject to the parties carrying out divestiture of the product relating to the relevant markets for formulations. Additionally, in a few of the cases, CCI has taken note of the non-compete clauses entered into between the parties and directed that these clauses be modified in order to reduce the period/duration as well as scope of obligation (products, business activities, geographical areas, etc).

The Way Ahead

Given the above trend and the changes taking place in the global pharmaceutical industry, combined with CCI’s evident interest to continue to examine alleged distortions affecting the sector, the following aspects of the pharmaceutical industry can be said to be prone to greater scrutiny from CCI in the near future.

The examination of the conduct by CCI into various aspects of the pharmaceutical industry may be divided in the following categories in accordance with CCI’s mandate:

A) Collusive conduct;
B) Abuse of dominance;
C) Conduct evincing both anti-competitive agreements and abuse of dominance;
D) Anti-competitive mergers/acquisitions/amalgamations.

A) Collusive conduct

CCI has consistently treated collusive conduct in public procurement as the most pernicious form of anti-competitive conduct covered by the Competition Act and the parties found in violation have been visited with harsh penalties. The recent decision by CCI to penalize two major global pharmaceutical companies for indulging in collusive activity indicates that the CCI has its eyes peeled for anti-competitive agreements in public procurement activities undertaken by state agencies. Additionally, CCI has also penalized 4 public insurers for indulging in collusive activity in the selection of insurers for the Rashtriya Swasthya Bima Yojna (“RSBY”) scheme being operated by the Government of Kerala.
In light of CCI’s focus on pharmaceuticals and public procurement, the pharmaceutical companies involved in the participation in tenders issued for procurement of drugs under the National Health Mission, RSBY or other health schemes by the various state agencies, must exercise abundant caution while participating in these tenders. Companies are advised to formulate competition law compliance manuals especially for bidding processes and may have them updated at frequent intervals.

CCI is also likely to increase scrutiny of alleged collusive conduct present at various stages of procuring pharmaceutical products/services distribution chain. There have been various diverse examples of this trend. For instance, CCI imposed a penalty of Rs. 3.81 crores (USD 575,000) on a leading super speciality hospital for entering into an allegedly anti-competitive exclusive agreement with a stem cell bank. Although the said order of CCI was set aside on appeal before COMPAT, but the said order passed by COMPAT is presently under appeal before the Supreme Court. Additionally, CCI has also dealt with cases involving alleged collusive conduct in supply or services for medical equipment to hospitals or medical practitioners. Other instances of such collusive conduct could include alleged collusion between:

- Manufacturers and Doctors
- Manufacturers and Pharmacists
- Manufacturers, Doctors and Pharmacists
- Manufacturers and Hospitals

It may be noted that the said collusion may not necessarily be between players operating at different levels of the pharmaceutical industry, but could also include alleged collusive conduct between players operating at the same level too; for instance between doctors inter se.

Having stated the above, it is pertinent to note that CCI has also initiated a baseline study/survey of the practices of pharmaceutical and healthcare delivery systems, services in the Delhi and NCR region.

In addition to the various aspects of the pharmaceutical industry that are susceptible to CCI scrutiny for alleged collusive conduct (Section 3) dealt with above, there are various aspects of the pharmaceutical industry which may attract CCI scrutiny for alleged abuse of dominance (Section 4).

**B) Abuse of dominance**

The possibility of abuse of dominance arising from exercise and protection of exclusive rights by patent-holders (considered to be in a position of dominance) in the pharmaceutical industry provides scope for CCI scrutiny.

CCI has sought to examine such conduct concerning the allegedly one-sided terms in the licensing agreement entered into by Gilead Sciences Inc. for

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10 Mr. Ramakant Kini v. Dr. L.H. Hirannandani Hospital, Powai, Mumbai, [Case No. 39/2012], decided on February 5, 2014.
11 Dr. L.H. Hirannandani Hospital v Competition Commission of India & Anr [Appeal No. 19/2014], decided on December 18, 2015.
12 Competition Commission of India v Dr. L.H. Hirannandani Hospital & Anr [Civil Appeal No. 9543/2016].
13 A Foundation for Common Cause & People Awareness v. PES Installations Pvt. Ltd. & Ors., [Case No. 43/2010], decided on April 16, 2012.
Effective competition regulation of the pharmaceutical markets is considered an important method to ensure that consumers consistently have access to good quality medicines at a reasonable price.

distribution of Antiretroviral ("ARV") drugs used for treatment of HIV infection.\textsuperscript{15} In the said case, the matter could not proceed further because CCI did not find evidence of a \textit{prima facie} case. However, the fact that CCI took cognizance of the case indicates that CCI considers that it has the necessary jurisdiction to determine validity of a conduct (under the provisions of the Competition Act) despite the conduct being undertaken by virtue of patent rights.

A more direct example of this trend is visible in a case involving exercise and protection of intellectual property rights in the technology sector\textsuperscript{16} where CCI has affirmed its \textit{prima facie} view that CCI is entitled to determine whether the terms and conditions at which patents held by Ericsson are licensed to other companies constitute an abuse of dominance or not. Though CCI’s jurisdiction to examine potentially abusive conduct of a patent-holder has been affirmed by the High Court of Delhi\textsuperscript{17} but an appeal against the said decision is pending before a larger bench\textsuperscript{18} which has refused to stay the CCI investigation\textsuperscript{19}. Despite the pending appeal before the Division Bench of the High Court of Delhi, the initial denial of stay has left the area open to increased scrutiny.

In addition to the above aspects which may attract CCI scrutiny for allegedly constituting either anti-competitive agreements (Section 3) or abuse of dominance (Section 4), there are other aspects which may attract CCI scrutiny from both the perspectives i.e from Section 3 and Section 4.

C) Conduct evincing both anti-competitive agreements and abuse of dominance

The conflict between the exclusive right granted by a patent and the obligation not to abuse such a dominant position could also cause increased scrutiny by CCI into patent settlement agreements entered into by brand name/originator companies with generic companies. Alleged patent settlement agreements like these have been the subject of intense anti-trust scrutiny by competition regulators in the United States and Europe. With various similar deals/agreements having been entered into in India recently, it may be in the interest of the companies involved to guard themselves against allegations of anti-competitive conduct attached to these agreements.

\textsuperscript{15} Manoj Hirasingh Pardeshi v. Gilead Sciences Inc., [Case No. 41/2012], decided on: March 5, 2013.
\textsuperscript{16} Micromax Informatics Limited v. Telefonaktiebolaget LM Ericsson (Publ), [Case No. 50/2013], decided on: November 12, 2013; Intex Technologies (India) Limited vs Telefonaktiebolaget LM Ericsson, [Case No. 76/2013], decided on: January 14, 2014; M/s Best IT World (India) Private Limited (iBall) vs M/s Telefonaktiebolaget LM Ericsson (Publ) & Other, [Case No. 04/2015], decided on: May 12, 2015.
\textsuperscript{17} Telefonaktiebolaget LM Ericsson (Publ) v Competition Commission of India & Anr [W.P.(C) 464/2014 & W.P.(C) 1006/2014], decided on March 30, 2016.
\textsuperscript{18} Telefonaktiebolaget LM Ericsson (Publ) v Competition Commission of India & Anr [LPA No. 216-247/2016]
\textsuperscript{19} Telefonaktiebolaget LM Ericsson (Publ) v Competition Commission of India & Anr [LPA No. 216-247/2016]; Order dated April 19, 2016.
Additionally, medical equipment suppliers could also face anti-trust scrutiny by CCI with allegations regarding both anti-competitive agreement and abuse of dominance being raised against them, especially concerning their aftermarket services.

Besides the above, methods referred to as patent pools, ever-greening, product hopping, abusive denigration (or a combination of these) considered to be prevalent in the pharmaceutical industry could also become subject of CCI intervention. These methods have been the subject of anti-trust scrutiny by regulators in various jurisdictions and the companies involved should be mindful because their conduct may attract the allegation that originator drug companies are employing these methods simply to extend the scope or duration of their monopoly/patent, which may be considered in contravention of Section 3 or Section 4 of the Competition Act.

Apart from the above, it may be noted that CCI’s examination and scrutiny is not restricted to behavioural matters dealt with above but also extends to mergers, acquisitions and amalgamations in the pharmaceutical industry.

D) Anti-competitive mergers/acquisitions/amalgamations.

On March 4, 2016, the Central Government has raised the financial threshold limit for companies seeking nod from the CCI for proposed mergers and acquisitions. The Central Government has also increased the thresholds for the small target exemptions\(^\text{20}\), popularly known as the de minimis exemption.\(^\text{21}\)

An increasing number of pharmaceutical companies around the world are seeking to expand and consolidate their platform of capabilities in their endeavour to either develop indigenous branded generics or to acquire established branded generics. The recent notifications will aid the increased activity on the mergers and acquisitions front in the pharmaceutical industry globally. However, the transactions falling within the thresholds may be subject to greater scrutiny.

Given this trend, it is likely that the Indian pharmaceutical industry will also be affected by it as Indian companies may be involved in purchase of certain brands/divisions, including those being divested or otherwise. Also, a wider international transaction may have certain aspects attracting the notification requirements in India. Therefore, the merger control regime is expected to see more activity in the near future.

Conclusion

Given the above context and CCI’s proactive stance when dealing with the pharmaceutical industry, there are various aspects of the pharmaceutical industry (though innocuous or/and unexposed to CCI scrutiny so far) that may be impacted by CCI’s examination in the near future. Accordingly, the industry as a whole, and the enterprises concerned, need to be aware of the risks ahead and stay prepared to avoid them.

\(^{20}\) An exemption from CCI notification is available if the enterprise whose control, shares, voting rights or assets are being acquired (including its unit, divisions and subsidiaries) has either turnover of less than INR 10 billion (approx. USD 148.7 million) in India or assets of the value less than INR 3.5 billion (approx. USD 52 million) in India.

\(^{21}\) Notification S.O. 675(E) & S.O. 674 (E), issued by the Ministry of Corporate Affairs (dated March 4, 2016).
Necessity has been rightly called the mother of invention. It is this necessity which spurs innovations as well. If such innovations and inventions are nipped in the bud, the world would be bereft of some great benefits derived from them; imagine a scenario where the medicinal properties of penicillin would not have been explored. However, since not all great ideas materialise effectually, it is important to keep a check and balance on these ideas and their effects before they can be widely circulated.

The pharmaceutical and healthcare industry benefits immensely from a surge of ideas. However, while it is essential to cultivate new ideas in order to derive their fruits, it is also vital to save the public from the potential ill-effects of these innovations. New drug molecules and formulations cannot be put to commercial use unless their safety, efficacy and quality can be certified to be safe for use by the public at large. This is why it is absolutely imperative for a country to promote as well as appropriately regulate the carrying out of clinical trials. A clinical trial can be simply understood as an experiment to determine the effectiveness, safety and efficiency of new methods of treatment.

The pharmaceutical and healthcare industry in India has been witnessing tremendous growth over time. With the advent of newer drug molecules and methods of treatments in India and the world over, it is but imperative that these also be made available to the Indian public at large. Smooth carrying of clinical trials and removal of regulatory impediments in its conduct is likely to further contribute to the growth of this industry in India.

This article aims to study the regulatory landscape governing clinical trials in India and the effect of the recently proposed amendments to the framework of laws governing the conduct of clinical trials in India. For the purpose of our analysis herein, we have considered the current regulatory framework including a snapshot of the recent changes and the pending amendments to the law governing the conduct of clinical trials in India.

Current Regulatory Framework

In India, the Drugs and Cosmetics Act, 1940 (“D&C Act”) and the Drugs and Cosmetics Rules, 1945 (“D&C Rules”) are the principal legislations for the regulation of clinical trials and the Central Drugs Standard Control Organization (“CDSCO”) is the primary regulatory authority under the said legislations. The Drugs Controller General of India (“DCGI”) is the principal licensing authority under the D&C Rules and oversees the conduct of clinical trials in India.

While the term “clinical trial” has not been defined in the principal act, the D&C Rules defines a “clinical trial” to mean “a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical pharmacological (including pharmacodynamic and pharmacokinetic) and/or adverse effects with the objective of...
determining safety and/or efficacy of the new drug”. It is pertinent to note that clinical trial has been defined in the D&C Rules only in the context of a new drug.

Clinical Trial Phases

Prior to manufacturing or marketing a new drug in India, clinical trials need to be conducted in accordance with the D&C Rules. The phases of clinical trials as set out under the D&C Rules are as under:

Phase I - Human Pharmacology
- At this stage the safety of a new medicine is tested on humans for the first time. A small number of subjects (8-20) comprising of healthy individuals as well as patients are tested at this stage.
- **Objective:** To determine the safety and tolerability of identified dosages; side effects; study absorption, distribution, metabolism and excretion; and observe pharmaco dynamic qualities such as efficacy.

Phase II - Therapeutic Exploratory Trials
- This phase is conducted on a larger group of subjects (100-200) which usually comprises of patients suffering from the disease for which the drug is intended.
- **Objective:** To determine the efficacy of the drug in treating identified conditions under study; determine immediate side effects; counter indications and adverse risks. These studies are usually done on a small number and select set of patients.
- Observations from this phase become the guiding templates for Phase III in terms of dosage and treatment regimens.

Phase III - Therapeutic Confirmatory Trials
- This stage can be conducted only after the studies of Phase I and Phase II are found to be positive.
- Conducted on a larger identified population (3000) to confirm preliminary trial results obtained from Phase I and Phase II - that the drug is safe and effective for use in the treatment of the indicated condition.
- This stage involves testing on a larger group of patients including several thousand subjects and lasts for a period of 1 year or more.
- **Objective:** To compare the medicine against existing treatment or a placebo and determine any serious adverse side effects over a prolonged period.
- Another objective is to test use of the drug in larger populations and at different stages of the identified condition and across different geographical regions within the country.
- **Drugs approved outside India:** Phase III trials are required to be conducted in India for drugs approved outside India to generate evidence of safety and efficacy of the drug amongst Indian patients.
- The idea is to ensure similar efficacy and further that test data generated in India is similar to that which is generated abroad to ensure that the drug is equally efficacious in the Indian population as well or that the drug does not have any
serious side effects particularly in the Indian population.

**Phase IV - Post Marketing Trials**
- Applicable after regulatory approval is obtained and the drug is released in the market.
- Usually carried out in the first 1000 patients that receive the approved drug.
- **Objective:** To continue the study of side effects, safety and effectiveness of the drug.

**Phase V - Post Marketing Studies**
- After the drug is granted approval and launched in the market, observational studies are undertaken to keep a check on side effects and counter indications.

**When required**

The requirement of conducting clinical trials is absolute. No drug can be approved for marketing in India unless and until some, if not all, phases of clinical trials are conducted in India. While there are provisions for approval of drugs without trials, such provisions only apply to approval requests in cases where the requirement of the drug is emergent to cater to a pressing national need.

Otherwise:
- For all New Chemical Entities (“NCE’s”) developed in India to be marketed in India, all the trial phases (Phases I-IV) will be carried out in India.
- For all NCEs developed outside India which are of relevance to our population, it is presently not always necessary to carry out Phase I trials in India, provided Phase I trials have either been done or are being done in the country of origin.
- Drugs which are already in the market in well-regulated countries with a good post approval marketing surveillance reports for more than 4 years, may also be permitted for direct marketing in India, subject to strict Post Marketing Surveys for 4 to 6 years or after bridging studies (that show safety and efficacy in the Indian population), on a case-by-case basis.
- NCE’s undergoing clinical trials, drugs which have been in the regulated market for less than 4 years, and drugs marketed in countries with an inefficient or no regulatory system will have to go through Phase III clinical trials before permission is granted for marketing the drug in India.
### Types of Clinical Trials

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open Uncontrolled Trial</td>
<td>- There is no comparison with another drug.</td>
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<td>- These trials are very rare and are only carried out when a controlled</td>
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<td>comparative trial is not possible.</td>
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<td>Controlled Comparative Trial</td>
<td>- One group of patients is given the drug on trial and the other group is</td>
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<td>given another drug (or even a placebo).</td>
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<tr>
<td>Randomized Controlled Trials</td>
<td>- The drugs are allocated according to a process of randomization such as</td>
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<td>the use of random numbers, to reduce bias.</td>
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<tr>
<td>Non-Randomized Trial</td>
<td>- The drugs are not given randomly but given with specific identification</td>
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<td>(drug, patient, indication) parameters.</td>
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<td>Open Trials</td>
<td>- Patients know that they are receiving the drug that is being clinically</td>
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<td>evaluated.</td>
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<td>Single-Blind Trial</td>
<td>- Either the patient or the doctor does not know which drug is being given</td>
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<td>to which patient.</td>
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<tr>
<td>Double-Blind Trial</td>
<td>- Neither the patient nor the doctor knows which patient is receiving which</td>
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<td>drug.</td>
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<td>Observational Clinical Trial</td>
<td>- The investigator observes the effect of a drug but does not intervene.</td>
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<td>- The investigator has no role in the administration of the drug.</td>
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<td>Adaptive Clinical Trial</td>
<td>- A type of randomized clinical trial which allows modifications of the</td>
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<td>ongoing trial while aiming to preserve the statistical validity and</td>
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<td>integrity of the trial.</td>
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<td>Add on Studies</td>
<td>- Both patient groups receive the same treatment, but one group also</td>
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<td>receives another drug which may make a difference. The other group</td>
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<td></td>
<td>receives a placebo. Could be randomized and double blind.</td>
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</tbody>
</table>
Public Interest Litigation to strengthen clinical trials leading to recent changes

In the wake of a public interest litigation filed by the Swasthya Adhikar Manch (a non-governmental organisation) against the Union of India in the Supreme Court of India in February, 2012 (“Swasthya Adhikar PIL”), the D&C Rules were amended and the CDSCO issued a number of guidelines to strengthen clinical trial regulations in India after January, 2013. A brief summary of the changes in the legal provisions set out in the D&C Rules prior to 2013 and post 2013 are set out below:

<table>
<thead>
<tr>
<th>Provision</th>
<th>Pre 2013 Position</th>
<th>Post 2013 Position</th>
</tr>
</thead>
</table>
| Compensation for death or injury during clinical trials. | No specific provisions with respect to payment of compensation in the event of death or injury caused as a result of clinical trials. Only the informed consent checklist requires the sponsor to provide information regarding payment of compensation to the subject in the event of any trial related serious adverse event (“SAE”). | With effect from January 30, 2013, Rule 122DAB of the D&C Rules introduced provisions for compensation in case of injury or death during clinical trials to provide the following:  
(i) In case of injury occurring to the subject, the subject shall be given free medical management as long as required or until it is established that the injury was not related to clinical trial, whichever is earlier.  
(ii) If the injury is related to clinical trial, the subject shall be entitled to financial compensation as determined by DCGI.  
(iii) In case of a non-permanent injury, the compensation payable shall be commensurate with the nature of the non-permanent injury. |
and loss of wages of the subject.

(iv) In case of death, the nominee of the subject is entitled to financial compensation as determined by the DCGI.

(v) All expenses relating to medical management and financial compensation due to the aforesaid shall be borne by the sponsor of the clinical trial.

(vi) The sponsor is required to furnish an undertaking to pay compensation, along with the application for conducting a clinical trial.

Appendix XII to Schedule Y of the D&C Rules has been introduced with effect from January 30, 2013, to set out the provisions in relation to method for determining quantum of compensation in case of death or injury during clinical trials.

<table>
<thead>
<tr>
<th>Provision</th>
<th>Pre 2013 Position</th>
<th>Post 2013 Position (Subsequent to amendment of the D&amp;C Rules)</th>
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</thead>
<tbody>
<tr>
<td>Meaning of clinical trial related death or injury.</td>
<td>Clinical trial related death or injury was not defined.</td>
<td>Any injury or death of the subject occurring in clinical trial owing to the following shall be considered as</td>
</tr>
<tr>
<td>Provision</td>
<td>Pre 2013 Position</td>
<td>Post 2013 Position (Subsequent to amendment of the D&amp;C Rules)</td>
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<td>clinical trial related injury or death:</td>
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<td>(i) Adverse effect of investigational product.</td>
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<td>(ii) Violation of approved protocol, scientific misconduct or negligence of the sponsor, the sponsor’s representative or the investigator.</td>
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<td>(iii) Failure of the product to provide intended therapeutic effect in case the standard care, though available, was not provided as per clinical trial protocol.</td>
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<td></td>
<td></td>
<td>(iv) Use of placebo on placebo controlled trial in case the standard care, though available, was not provided as per clinical trial protocol.</td>
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<td>(v) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol.</td>
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<td>(vi) Injury to child in-utero because of participation of parent in clinical trial.</td>
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<td>(vii) Any clinical trial procedure involved in the study.</td>
</tr>
<tr>
<td>Provision</td>
<td>Pre 2013 Position</td>
<td>Post 2013 Position (Subsequent to amendment of the D&amp;C Rules)</td>
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<tr>
<td>Consequences of failure to pay compensation.</td>
<td>No consequences were set out.</td>
<td>Failure of sponsor to provide compensation may result in the DCGI cancelling or suspending the clinical trial and/or restricting the sponsor to conduct any further clinical trials in the country, after giving the sponsor an opportunity to show cause as to why such an order should not be passed.</td>
</tr>
<tr>
<td>Details of compensation paid.</td>
<td>No such information was required to be provided.</td>
<td>Sponsor required to submit details of compensation provided for clinical trial related injury or death to the DCGI within 30 days of receipt of order of the DCGI for payment of compensation.</td>
</tr>
<tr>
<td>Registration of clinical trials with the Clinical Trials Registry of India.</td>
<td>Registration of clinical trials with the Clinical Trials Registry of India was voluntary from June 15, 2009 until January 30, 2013.</td>
<td>With effect from January 30, 2013, prior to enrolling the first patient for the study, each clinical trial has to be mandatorily registered with the Clinical Trials Registry of India.</td>
</tr>
<tr>
<td>Status report of each clinical trial.</td>
<td>Sponsors were required to submit a status report on the clinical trial including premature discontinuation of any study, at prescribed periodicity.</td>
<td>Annual status of each clinical trial, as to whether it is ongoing, completed or terminated, has to be submitted to the DCGI by the sponsor including detailed reasons for the same.</td>
</tr>
<tr>
<td>Provision</td>
<td>Pre 2013 Position</td>
<td>Post 2013 Position (Subsequent to amendment of the D&amp;C Rules)</td>
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<tr>
<td>Registration of ethics committee (a committee comprising of medical,</td>
<td>There was no requirement for registration of the ethics committee.</td>
<td>With effect from February 8, 2013, an ethics committee is required to be registered with the DCGI, prior to reviewing or approving any clinical trial. Registration shall be valid for a period of 3 years from the date of issue unless it is suspended or cancelled.</td>
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<td>scientific, non-medical and non-scientific members whose responsibility</td>
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<td>is to ensure the protection of the rights, safety and well-being of</td>
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<td>human subjects involved in clinical trials and responsible for reviewing</td>
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<td>and approving the protocol, the suitability of investigators, facilities,</td>
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<td>methods and adequacy of information to be used for obtaining and</td>
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<td>documenting informed consent of the study, subject and adequacy of</td>
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<td>confidentiality safeguards)</td>
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<tr>
<td>Reporting of SAE by the sponsor</td>
<td>Any unexpected SAE occurring during clinical trial to be communicated within 14 days by the sponsor to DCGI and to other investigators.</td>
<td>Any SAE occurring after due analysis to be forwarded by the sponsor to the chairman of the ethics committee, the DCGI and head of institution where the trial is being conducted, within 14 days of occurrence of the SAE.</td>
</tr>
<tr>
<td>Reporting of serious events by the investigator</td>
<td>Any serious and unexpected adverse effect to be reported to the</td>
<td>Any SAE has to be reported to the sponsor or their authorised representative,</td>
</tr>
<tr>
<td>Provision</td>
<td>Pre 2013 Position</td>
<td>Post 2013 Position (Subsequent to amendment of the D&amp;C Rules)</td>
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<tr>
<td>Responsibility of ethics committee</td>
<td>The responsibility of the ethics committee included reviewing and according approvals to the trials and conducting ongoing review of the trials.</td>
<td>In addition to its responsibilities in relation to approvals and review of trials, in case of SAE, the ethics committee is required to forward its report on the SAE after due analysis along with an opinion on financial compensation payable by the sponsor or their representative, to the DCGI within 30 days of occurrence of the SAE.</td>
</tr>
<tr>
<td>Information to be provided by the investigator to the subject prior to obtaining his informed consent.</td>
<td>All information in relation to clinical trial as set out in checklist in Appendix V of Schedule Y to the D&amp;C Rules.</td>
<td>All information in relation to clinical trial as set out in Appendix V of Schedule Y to the D&amp;C Rules including details regarding the right of the subject to claim compensation for any trial related injury or death.</td>
</tr>
</tbody>
</table>

Three tier committee for review of clinical trials on new chemical entities

- In accordance with the Supreme Court’s order dated January 3, 2013 in the Swasthya Adhikar PIL, the Ministry of Health and Family Welfare, Government of India (“MOHFW”) constituted the following 2 new committees for supervising clinical trials on new chemical entities (in addition to the New Drugs Advisory Committees (“NDACs”)/Investigational New Drugs Committee (“IND”) which presently evaluate application for new drugs):
  
  (i) An apex committee under the chairmanship of the Secretary, MOHFW, to take stock of new approvals and to supervise and monitor the conduct of clinical trials in the country; and
(ii) A technical committee to review the recommendations by the NDACs and IND committees and give inputs to the apex committee for supervising and monitoring the applications for clinical trials.

**Directions for monitoring clinical trial by the DCGI**

- The DCGI vide order dated April 26, 2013 directed all the CDSCO zonal offices to keep records of investigators and clinical trial sites (which fall under their jurisdiction) and to constitute an expert committee to conduct clinical trial inspection. Such expert committees are required to visit the clinical trial sites in their jurisdiction at least once a year to verify compliance with the regulatory requirements.

**Mandatory Audio-Visual Recording of the Consent**

- The MOHFW proposed an amendment to the D&C Rules vide notification dated June 7, 2013 to include the requirement of audio-visual recording of informed consent. Subsequently, the MOHFW by order dated November 19, 2013 decided that in all clinical trials (including global clinical trials), in addition to the requirement of obtaining written informed consent, an audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent, should be done while adhering to the principles of confidentiality. While the draft guidelines on “Audio-visual recording of informed consent process in clinical trial” have been issued by the MOHFW on January 9, 2014, *the D&C Rules have not been amended as yet to include the above provisions.*

**Contracts between Sponsor and Investigator/Contract Review Organisations**

- The DCGI has, by an order dated August 30, 2013, issued instructions directing that while making an application for undertaking a new clinical trial, the sponsor is also required to furnish the details of the contract entered into by the sponsor with the principal investigator/contract review organisations with regard to financial support, fees and payments in kind payable by the sponsor.

**Ranjit Roy Chaudhury Committee Report**

In the wake of concerns regarding the safety of clinical trial subjects and to streamline and strengthen the regulatory mechanism for clinical trials, the MOHFW constituted an expert committee, headed by Professor Ranjit Roy Chaudhury ("Roy Committee") vide its order dated February 6, 2013, with a mandate to formulate policy guidelines and standard operating procedures ("SOPs") for approval of new drugs, clinical trials and banning of drugs and fixed dose combinations. The Roy Committee released its report in July 2013, *inter alia*, dealing with issues pertaining to and recommending guidelines and SOPs for clinical evaluation of new drugs, clinical trials, post marketing surveillance ("PMS") of drugs, technical review committees, reorganisation of the CDSCO and constitution of a Central Accreditation Council for overseeing the accreditation of institutes, clinical investigators and institute ethics committees ("IEC"), etc. The government accepted and decided to implement various recommendations of the Roy
Committee including those on the conduct of clinical trials in accredited sites by accredited investigators with the oversight of accredited ethics committees – the government decided that since this was a long term measure requiring amendments to the D&C Rules, in the interim, the Quality Council of India (QCI) would be considered for creating a system for accreditation of investigators, ethics committee and clinical trial sites. The Roy Committee also recommended various measures for strengthening the clinical trial processes and for ensuring the safety of the trial subjects, such as – the measures requiring mandatory audio-visual recording of the subject’s consent, reporting of adverse effects and SAEs and payment of compensation in relation to such adverse effects, mandatory PMS for all drugs permitted to be marketed in India to generate additional information on treatment risks, adverse effects, serious adverse effects, benefits, the effect of the drug on various populations and any adverse events observed after its large-scale long-term use, etc.

Orders passed by the CDSCO

On the basis of the recommendations made by the Roy Committee, the CDSCO has passed the following orders:

- **Undertaking to market NCE in India:** In case Indians participate in global clinical trials of NCE(s) to be used for diseases prevalent in India, then sponsors/clinical trial applicants shall provide an undertaking to the CDSCO that after approval for the marketing of such an NCE/biological entity in the innovator country or in a well regulated developed country has been obtained, the sponsor will file an application to the CDSCO seeking approval for marketing of such drugs in India. After receipt of approval from the CDSCO, the NCEs shall be marketed in India speedily, preferably by production within India.

- **Waiver of clinical trial on Indian population:** In case of a national emergency, extreme urgency or an epidemic, for orphan drugs, for rare diseases and drugs indicated for conditions/diseases for which there is no therapy, clinical trials on Indian population may be waived for approval of new drugs, provided such drugs have already been approved outside India.

- **Approval of Academic Clinical Trial:** The Roy Committee deliberated on the issue regarding whether the same yardstick (for approval process as well as payment of compensation) that is applicable to ‘commercial’ research, i.e., pharmaceutical company driven research, should be applied to academic research (i.e., non-pharmaceutical company related research) conducted by medical colleges and research institutes. However, the Roy Committee opined that the subjects should be entitled to the same compensation irrespective of the nature of the research. The government should levy a cess and create a fund which should be made available to the academic researchers/institutions from where such compensation can be paid. The Roy Committee also recommended that in order to simplify the approval process, academic clinical research may be approved by the institutional ethics committee without further approval from the DCGI. However, if a new drug is being evaluated or a new use for an existing drug is being evaluated, then approval of the DCGI shall be needed as per the D&C Rules. The CDSCO, in
No drug can be approved for marketing in India unless and until some, if not all, phases of clinical trials are conducted in India.

turn, has accepted the Roy Committee’s recommendation regarding the simplified approval process (but the recommendation regarding the creation of the compensation fund has not been ordered by the CDSCO so far).

- **Ancillary care to clinical trial subjects**: In case the clinical trial subjects are suffering from any other illness during the conduct of a clinical trial, then ancillary care should be provided to them in the same hospital/trial site, wherever required.

- **Compensation for injury or death discerned at a later stage**: In case any drug related anomaly is discerned at a later stage and accepted to be a clinical trial related injury or death, then the sponsor/manufacturers/clinical trial applicants shall provide compensation to the clinical trial participant or their nominee, as the case may be.

- **Clinical trial on Medical Devices**: The procedure for clinical trials of medical devices in relation to the approval, accreditations of investigators, sites, ethics committee, etc., shall be similar to the clinical trials of new drugs/vaccines.

- **Limitation on number of clinical trials**: The number of clinical trials an investigator can undertake shall be commensurate with the nature of the trial, facility available with the investigator etc., and shall not exceed 3 trials at a time.

- **Procedure for review of clinical trial applications**: The new ‘drugs advisory committee’ shall be renamed the ‘subject expert committee’. Application of clinical trials and new drugs shall be initially evaluated by the subject expert committee and it shall send its recommendations to the technical review committee. The technical review committee shall be constituted under the Directorate General of Health Services consisting of experts from various areas such as clinical pharmacology, regulatory clinical toxicology, etc. Thereafter, the apex committee shall grant its approval for clinical trials and new drugs based on recommendations of the technical review committee.

**Proposed Changes**

The pharmaceuticals and healthcare industry is dynamic with fast growing and changing needs. The D&C Act, on the other hand, is a relatively old piece of legislation (having been enacted in 1940). With improvements in technology and healthcare requirements, there is need for a regulatory framework that both strengthens and better facilitates the regulatory framework and processes, particularly in respect of clinical trials. Accordingly, certain amendments to the D&C Act have been proposed with the Drugs and Cosmetics (Amendment) Bill, 2013 (‘2013 Bill’) being the most recent bill to have
been introduced in the Parliament. More recently, after the change in government at the centre in 2014, the 2013 Bill has been put on hold (status: pending) and a new draft amendment bill – Drugs and Cosmetics (Amendment) Bill, 2015 (“2015 Draft Bill”), was released in the public domain inviting comments from various stakeholders.

The Union Cabinet, by way of its Press Release dated June 22, 2016, has decided to withdraw the 2013 Bill. Keeping in view the objective of make in India, it has been decided to comprehensively review the existing law with two-fold objectives - to facilitate the ease of doing business and substantially enhancing the quality and efficacy of the products. The Ministry of Health and Family Welfare has, accordingly, undertaken an exercise at two levels: (i) to frame separate rules under the existing Act for regulating medical devices; and (ii) to bring out separate legislations for regulating medical devices and Drugs and Cosmetics.

A snapshot of the proposed amendments under both bills, referred above, is given below:

**2013 Bill**

The 2013 Bill was introduced by the then Health Minister, Ghulam Nabi Azad, to amend the D&C Act on August 29, 2013. The key proposed changes in the 2013 Bill with respect to clinical trials are as follows:

- **Introduction of definition of “clinical trials”:** The 2013 Bill proposed insertion of a definition for “clinical trials” in respect of drugs, cosmetics and medical devices for determining the safety, efficacy, tolerance or performance of each of them (as the case may be).

- **Introduction of separate chapters on clinical trials:** The 2013 Bill proposes to introduce detailed provisions in relation to permission for conducting clinical trials, registration of the ethics committee, record maintenance, penalty, etc., for ensuring safety, efficacy and quality in the conduct of clinical trials.

- **Key changes for regulation of clinical trials:** The following are the major changes proposed under the 2013 Bill for conducting and regulating clinical trials:

  (i) **Initiating or conducting a clinical trial:**

  - Permission of the Central Licensing Authority (being the DCGI) is required for initiating or conducting a clinical trial in respect of a new drug, an investigational new drug, medical device, investigational medical device or cosmetic or bioavailability or bioequivalence study of any drug in human subjects. It is important to note that as opposed to the D&C Act, the 2013 Bill defines the term “medical device” thereby extending the permission required to all medical devices and not restricted to only notified medical devices.

  - Further, registration with the Central Drugs Authority of India (to be constituted under the 2013 Bill) and approval of the ethics committee is required for initiating or conducting a clinical trial.

  - However, no permission from the Central Licensing Authority will be required to initiate or conduct any bioequivalence or bioavailability
study of an approved drug by government institutes, hospitals, autonomous medical or pharmacy institutions for academic or research purposes.

(ii) **Penalty provisions:**

- In case a person conducts a clinical trial on any drug, an investigational new drug, any medical device or an investigational medical device in contravention of the above, they shall be punishable with imprisonment ranging from 3 to 5 years with a fine extending to Rs. 10 lakhs payable to the participant or his legal heir, as the case may be. In case the conduct of such a clinical trial causes grievous hurt or death of a trial participant, the term of imprisonment shall range from 5 to 10 years and with a fine of not less than Rs. 25 lakhs. In case of a repeated offence, the convict will be punished with imprisonment ranging from 5 to 10 years and a fine of at least Rs. 30 lakhs. Similar penal provisions have been put in place for conduct of clinical trials with cosmetics without obtaining prior permission and registration and for conducting a clinical trial on any drug, an investigational new drug, any medical device, an investigational medical device or cosmetic in contravention of the conditions on which the permission has been granted under the relevant provision of the 2013 Bill.

- A prosecution under the 2013 Bill shall be initiated only on the complaint made by a Drug Control Officer or a Medical Officer appointed by the Central Drugs Authority, a gazetted officer of the Central Government authorised by the government, an aggrieved person or any recognised consumer association.

(iii) **Waiver of pre-clinical and clinical data requirements:** The Central Licensing Authority may, in public interest, abbreviate, deter or omit pre-clinical and clinical data requirements for approval of clinical trials of drugs indicated in life threatening, serious diseases or diseases of special relevance to the country.

(iv) **Injury or death during a clinical trial:**

- Whether an injury or death of a person in the course of a clinical trial has been caused due to the clinical trial shall be decided by the DCGI.

- The manner of providing medical treatment to a person who has been injured during the course of a clinical trial shall be prescribed.

- In case of injury or death of a person due to the clinical trial, the person conducting the trial shall be required to pay such compensation as may be decided by the DCGI or such authority as may be prescribed.

(v) **Ethics Committee:** The ethics committee comprising of at least 7 members (including 3 or more persons from medical field, 1 legal expert, 1 social scientist and 1 person from community having prescribed qualifications and experience) shall be registered with the Central Licensing Authority (being
the DCGI) and such registration will be valid for a period of 5 years. The functions of the ethics committee would include granting approval for the clinical trial protocol and other related documents, making a periodic review of the trial, on contravention of the terms of the approval – revoking its approval to a clinical trial for reasons to be recorded in writing and perform other prescribed functions and responsibilities. If the registration of an ethics committee is cancelled for failure to discharge its functions and responsibilities, then the members of the committee shall be disqualified from becoming a member of any other ethics committee for a period of 5 years.

Introduction of the Drugs and Cosmetics (Amendment) Bill, 2015 for public comments

The 2015 Draft Bill also has separate chapters on clinical trials with detailed provisions in relation to granting of permission for conducting clinical trials, registration of the ethics committee, record maintenance, penalty etc. The key changes proposed by the 2015 Draft Bill, in comparison to the 2013 Bill, are as follows:

- **Conduct of clinical trials:** No person, sponsor, clinical research organisation or any other organisation or investigator shall conduct any clinical trial in respect of a new drug, investigational new drug, notified category of new medical device and investigational new medical device, new cosmetic, bioavailability or bioequivalence study of new drug in human participants except under and in accordance with the permission granted by the Central Licensing Authority (being the DCGI) and approval of the ethics committee. The 2015 Draft Bill has watered down this provision to only include *notified category of medical devices*. Further, the requirement of *registration with the Central Drugs Authority of India* has been dispensed with. The penalty, in respect of the conduct of the trial in contravention of the above, has also been *significantly watered down*, in as much as the penalty provision is now for *either* imprisonment or fine as compared to *both* imprisonment and fine provided for under the 2013 Bill. Further, the compensation in the aforesaid cases will not be payable to the trial participant.

- **Rules to prescribe further details:** The authority for determining and the manner of ascertaining whether an injury or death of a person in case of a clinical trial has been caused by a clinical trial or not, the manner of medical treatment and payment of compensation to a participant injured or disabled in a clinical trial and of the payment of compensation in case of death, shall be prescribed under the D&C Rules – under the 2013 Bill such matters were to be determined by the DCGI.

- **Ethics committee:** The constitution, registration, functions and responsibilities of the ethics committee are to be as prescribed – the 2013 Bill on the other hand contained specific provisions on these aspects. If the registration of an ethics committee is cancelled for failure to discharge its functions and responsibilities,
then the members of the committee shall be disqualified from becoming a member of any other ethics committee for a period of 2 years – as opposed to 5 years under the 2013 Bill.

The Way Forward

India’s diverse population makes it a key destination for conducting clinical trials. However, owing to soft enforcement of trial procedures and protocols, the industry has been plagued by instances of patient deaths owing to illegal trial practices. This has stirred the legislature which has since taken up the issue seriously. The Supreme Court has also established guidelines that need to be followed while conducting trials in India. The objective is to ensure patient safety and establish proper systems of trial monitoring, ethical practices and patient compensation. The move has been necessitated given that the immediate past, which has been chequered to say the least, has resulted in a number of clinical research organisations moving shop from India to other destinations, which has had significant economic repercussions.

The need of the hour is more stringent laws that impose increased obligations on all players to act with the utmost ethical integrity while conducting trials to ensure minimal patient fatalities and also prescribe penalties for violations of established trial requirements.

A dynamic industry such as the pharmaceuticals industry needs a constant boost for innovation. While the government has shown its affinity to promote clinical trials by setting up an effective framework, what remains to be seen is how effectively the regime enshrined in the D&C Act and the D&C Rules is implemented and whether this change makes India a preferred choice for carrying out clinical trials.

While it is important to have robust laws governing clinical trials, given the potential growth of the pharmaceutical industry and more generally - the healthcare sector in India, it is vital to ensure that the regulatory framework is nuanced so as to ensure smooth running of the business, without imposing onerous conditions which may plague the industry with red-tapism, acting as a deterrent for the sector as a whole.

As a final take away, it is absolutely imperative that perhaps a refurbished 2013 Bill, see the light of day as the amendments therein, along with the Supreme Court’s directives, adequately cover the need of the hour – a proper system in place for monitoring clinical trials, compensation to patients and overall ethical trial practices to be followed. Till such times as these systems are not put in place, India will have to continue to lose out on revenues that clinical trials bring into the country.
Medical Devices in India

Key industry sector
Growing faster than the pharmaceutical industry
The Indian medical device industry is, according to a recent FICCI report, currently valued at USD 2.5 billion and contributes a mere 6% of the USD 40 billion Indian healthcare sector (of which the medical device industry is a subset). The medical device industry is growing at a faster annual rate of 15% as compared to the annual growth rate of 10%-12% of the healthcare sector.

Why this growth?

- Increased public spending on healthcare
- Many health insurance plans now cover medical devices
- Increase in industry investments in healthcare
- Increased disposable incomes – more and more people can now afford quality medical devices
- Increased availability

No specific definition
Is it a device or is it a drug?
The term ‘medical devices’ has been covered under the definition of the term “drug” as has been defined in the Drugs and Cosmetics Act, 1940 (“Act”) read with the Drugs and Cosmetics Rules, 1945 (“Rules”).

Section 3(b)(iv) of the Act includes certain devices under the definition of a drug stating:

“(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board”.

As the above definition indicates, medical devices that are notified and identified so by the Indian Ministry of Health and Family Welfare (“Ministry”) have to be so identified and notified as a drug under Section 3(b)(iv) of the Act.

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1 The medical devices and equipment industry, available at: http://www.ficci.com/sector/76/Project_docs/Medical_Devices_and_Equipment_Sector_profile.pdf, last accessed on May 13, 2016.
As of date hereof, the Ministry has identified the following devices as “drugs” under Section 3(b)(iv) of the Act:

- Disposable Hypodermic Syringes
- Disposable Hypodermic Needles
- Disposable Perfusion Sets
- Cardiac Stents
- Drug Eluting Stent Catheters
- In vitro Diagnostic Devices for HIV, HBsAg and HCV
- I.V. Cannulae
- Bone Cements
- Heart Valves
- Scalp Vein Set
- Orthopaedic Implants
- Internal Prosthetic Replacements
- Intra Ocular Lenses
- Ablation Devices

In addition, the following products are regulated as “drugs” under the Act and Rules:

- Blood Grouping Sera
- Ligatures, Sutures and Staplers
- Intra Uterine Devices (Cu-T)
- Condoms
- Tubal Rings
- Surgical Dressings
- Umbilical Tapes
- Blood/Blood Component Bag

The industry is largely unregulated given that there exist no specific regulations that expressly identify an approval and compliance/regulatory pathway for medical devices. This is largely owing to the ambiguity that arises given the grey areas that the current definition (or absence thereof) creates.

There exists ambiguity regarding the regulatory regime applicable to devices that have not been so expressly classified. Medical device manufacturers are often faced with the dilemma as regards applicability of existing regulatory pathways for approval. Given this ambiguity, an inference could be drawn that medical devices that are not specifically identified and notified by the Government do not fall under the definition of “drug” as above and consequently there is nothing under the Act which would appear to hinder import or marketing of medical devices that are not expressly identified and notified by the Government. Of course, existing laws pertaining to import (customs laws) would apply. In fact, in the wake of the prevailing ambiguities, the Central Drugs Standard Control Organisation (“CDSCO”) (Medical Device and Diagnostic Division), Ministry has issued an Office Order dated July 9, 2014\(^3\) clarifying that “any devices other than above do not require any registration, license, permission or NOC for their import or manufacture, sale and distribution so far as the provisions of the Act and Rules are concerned” (“CDSCO Clarification”).

Currently if a device falls under the category of notified devices, the Act would regulate import, manufacture, distribution, quality control and sale of the same. However, the absence of a comprehensive and all encompassing regulatory regime is a key drawback

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that currently plagues the industry notwithstanding the aforesaid clarification issued by the CDSCO.

**FDI in the Medical Devices Industry.**

*Aggressive outlook.*

The Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, Government of India ("DIPP") has recently permitted 100% foreign direct investment ("FDI") in the medical devices industry (both Greenfield and Brownfield ventures) whereby manufacturers in India will be able to bring in FDI through the automatic route.\(^4\) This is a move away from the previous inclusion of medical devices under the umbrella of drugs where 100% FDI was allowed through the automatic route in new (Greenfield) projects only and FDI in existing ventures (Brownfield) was permitted only with prior approval of the Government. Thus, the DIPP has expressly carved out the medical device industry from the pharmaceutical industry in making 100% FDI permissible through the automatic route. Medical instruments, diagnostic tools and clinical implants have been included in the identified categories for this purpose. This has been interpreted as an attempt by the Government at promoting local manufacturing of these products as part of the Government’s ‘Make in India’ initiative. The move by the Government has been met with both aplomb as well as speculation. Whether this initiative will actually give the intended boost to local manufacturing or whether it results in foreign manufacturers and established international players setting up shop here in the form of subsidiaries, only time will tell.

This is a clear indication of the Government’s intent to remove the medical device industry from the larger aegis of the pharmaceutical industry.

**Regulatory Authority: Central Drugs Standard Control Organization.**

*Guidelines formulated.*

The CDSCO is the central regulatory authority that is responsible for regulating (notified) medical devices in India. State Governments are responsible for state level regulation. Enforcement is achieved through the office of the Drugs Controller General of India and state level Drug Controllers located at various state level drug authorities.

As set out above, the CDSCO has issued specific guidelines that pertain to identified devices. While these are at best guidance documents, they may be considered as an outline of the pathway for future medical device regulation in the country, an indicative guidance regarding the direction which the CDSCO is likely to take in establishing its import and registration requirements for medical devices in the future.

Import of Medical Devices.

*If not a drug then only import regulations apply.*

Registration and import licenses are subject to the control of the Central Government and extant legislations that regulate such imports.

Registration and import license requirements under the Act are limited to medical devices that are included in the above noted classification as “drugs”. To the extent that a device is not identified and notified, the best inference drawn would be that such device would not come under the definition of “drug” as defined under the Act and as such regulatory requirement would not apply. It may, however, be noted that, if a device is, at a later date identified as a medical device, falling under the definition of the term “drug”, vide a Central Government notification to that effect; in such a scenario, the applicability (retrospective or prospective) of such notification would be based on the text of such notification and as such regulatory approval could very possibly be required at that time. There is usually a grace period given in case applicability of a notification is retrospective in nature.

Marketing and Distribution Licenses.

*Subject to applicability of extant regulations.*

Marketing and distribution licenses are subject either to the control of the State or Central Government, depending on specific circumstances.

Part VII of the Rules deals with license requirements for the “Manufacture for sale or for distribution of drugs other than homeopathic medicines.” Relevant licenses are applied for under Form 20 (Rule 61(1)) and Form 24 (Rule 69(1)(c)) of the Rules. However, if a device does not fall within the category of devices that have been classified as a “drug”, then in view of the CDSCO Clarification it can be concluded that these requirements will not apply. However, it may be kept in mind that if a device is at a later date identified as a medical device hence falling under the definition of the term “drug” vide a Government notification to that effect, in such a scenario, the prospect or retrospect applicability of such notification would be based on the text of such notification and as such regulatory approval could very possibly be required.

Proposed Law.

*Medical Devices Regulation Bill, 2006.*

Given the ambiguity that exists regarding the regulatory landscape as applicable to medical devices, the Medical Devices Regulation Bill was proposed in 2006 (“2006 Bill”). The proposed 2006 Bill, Specifically defines the term ‘Medical Instrument’ to be covered under this ambit. The 2006 Bill effectively seeks to regulate medical devices in general. A proposal has been made therein as regards establishing a separate regulatory authority that would deal with approvals for medical devices. The 2006 Bill is currently pending in Parliament.
Proposed Amendments to the Act.

Drugs and Cosmetics (Amendment) Bill, 2015.

A draft of the Drugs and Cosmetics (Amendment) Bill, 2015 (“2015 Draft Bill”) contains proposed amendments. An attempt has been made to expressly define medical devices and bring the same in line with the Global Harmonization Task Forces (“GHTF”) definition of medical devices. The 2015 Draft Bill introduces provisions for clinical trials and increased regulation of medical devices. The 2015 Draft Bill also envisages the establishment of: (a) hierarchical structure of regulatory bodies; and (b) strict legal action for any contravention.

Key Industry Associations.

Fighting the cause.

- Association of Indian Medical Device Industry
- Association of Diagnostics Manufacturers of India
- Society for Biomaterials & Artificial Organs (India)
- National Biomedical Engineering Society
- Medical Surgical and Healthcare Industry Trade Association

Conclusion

If a device is not included within the definition of a “drug”, the provisions of the Act and Rules would not apply as far as regulatory requirements under the Act and Rules are concerned.

However, if the proposed revisions to Schedule M-III5 (under Rule 76 of the Rules – which specify the Quality Management System – For Notified Medical Devices and In-vitro Diagnostics), result in enlarging the scope of the definition of drugs under the Act to include additional devices, we would see greater controls being exercised on medical devices. While these amendments would certainly give much needed clarity, the same are still in their nascent stages and will only be applicable if and when they are notified in the Official Gazette of India or otherwise form a part of a suitably titled law.

Till then the current status quo remains and the industry can view this attempt at enlarging the scope of medical devices falling within the category of “drugs” as indicative of where the Government and the industry might be headed when it comes to regulations affecting medical devices in India.

Unless the law becomes clear, non-notified medical devices continue to enjoy their special status and import of such devices (that are not notified) is free from regulatory hurdles (pursuant to the registration and other requirements) under the Act and Rules. However, there have been cases where customs officials, at the port of entry in India, not aware of the exact regulatory status of devices in question have withheld consignments in exercise of their powers of seizure for want of more information as regards the regulatory status of the device at the time of import. Therefore, the emergent need of the hour is more clarity on what constitutes a medical device and proper dissemination of such information to all concerned authorities.

5 Quality management system for notified medical devices and in-vitro diagnostics available at: http://cdsco.nic.in/writereaddata/Revised%20Schedule%20MIII%20as%20per%20ISO%2013485%20%5B%20IIS%2015579%5D%20D.pdf, last accessed on: May 13, 2016.
The Indian Pharmaceutical Industry and Patents

The pharmaceutical industry derives impetus from research and innovation. With the increase in the number of players in the pharmaceutical market, the need to protect such research and innovation from potential misuse has exponentially increased. The pharmaceutical industry is also an intensively scrutinized and regulated industry owing to its impact on public health. Consequently, while on one hand, patent law has been an important tool in the hands of the pharmaceutical industry to protect inventions, on the other hand, it has been a subject matter of numerous policy decisions and interpretations to balance the interest of big pharmaceutical companies vis a vis the vested public interest in the industry.

TRIPS Agreement

The agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") was one of the most contentious issues in the Uruguay Round of multilateral trade negotiations. TRIPS was concluded among 125 nations, including India, in April 1994 at Marrakesh and covers copyrights, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits, and trade secrets. TRIPS was signed with a view to reduce impediments to international trade, promote effective and adequate protection of intellectual property rights and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.1

Signatories to TRIPS were required to enact domestic legislations and provide effective administrative infrastructure for the protection of intellectual property as part of implementation of the provisions of TRIPS. India became a signatory to the TRIPS in 1994 and ratified it in 1995. India, being a developing country, received the benefit of Article 65 of TRIPS, which enabled it to bring certain amendments (relating to product patents) in consonance with the TRIPS agreement in 10 years. The Patents Act, 1970 ("Patents Act") of India was subsequently amended to include the standards laid down by TRIPS.

Introduction of the compulsory licensing regime: The Patents (Amendment) Act, 2002

The Patents (Amendment) Act, 2002 brought about a number of changes in the Patents Act including:

- 20 year patent term;

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1 Preamble to TRIPS
• 48 months time given (from priority date) for filing a request for examination;
• provisions relating to working of patents;
• compulsory licensing; and
• introduction of Section 104A to the Patents Act which cast the burden of proof on the defendant to establish non-infringement in suits concerning infringement.

Grant of product patents in India: The Patents (Amendment) Act, 2005

The Patents (Amendment Act), 2005, which was brought into force from January 1, 2005, brought out the following significant amendments to the Patents Act:

• product patents in the areas of drugs and pharmaceuticals;
• introduction of Section 3(d) to the Patents Act which imposed additional restrictions on patentable subject matter and rendered un-patentable a new form of a known substance sans enhancement of efficacy, discovery of a new property or new use of a known substance or known process, machine or apparatus, unless such known process resulted in a new product or employed at least one new reactant;
• requirements of submission of biological material (if it cannot be described in accordance with the stipulations in Section 10(4)(a) and (b) of the Patents Act and if such material is not available to the public) to an international depository;
• pre-grant oppositions; and
• requirement of assignments to be in writing and duly executed.

The Patents (Amendment) Act, 2005 was perhaps the single most important amendment in as far as the pharmaceutical industry is concerned. As set out above, it not only extended protection to product patents (only process patents were covered previously) but also imposed additional restrictions on what was un-patentable. Section 3(d) of the Patents Act was perceived as perhaps the single most dramatic addition, which in a way prevented evergreening in the pharmaceutical space – a move that has often been seen as being favourable to generics. It is interesting to note that apart from India, other countries like Brazil, South Africa, Australia, and Thailand have safeguards against evergreening.

Overview of the Patents Act – Important Provisions

• Section 2 of the Patents Act: Inventions that are new and novel, possess an inventive step and have industrial application are patentable.

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2 Introduced in accordance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure is an international treaty signed in Budapest, Hungary, on April 28, 1977 to which India acceded on September 17, 2001.
3 Attempts to obtain extra patent protection on variations of the original drug, such as new forms of release, dosages, combinations or variations, or new forms of previously patented drugs.
4 An invention is considered as new and novel if it is not anticipated by prior publication, prior use or prior public knowledge.
5 Having technical advancement
Section 3 of the Patents Act: In terms of Section 3 of the Patents Act, the following inventions are not patentable:

- Contrary to public order or morality or prejudicial to human, animal or plant life or health or to the environment.
- A scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature.
- A new form of a known substance which does not result in the enhancement of the known efficacy of the substance, new property, new use, mere use of a known substance, mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.\(^6\)
- Combination inventions, where a particular substance results from a simple mixture of properties of known components, the resulting substance or the process of producing the resulting substance would not be patentable. However, where such properties show a combined effect that is beyond the expression of their individual effects, functionally linked to each other, the same may be patentable.
- Methods and process of administering medicines orally, intravenously, topically or trans-dermally. Surgical, curative, prophylactic, diagnostic (methods of diagnosis of diseases by investigating history and symptoms and by applying tests) and therapeutic prevention as well as methods of treatment or cure of disease.
- Plants and animals in whole or in part, seeds, animal/plant species or varieties\(^7\) and biological processes for production or propagation of plants and animals.
- Traditional knowledge.

A plain/simple reading of Section 3 of the Patents Act shows that it places significant emphasis on efficacy. Absent proper proof of the same, the matter would be rendered un-patentable. In an attempt to prevent *evergreening* of patents, the law as it stands today does not allow patents for minor modifications to existing forms and thereby prevents undue monopoly afforded to industry players as a result of such extended period of patent protection. The aforesaid provision, which has catapulted India to notoriety in the international area and has emerged as a bone of contention with multinational corporations, aims to strike a balance between patent protection afforded in the pharmaceutical industry with the growing need to provide access to affordable medicines and healthcare services to members of the general public.

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\(^6\) Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

\(^7\) Plant varieties are provided protection in India under the provisions of the 'Protection of Plant Varieties and Farmers' Rights Act, 2002.
Section 84 of the Patents Act: compulsory licensing

A compulsory license is an authorization given by the Government to a third party (not necessarily being the patent holder), whereby such third party is granted permission to make, use, or sell a product that is covered by a granted patent. The objective of inclusion of this provision in the Patents Act (as drawn from TRIPS) is to:

- Prevent abuse of a patent whereby the patentee misuses its monopoly to the detriment of the general public;
- Address growing public health concerns regarding easy availability and affordability of life-saving drugs; and
- Provide for drugs at cheap prices where requirement of such drugs is dire.

A compulsory license can be obtained under an application to the Controller of Patents after expiry of three years from the date of grant of the patent. Any interested person can make the same. The application for grant of a compulsory license can be made on any of the following grounds:

- Reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- The patented invention is not available to the public at a reasonably affordable price, or
- The patented invention is not worked in the territory of India.

In addition to the above, the Central Government can also *suo moto* issue compulsory licenses under Section 92 of the Patents Act in cases of either a “national emergency” or “extreme urgency” or in cases of “public non-commercial use”.

A longstanding topic of controversy in the industry remains that despite existing provisions pertaining to compulsory licensing, such licenses have not been issued as liberally as might have been required.

Cases under the Patents Act: Aids to interpretation

Case laws act as an important tool to interpret various provisions of a statute. We have set out below some of the key judgements of Indian Courts which have touched upon some of the important aspects of the Patents Act. These judgements have been followed closely by the international as well as the domestic drug manufacturers.

1. The Gleevec Case: Novartis AG v. Union of India

The Gleevec case, which set the law on patentability, is considered the “mother of all pharmaceutical patent litigations in India”. This tested Section 3(d) of the Patents Act. The Supreme Court, while examining the patent application filed by Novartis AG claiming the beta-crystalline form of Imatinib Mesylate (used in the treatment of multiple cancers, most notably Philadelphia chromosome-positive chronic myelogenous leukaemia) held as follows:
- **Novelty:** In case an invention if it is not novel, it is not patentable. Accordingly, a beta-crystalline form of a free base which did not offer any enhanced efficacy properties was the same substance as the patented form and as such, was unpatentable under Section 3(d) of the Patents Act.

- **Efficacy:** In case an invention as claimed was merely a *new form of a known substance*, one that did not result in any enhancement of *efficacy*, it is not patentable. Since the term efficacy was not defined in the Patents Act, the Court, based on the dictionary meaning of the term, observed it to be “*the ability to produce a desired or intended result*”. Further, the Court held that the test of efficacy depends “*upon the function, utility or the purpose of the product under consideration*”, thereby interpreting *efficacy* as *therapeutic efficacy* in cases of medicines, whose function is to cure disease. However, the exact scope of therapeutic efficacy has been left as an open issue to be dealt with in successive litigations.

The parameters for proving enhanced therapeutic efficacy in case of drugs would be subject to a narrow and strict interpretation of Section 3(d) of the Patents Act. Reliance was placed on the explanation included in the said Section wherein derivatives were required to differ in properties with regard to efficacy. The Supreme Court held that the *new form of a known substance, in order to pass the muster of enhanced efficacy under Section 3(d) of the Patents Act, needs to have glaring beneficial properties over the known substance*. Additional properties such as improving storage, workability in terms of processing and inherent pharmacological properties do not qualify as therapeutic efficacy. *An increase in bioavailability can be looked as enhancement of therapeutic efficacy if such increase is evidenced by research data.*

- **Incremental innovation:** The Supreme Court also observed that even though efficacy is subject to strict interpretation, *the same would not imply a bar on all incremental inventions of chemical and pharmaceutical substances.*

2. **The Tarceva - Erlotinib case: F. Hoffman- LA Roche Ltd. and Another v. Cipla Ltd.**

This was India’s first pharmaceutical patent infringement ruling in the post-TRIPS era. The case was decided on merits of public policy and technicalities. The case involved the patent granted to F. Hoffman- LA Roche Ltd. (“Roche”) (jointly with Pfizer), which covered Erlotinib (used to treat non-small cell lung cancer, pancreatic cancer and several other types of cancer) in its base form and manufacture and sale of a generic version of the same in India by Cipla Ltd. (“Cipla”).

- **Refusal to grant an interim injunction:** The plea for grant of an interim injunction by Roche was rejected as *an interim injunction would impede access of the life saving drug to the public at large.*
Public interest: While according greater importance to public interest, the Delhi High Court held that the requirements of the public in terms of accessibility to life saving drugs trump the requirement of an injunction in favour of Roche.

Insufficient disclosure: Failure of Roche to inform the Controller of a second application filed by it claiming the polymorph B form of Erlotinib during prosecution of the patent in the suit, made Roche guilty of insufficient disclosure. Roche was required to make a proper disclosure that the patent in suit covers the drug in question and further the effect of other related applications that could have an effect on the claims made with respect to the patent being contested.

Challenge and counter claim to be decided by trial: As Roche was not able to make out a prima facie case in its favour and the ownership of the patent was challenged by way of a counter claim as regards its validity, the same was directed to be decided by way of a proper trial.

Outcome of the trial: The patent obtained by Roche for Erlotinib in its base form was held to be valid. The judge held that there was no infringement on part of Cipla given that the version marketed by Cipla, as Erlocip was essentially the polymorph B form of Erlotinib, on which no patent right existed in favour of Roche as its patent application claiming this polymorph B had previously been rejected.

Mediation and aftermath: Subsequently, both parties appealed against the order of the single judge. In April 2014, the Delhi High Court ordered both parties to engage in mediation with a view to settle their disputes. This was a first of its kind reference to mediation in pharmaceutical patent cases. In November 2014, mediation talks were reported to have failed. The said matter has now been decided by the Hon’ble High Court of Delhi.

Outcome of the Appeal: The Division Bench delivered its decision on November 27, 2015. The bench reversed the dismissal of Roche’s infringement claims, upheld the dismissal of Cipla’s counterclaim and further imposed costs of Rs. 5,00,000/- on Cipla. The bench did not award any injunction against Cipla given that the patent term was to expire in March, 2016. Cipla was however asked to render accounts to Roche (the Suit was restored for that purpose.

Infringement by Cipla: The court upheld the validity of Roche’s patent as the court found that the patent contained a broad claim that was not limited to any polymorphic version of the claimed compound. The court held that, any and all forms of this compound would be covered by the patent as they would fall under the broad claims of Roche’s patent. The court also held that manufacture of a polymorph would entail manufacture of the patented product as an intermediary step. It was not possible to avoid infringing on this count.
5 step test for Obviousness: The court has laid down its proposition of law pertaining to Section 3(d) of the Patents Act (the said section prohibits patent grant to new forms of known substances). The judgment lays down a 5 step test for Obviousness that needs to be conducted to determine lack of inventive step:

i. The various ways that others sought to solve the problems existing;
ii. The types of problems encountered;
iii. The rapidity with which new inventions are made in this art;
iv. The sophistication of the technology involved; and.
v. The educational background of those actively working in the field.

A 16 step test for assessing infringement: The court held that in assessing infringement, the product has to be compared with the claims of the patent. A 16 step test has been laid down for assessing infringement in this case. The product has to be compared with the claims of the patent. Principles of claim construction could be summarized as under:

i. Claims define the territory or scope of protection.
ii. There is no limit to the number of claims except that after ten claims there is an additional fee per claim.
iii. Claims can be independent or dependent.
iv. The broad structure of set of claims is an inverted pyramid with the broadest at the top and the narrowest at the bottom.
v. Patent laws of various countries lay down rules for drafting of claims and these rules are used by Courts while interpreting claims.
vi. One rule is that claims are a single sentence defining an invention or an inventive concept.
vii. Different claims define different embodiments of same inventive concept.
viii. The first claim is a parent or mother claim while remaining claims are referred to as subsidiary claims.
ix. If subsidiary claims contain an independent inventive concept different from the main claim then the Patent office will insist on the filing of a divisional application.
x. Subject matter of claims can be product, substances, apparatus or articles; alternatively methods or process for producing said products etc. They may be formulations, mixtures of various substance including recipes. Dosage regimes or in some countries methods of use or treatment may also be claimed.

10 Section 10(4)(c) of the Patents Act, 1970
11 1st Schedule of the Act
12 Manual of Patents Office Practice and procedure
xi. Where claims are dependent it incorporates by reference everything in the parent claim, and adds some further statement, limitations or restrictions.\textsuperscript{13}

texthelp

xii. Where claims are independent although relating to the same inventive concept this implies that the independent claim stands alone, includes all its necessary limitations, and is not dependent upon and does not include limitations from any other claim to make it complete. An independent Claim can be the broadest scope claim. It has fewer limitations than any dependent claim which is dependent upon it.\textsuperscript{14}

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xiii. For someone wishing to invalidate a patent the said person must invalidate each claim separately and independently as it is quite likely that some claims may be valid even while some are invalid.

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xiv. At the beginning of an infringement action the Courts in the United States conduct what is known as a “Markman hearing” to define the scope of the claims or to throw light on certain ambiguous terms used in the claims. Although this is not technically done in India but functionally most Judges will resort to a similar exercise in trying to understand the scope and meaning of the claims including its terms.\textsuperscript{15}

xv. The parts of the claim include its preamble, transition phrase and the body. The transition phrase includes terms like:- (a) Comprising; (b) Consisting; (c) Consisting essentially of; (d) Having; (e) Wherein; (f) Characterized by; Of these terms some are open ended, such as comprising which means that if the claim contains three elements A, B and C it would still be an infringement for someone to add a fourth element D. Further some terms are close ended such as consisting of, i.e. in a claim of three elements, A, B and C a defendant would infringe if he has all three elements. In case the defendant adds a fourth element D he would escape infringement.

xvi. Each claim has a priority date so that in a group of claims in a specification you could have multiple priority dates. This only means that if a patent application with certain priority date and claims was followed by another application with different claims and different priority dates, then if they were consolidated or cognate with another application, each claim would retain the original priority date.\textsuperscript{16}

\textsuperscript{13} Landis on Mechanics of Patent Claim Drafting.
\textsuperscript{14} Landis on Mechanics of Patent Claim Drafting.
\textsuperscript{15} In the case of (52 F3d 967 also 517 US 370) Herbert Markman Vs Westview the Courts held that an infringement analysis entails two steps—(a) First step is to determine the meaning and scope of the patent claims asserted to be infringed. (b) Second step is to compare the properly construed claim with the device accused of infringing.
\textsuperscript{16} Section 11(1) of the Patents Act, 1970.
3. **The Sitagliptin Case: Merck Sharp and Dohme Corporation and Others v. Glenmark Pharmaceuticals Ltd.**\(^1\)

This case marks the move of pharmaceutical patent litigation between innovators and generics from anti-cancer and anti-retroviral drugs to anti-diabetes drugs. It involved Merck Sharp and Dohme Corporation ("Merck") alleging infringement of its patented drug Sitagliptin (used for treatment of diabetes mellitus type 2) by Glenmark Pharmaceuticals Ltd. ("Glenmark") which was selling the generic equivalent of Sitagliptin under the brand names Zita and Zitamet.

- **Prima facie case:** The division bench of the Delhi High Court noted that Merck had established a strong prima facie case on merits. The Court found that Glenmark was using Sitagliptin in a free base form. Glenmark’s argument that Sitagliptin Phosphate Monohydrate could be manufactured directly and without using the free base form of Sitagliptin, did not find favour with the Court.

- **Public interest:** The Delhi High Court looked into public interest before granting the injunction and if the injunction would reduce the access to drugs. *Given that the price difference between the two drugs was not much and as there was no reason to assume that an injunction would deny access to cheaper drugs to the public for the treatment of diabetes, the Court allowed the injunction.*

- **Strong case of infringement:** The Court considered whether public interest can be overlooked in maintaining the integrity of the patent system itself, so that a legitimate monopoly is not distorted. The Court held that *where a strong case of infringement is established, there is an interest in enforcing the Patents Act.* The Court noted that even though the loss of sales can be compensated monetarily ultimately if the patentee prevails, a closer look at the market forces reveals that the damage can in some cases be irreparable.

- **Interim arrangement securing interest of both parties:** As Merck stated that it would compensate Glenmark for loss of earnings if the suit were to be dismissed, the Delhi High Court observed that Glenmark, if successful, will be able to return to the market without any handicap and will be compensated at market value for the period for which it was excluded.

- **Appeal in the Supreme Court:** Subsequently, Glenmark appealed to the Supreme Court of India and the operation of the injunction order was stayed. Recently, the Supreme Court allowed Glenmark to sell its existing stock of Zita and Zitamet, but, restricted it from processing any unfinished formulation of Sitagliptin Phosphate Monohydrate (SPM) 3.

- **Supreme court observation:** This matter is of particular interest given that *the Supreme Court has expressed a desire that highly contested commercial cases require immediate attention and disposal to ensure a suitable commercial environment which is vital to national interests.* This is perhaps the only pharmaceutical patent matter where the Supreme Court had exercised its

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\(^1\) MANU/DE/2963/2015
jurisdiction under Article 142 of the Constitution of India and has set timelines for the recording of evidence and hearing of arguments at the trial stage.

4. The Compulsory licensing saga: Natco Pharma Ltd. v. Bayer Corporation

This is arguably the first and most prominent case where the compulsory licensing regime, as set out under Section 84 of the Patents Act, was thrown into prominence. The compulsory license for the anti cancer drug Sorafenib Tosylate, marketed by Bayer Corporation (“Bayer”) under the brand name Nexavar, was granted to Natco Pharma Ltd. (“Natco”) on a non-exclusive, non-assignable basis and Natco was required to pay 6% royalty to Bayer. The said judgment was on account of satisfaction of the following grounds on which compulsory licensing can be granted under Section 84 of the Patents Act:

- **The reasonable requirements of the public with respect to the patented invention have not been satisfied:** In the statement of working of patents filed by Bayer, it was declared that only 200 bottles were imported during 2008-2010 into India while there were approximately 23,000 patients of kidney and liver cancer requiring treatment in India.

- **Non availability of the patent invention to the public at a reasonably affordable price:** The Controller held that both the public and the patentee were not variables in the reasonableness calculation and “reasonable and affordable price” has to be construed primarily with reference to the public. While the public at large was divided into various strata, Bayer should have priced the drug at price points catering to such varied strata of the public.

- **Not working in the territory of India:** Bayer was not manufacturing the drug in India but was merely importing limited quantities of the same. *Mere importation cannot amount to ‘working’ of a patented product for the purposes of the Patents Act.*

Bayer’s appeal against this order was dismissed. The topic of compulsory licensing has been the centre of extensive debate ever since this first case came to light and India’s first compulsory license was granted after protracted and complex litigation.

5. The Onbrez litigation: Novartis AG v. Cipla Ltd.

This is a case where a generic manufacturer tried to get the Government to revoke the patent under Section 66 and 92 of the Patents Act on grounds of failure to work the patent, public interest, and high prices.

- **While Section 66 of the Patents Act relates to revocation of patents when the patent is exercised in a manner which is generally prejudicial to the public, Section 92(3) of the Patents Act deals with compulsory license under special circumstances.**

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18 Article 142 of the Constitution of India confers powers on the Supreme Court to pass such decree or make such order as is necessary for doing complete justice in any cause or matter pending before it.

19 Order No. 45/2013 (Intellectual Property Appellate Board, Chennai).

20 For the treatment of primary kidney cancer (advanced renal cell carcinoma), advanced primary liver cancer (hepatocellular carcinoma), and radioactive iodine resistant advanced thyroid carcinoma.

21 MANU / DE / 0019 / 2015
circumstances of national emergency, extreme urgency or public non-commercial use. Cipla’s request to revoke the patent was rejected by the Ministry as a compelling case for revocation was not made.

- Novartis AG sued Cipla alleging infringement of its Indaceterol (used for treatment of chronic obstructive pulmonary disease) patents. The Delhi High Court granted a temporary injunction against Cipla. It applied the principles laid down in *F. Hoffman- LA Roche Ltd. and Another v. Cipla Ltd.*, and observed that, “...if there is a strong prima facie case and the validity is not further seriously questioned, then there is a clear way out to grant injunction.”

- Taking note of Cipla’s acts of launching their generic version while the application to the Ministry was still pending, the Court observed that a mere citation of the grounds and conditions for grant of a compulsory license did not give Cipla the right to infringe on the patents held by Novartis AG, till such time the patents are valid. The Court took the view that patent rights being statutory rights, the same cannot be nullified by virtue of Section 48 of the Patents Act (which pertains to rights of patentees), while they are valid.

- Cipla challenged the order of the learned single judge before a division bench of the Delhi High Court. The matter is pending. We understand that Cipla’s offer to pay reasonable royalty to Novartis, has been rejected.

**Conclusion: A long path traversed. A longer path ahead. Questions remain.**

Though patent law in India has existed over the years, jurisprudence related to pharmaceutical patents, especially in the pharmaceutical industry, is still developing. From granting product patents, to specifically identifying patentable subject matter and incorporation of provisions for compulsory licensing, the law has come a long way since its inception. With India’s accession to TRIPS, a conscious effort has been made to ensure that our laws are TRIPS compliant.

While disputes between patent holders and infringers abound, Courts in India are getting increasingly sensitive to the complex and technical issues that form the pith and substance of complex pharmaceutical patent litigation. Patent litigation turns on expert opinion and evidence, which is often absent at the preliminary stages of litigation especially the preliminary and interim injunction stage and as such the practice of passing ex-parte interim injunctions has given way to a more rational and balanced
approach, wherein questions of *prima facie* infringement, balance of convenience of the parties and irreparable injury are weighed, analyzed and rationalized along with a larger public policy perspective. The Supreme Court has time and again insisted that patent matters should be handled on an expedited basis especially where issues of public health, access of life saving drugs and commercial interests are involved and that matters should head to trial.

With litigation on the rise, a new trend of mediation and arbitration has also emerged of late. Courts mindful of the severe socio-economic effects of injunctions and parties mindful of high costs of litigation and commercial pitfalls have started looking at alternate dispute resolutions methods such as mediation and arbitration to resolve issues in conflict. While this initiative is still in the nascent stage, it would be interesting to see what kind of settlements emerge and how these are viewed by authorities especially the Competition Commission of India. Are we headed in the same direction as the United States in terms of patent litigation, settlements, and Federal Trade Commission investigations as a sequence?

The Supreme Court’s judgment in the Novartis case has given rise to a general perception (of India amongst some of the developed nations of the world which house some of the big multinational corporation innovators) that India is no longer a country that respects and protects patent rights of innovators. India’s patent laws have at times been termed as anti TRIPS, while India has argued that it is fully TRIPS compliant and advocated against TRIPS PLUS provisions. India has done what any developing nation would do — amend its laws to comply with its international obligations under TRIPS to a degree whereby its compliance is exact. Not more, not less, but exact. India is TRIPS compliant in the background of the need to provide cheap and readily available drugs to the public at large. The move has been welcomed by most developing nations as they now look at India as an example of how domestic laws can be tweaked to ensure international compliance obligations whilst ensuring that domestic requirements are kept at a priority. This has caused many innovators to seriously rethink their India strategies and also take their woes to international forums where India’s presumed anti innovator patent regime has been subject matter of many debates. These debates continue at a national and international level and raise significant questions on the issue of balancing national interests against the backdrop of the current trend of economic reforms which are increasingly looking at attracting foreign investment into India. Will the Government’s push for increased foreign investment shadow its responsibility towards the citizens or will it tow a median path? A question that is pertinent.

Though India has been accused of enacting laws that are pro generic and anti innovator, the accusation is not largely true given that there have been instances where the Courts have supported the patent holder, however such cases have turned mostly on technicalities. The law is still developing and we can look forward to ground breaking jurisprudence from the Courts given that questions of law in many matters have still been left open. There is hope that the Courts would balance enforcement of statutory rights, socio-economic requirements and existing law with international obligations and the current push for greater investment in the industry. Whether the Courts will deliver on this or not, is a question that is waiting to be answered.
As a take home, the pharmaceutical industry should derive comfort from the fact that the genesis of the Patents Act in India is in consonance with international practices. Even though public interest and access to healthcare has become the mainstay of policy formulation and judicial interpretation, the balancing act of adopting international practices and standards for protection of patents and promoting innovation has gone a long way in maintaining India’s reputation of being the “Pharmacy of the World” and its international obligation and commitment of being a level player in a level playing field.
The Glivec Judgement - A case against Patent Ever greening

“Every country has to decide for itself what it wants and for India this is absolutely essential for the public and the patients of the country. You cannot allow monopolies to go on forever and ever and ever. There has to be a time limit and it got reflected in the judgement today. It certainly helps patients and public of India. There is no doubt about that.”

- Dr. YK Hamied, Chairman, Cipla

In April 2013, the Supreme Court of India rejected the plea of Novartis for patent protection for its anti-cancer drug sold in the name of Glivec or Gleevec. The judgment evoked extreme reactions. While some, like Dr. YK Hamied, greeted it as a landmark judgment which would make medicines more affordable, others such as originator pharmaceutical companies condemned it as harmful for innovation and foreign investment. With profits on one end of the scale and lives on the other, perspectives are easily polarised. However, innovation and access are supplementary when it comes to improving health and to chip away at either of these requires a clear understanding of the tradeoffs.

As discussed in earlier chapters, after India ratified the Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”) under the aegis of the World Trade Organisation (“WTO”), the Patents Act, 1970 (“Patents Act”) was amended to include the process patent regime with the product patent regime and increase the duration of patent period for drugs from 7 years to 20 years. India also introduced Section 3(d) to the Patents Act in 2005, which laid down the additional criteria of ‘enhanced efficacy’ to obtain a patent in India. It is this provision which came up for consideration in the Novartis judgement and has been the subject of heated discussions ever since.

The US patent system had also faced intense scrutiny for its patent proliferation (including frivolous patents), its increasing tendency to hinder competition rather than promote innovation, and especially for its capture by patent owners with deep pockets. A body of opinion argues vehemently that in fact the US patent system was broke and needed a radical overhaul. At such a time, the Supreme Court of India ruling – as a new and independent voice – was perceived to add to the momentum for a fundamental reassessment. The Supreme Court ruling was appealing because it asked a question that was both naive and salient. Was the Novartis patent a ruse to prolong an existing monopoly beyond reasonable limits?

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1 Novartis AG Vs. Union of India (UOI) and Ors., AIR 2013 SC 1311, decided on April 1, 2013.
The judgment marked a crucial conclusion to a saga that has been several decades in the making. The story could date back to 1972, when the Patents Act — grounded in the findings of the Bakshi Tek Chand and Ayyangar Committee Reports, 1959 — came into force, enabling the explosive growth of the Indian generics industry into the world’s largest exporter of bulk medicines; or, it could start in 2005, when India amended its patent law to comply with TRIPS, that established a new global regime of intellectual property. Irrespective of where we choose to begin, the Novartis judgment represents a definitive point in the story.

An article published in *The Hindu* in April, 2013 captured the three most important facets of the Novartis judgment. Firstly, the Supreme Court decision was not about the patentability of the Imatinib compound as such. The case the Supreme Court heard was whether Novartis’ beta-crystalline form of Imatinib was worthy of patent protection: its judgment was that this modification by Novartis did not satisfy the standard of inventiveness required under Indian patent law. Secondly, Indian patent law was still unchallenged at the WTO; Novartis’ earlier challenge to the constitutionality and TRIPS compatibility of Indian patent law was rebuffed by the Madras High Court in 2007 and no appeal was pursued. Lastly, the Supreme Court judgment effectively recast Indian patent law as being nuanced and original in its meshing of domestic political economy concerns with the integrated global economy it participates in.\(^2\)

This article is an attempt to analyse the implications of the Novartis judgement and explore the judicial trends in the larger debate of ‘national interest’ versus ‘IPR protection’ in the wake of the Novartis judgment.

**The Novartis Judgement**

In 1997, Novartis AG filed a patent application in the Chennai (Madras) Patent Controller’s office for the beta-crystalline form of Imatinib Mesylate, brand name Glivec (Gleevec), on the ground that it invented the beta-crystalline salt form (Imatinib Mesylate) of the free base, Imatinib. Novartis patent application was kept in the mailbox and was not opened until 2005 when the Patents Act was amended to comply with its obligations under TRIPS. In the meantime, Novartis had obtained Exclusive Marketing Rights (EMR) for marketing Glivec in India.

After the 2005 amendment to the Patents Act, Cancer Patients Aid Association (“CPAA”) and other generic companies filed pre-grant oppositions against Novartis’ patent application for Imatinib Mesylate, claiming that Novartis’ alleged ‘invention’ lacked novelty, was obvious to a person skilled in the art, and that it was merely a ‘new

form’ of a ‘known substance’ that did not enhance the substance’s efficacy. These arguments were based on the fact that Novartis had already been granted a patent in 1993 in the United States and other jurisdictions for the active molecule, Imatinib.

In January 2006, the Patent Controller in Chennai, in a landmark decision, refused to grant Novartis a patent on the grounds that the application lacked novelty, was obvious and was not patentable under Section 3(d). In June 2006, Novartis AG and its Indian subsidiary, Novartis India, filed a series of writ petitions challenging the decision of the Patent Controller before the Madras High Court. In April 2007, the Government of India notified the Intellectual Property Appellate Board (“IPAB”) to hear appeals relating to patents. Consequently, Novartis’ appeals were transferred to the IPAB.

In its decision issued in June 2009, the IPAB overturned the Patent Controller’s findings on novelty and inventive step and held that the beta-crystalline form of Imatinib Mesylate was new and involved an inventive step. However, the IPAB refused to grant it a patent on the ground that the beta-crystalline form of Imatinib Mesylate did not exhibit enhanced therapeutic efficacy over Imatinib Mesylate, the known substance. Challenging the IPAB’s order, Novartis approached the Supreme Court directly by filing a special leave petition challenging the IPAB’s interpretation and application of Section 3(d) to its patent application.

The Supreme Court allowed a special leave petition before itself directly from the decision of the IPAB to expedite legal proceedings.

To put the debate in context, Section 3(d) of the Patents Act states that:

“3 - The following are not inventions within the meaning of this Act, ...

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

According to the Supreme Court, the purpose of Section 3(d) of the Patents Act was to set up “a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds”. The Supreme Court held that:

- the ‘known substance’ was Imatinib Mesylate and not free base Imatinib as claimed by Novartis;
- there is no distinction between the ‘coverage’ or ‘claim’ in a patent and the ‘disclosure’ made therein;
- the only known advantage that the invention had against this known substance was a 30% increase in bio-availability of beta-crystalline form of Imatinib Mesylate. Although, an increase in bio-availability could result in ‘enhanced efficacy’, this had to be specifically claimed and Novartis had not established it before the Supreme Court; and
on the above basis, the application for the patent failed both tests of invention and patentability as laid down in the Patents Act.

Therefore, according to the Supreme Court, to qualify for a new patent, the new form of an old compound must not just be different from the old form, it must have ‘enhanced therapeutic efficacy’. However, the Supreme Court did not conclude that a new form of a known compound could never be patented or improving the bio-availability features of a drug does not improve its efficacy in the treatment in any case. Therefore, incremental inventions that meet the test may still be patented and the patentability standards maintained in countries like the USA and Canada. In these jurisdictions, multiple patents on new users, combinations and forms of known medicines are said to be responsible for keeping generic drugs out of the market.

Further, it is important to note that though the Supreme Court clarified that in case of medicines, ‘efficacy’ only means ‘therapeutic efficacy’, it did not further elaborate on the concept of ‘therapeutic efficacy’. For instance, whether ‘therapeutic efficacy’ refers only to the curative effect of a drug or also includes an innovation which reduces its toxicity and makes it safer for human consumption, remains open for discussion. Another important take away from the judgement is that the patent regime must be used for genuine innovation and not merely to thwart competition.

Patients v. Patents: The issue of ‘ever-greening’

The Novartis judgment also reignited the debate on ‘ever-greening’, the practice whereby drug manufacturers make small changes to a drug, often about to come off patent, in order to gain a new patent that extends its manufacturer’s control over it. It's not just about allowing Indian generics manufacturers to offer Glivec for a fraction of the Novartis price. Price was never the sole issue; the judgment is equally about establishing the principle that ‘ever-greening’ patents is not as easy in India as it is elsewhere, where the practice is common. Our lawmakers meant to check any attempt at repetitive patenting or extension of the patent term on spurious grounds, and blocked attempts to keep an invention ‘ever-green’.

Since Novartis

Predictably, there were polarising reactions to the Novartis judgement. Novartis and other pharma multinational corporations (“MNCs”) said that it was a regressive judgement which would discourage multinational investment in drug R&D in India and this would in turn adversely affect Indian patients by delaying the introduction of new drug discoveries. The Organisation of Pharmaceutical Producers of India, a platform for several major pharma MNCs, held similar views. Conversely, the generic drug manufacturing companies and civil society groups, such as Médecins Sans Frontieres and the CPAA, rejoiced in support of what was heralded as a major step towards providing affordable medicines to the large patient population in India and other developing and under-developed countries.

While the Supreme Court applied the law scrupulously and ultimately ruled on the facts of the case, the considerations of public policy and encouraging availability of cheap
generic drugs were apparent. The Supreme Court openly recognised these issues at the beginning of its judgement:

“The debate took place within a very broad framework. The Court was urged to strike a balance between the need to promote research and development in science and technology and to keep private monopoly (called an ‘aberration’ under our Constitutional scheme) at the minimum. Arguments were made about India’s obligation to faithfully comply with its commitments under international treaties and counter arguments were made to protect India’s status as “the pharmacy of the world”. The Court was reminded of its duty to uphold the rights granted by the statute, and the Court was also reminded that an error of judgment by it will put life-saving drugs beyond the reach of the multitude of ailing humanity not only in this country but in many developing and under-developed countries, dependent on generic drugs from India.”

Even before the Novartis judgement enunciated upon Section 3(d) of the Patents Act, one could argue that previous rulings of Indian courts also reflect the judiciary’s policy bias in favour of companies manufacturing generic drugs. Both the Supreme Court and the Delhi High Court allowed Cipla to manufacture and market a generic low cost version of the cancer drug Tarceva which was originally patented by a Swiss pharma company Hoffman La Roche. Similarly, the Delhi High Court rejected a petition by German MNC, Bayer Healthcare, to prevent Cipla from marketing a generic version of the cancer drug Nexavar.

On the flip side, it is also possible to argue that the Supreme Court’s reasoning in the Novartis case does not per se appear to be hostile to the recognition of patent rights in the Indian pharma space. What the Novartis judgement does is set a higher threshold for patentability of drugs in India than found in other countries, which may not be entirely unreasonable. It is important to bear in mind that the judgement of the Supreme Court was specific to the facts at hand and the decision has limited value as a precedent for future patent applications, which will be required to be judged on their own merits. The Supreme Court has not disallowed patents for incremental innovation and thus, the legal regime remains committed to incentivising innovation.

Although this may appear to be a directional focus on promoting generic drug manufacturers, the Indian judiciary and government are not intuitively hostile to foreign pharmaceutical companies. In a very recent case, US-based Merck Sharp & Dohme sought an interim junction against India-based Glenmark alleging that Glenmark had violated its IPR rights over its anti-diabetics medicines, Januvia and Janumet, by coming out with their own drugs containing the same salts. Merck claimed that it had invented ‘Sitagliptin’ salt used in its anti-diabetes drugs and has a patent over the molecule. However, Glenmark contended that its anti-diabetes drugs used ‘Sitagliptin Phosphate’ which Merck has no patent rights over. The Delhi High Court, in March 2015, granted Merck the interim injunction, saying that Merck had established a “prima facie case of patent infringement” by Glenmark.

Subsequently, though the injunction order was set aside by the Supreme Court, on August 4, 2015, the Supreme Court rejected Glenmark’s plea seeking permission to

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3 Merck Sharp and Dohme Corporation and Ors. v Glenmark Pharmaceuticals FAO (OS) 190 / 2013, C.M. Appl. 5755 / 2013, 466 & 467 / 2014
utilise its existing stock of Sitagliptin. A bench comprising justices Ranjan Gogoi and N V Ramana said that it didn’t consider it appropriate to create additional rights in favour of Glenmark at this stage, when the Delhi High Court hearing on the dispute between Glenmark and Merck is about to conclude. The judges further said that if the High Court order went in favour of Glenmark, it would be free to produce its drug anyway and even the company could seek permission from the High Court to allow it to use the existing stock.

Recently, the Commerce and Industry Minister of India, Ms. Nirmala Sitharaman publicly rebuffed the United States Trade Representative Report ("USTR") which questioned India’s IP policies. The USTR has placed India along with China and 11 other countries on the ‘Priority Watch List’ for having a poor record of protecting IPRs. The USTR dubs India and China as sources for most of the counterfeit pharmaceuticals shipped to the US and alleges that up to 20% of drugs sold in the Indian market are counterfeit, posing a serious threat to patient health and safety. Allegations such as these could seriously dent the image of India, which is one of the largest sources of generic drugs globally. Last year, the Indian pharmaceutical industry had achieved an export turnover of approximately Rs. 90,000 crore (USD 15.1 billion). The size and volume of the industry cannot be overlooked. India’s generic manufacturers play an important role as far as public health and welfare is concerned and importantly within the parameters of the law.

Conclusion

What some view as a discriminatory patent regime, others see as a mere innovation filter, implemented to ensure that the framework isn’t abused to the detriment of public health and welfare. The IPR regime scuppers ever-greening bids through an innovation filter. The Patents Act provides safeguards, including checks on ever-greening of patents and the broader framework for Compulsory Licensing ("CL"). All these conform to the Doha Declaration which states that "TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health". CL is an essential tool for governments as it facilitates the prevention of abuses of rights and encourages domestic capacities for manufacturing. Nothing in the TRIPS agreement limits governments from issuing CL.

On the brighter side, the Novartis judgment is likely to force multinational drug companies to overhaul their business strategy for India. MNCs cannot afford to ignore a market like India, so the judgment would have compelled them to balance public policy and profitability. They can contemplate adopting dual pricing and striking licensing agreements with local generic companies, even cutting the product prices to remain competitive in a highly lucrative market like India.
The Indian Pharmaceutical Industry – Labour & Employment Issues

Introduction

Labour laws in India have their origin in the principle of social justice that is enshrined as one of the fundamental objectives of state policy under the Indian Constitution. Labour law in India is a subject found in the concurrent list under the Constitution of India, as a result of which, both the Parliament and the state legislatures have the power to legislate on matters such as labour welfare, trade unions, industrial and labour disputes and factories. Approximately, 45 labour legislations have been enacted by the Parliament thus far. There is also a catena of labour legislations enacted by the state governments. In view of the sheer volume of labour laws that are in force in India, their applicability to a particular establishment is determined and affected by a variety of factors including: (a) categorisation of workforce; (b) nature/type of establishment and nature of industry; (c) location of establishment; (d) number of employees and/or other workforce; (e) salary of employees, etc.

In addition to the regulation of industrial relations, Indian labour laws also regulate terms and conditions of service to be provided to an employee such as payment of wages, working conditions, social security, etc. Additionally, several labour laws have been enacted to regulate service conditions of workforce employed in specific industries such as building and construction work, mines and the pharmaceutical industry.

This article aims to provide a brief overview of the treatment of employees in the pharmaceutical industry, key labour laws applicable to such employees and some key challenges faced by the industry.

Pharmaceutical Industry and (Indian) labour laws

The pharmaceutical industry in India is dynamic and gargantuan in nature. Recent developments which now permit 100% foreign direct investment in manufacturing of medical devices and proposed amendments to the Drug and Cosmetics Act, 1940 evidence the constant evolution of this industry. However, like any other industry, the pharmaceutical industry too is required to comply with labour legislations while dealing with the workforce employed in the industry in keeping with the state welfare principles.

When determining the applicability of labour laws to an establishment in general, the first and foremost factor is the distinction made by Indian labour and industrial laws between employees who are “workmen” (as defined under the Industrial Disputes Act, 1947 (“IDA”) and those who are not. Under the IDA, a “workman” is defined to include all those persons who are employed to do any manual, unskilled, skilled, technical,
operational, clerical work or supervisory work (drawing less than Rs. 10,000 per month). Employees who fall under the category of “workmen” are ordinarily afforded a greater degree of protection and benefits under the Indian labour and industrial laws.

On the other hand, “non-workmen”, though not statutorily defined, typically refer to those employees who are engaged in managerial functions or in a supervisory function and drawing more than Rs. 10,000 per month. Such employees are ordinarily governed by the terms and conditions of their contracts of employment and the provisions of the local Shops and Establishment Act of the relevant state, if applicable.

However, in connection with the workforce employed in the pharmaceutical industry, the Supreme Court of India, in its landmark judgment – *H.R. Adyanthaya v. Sandoz (India) Ltd.*¹, had held that medical representatives/sales promotion employees working in a pharmaceutical industry do not fall under the definition of “workman” under the IDA as the work of a sales representative is canvassing and promoting sales which is neither manual nor clerical nor technical nor supervisory. While debates were held whether to amend the definition of “workmen” to include sales promotion employees, the legislature considered it more appropriate to enact a special legislation for regulation of conditions of service of such sales promotion employees/medical representatives, namely the Sales Promotion Employees (Conditions of Service) Act, 1976 and the rules framed thereunder (together the “SPE Act”). However, by means of enabling provisions under the SPE Act, the IDA was made applicable to sales promotion employees for the purposes of proceedings under the IDA, in relation to an industrial dispute, to ensure protection during dismissal and retrenchment.

**SPE Act**

The SPE Act is a key legislation applicable to the pharmaceutical industry and regulates service conditions of employees employed in such industry (or any other industry as notified by the Central Government from time to time) and provides for various terms and conditions of employment such as appointment, leave, maintenance of registers and other documents. Some of the key provisions and obligations of the employer under the SPE Act are discussed below:

- An employer is required to issue an appointment letter, in the prescribed format, to all sales promotion employees on the date of their appointment. Every subsequent change to the appointment letters is required to be communicated to the employees either by personal service or registered post.

- The employer is also required to comply with other formalities such as maintenance of registers of all sales promotion employees, service books, a register for such service books and leave accounts in respect of each sales promotion employee.

- Sales promotion employees are entitled to various categories of holidays and leave in a calendar year, namely, a total of 10 holidays, 1/11th of the period spent on duty as privileged/earned leave and a total period of 15 days in every year as casual leave. Apart from the aforesaid categories of leave, sales promotion employees are also

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entitled to avail of medical leave, quarantine leave, extraordinary leave and study leave.

Additionally, the SPE Act also includes an enabling provision for the extension of other important labour laws to the sales promotion employees, such as the Workmen’s Compensation Act, 1923, IDA, Minimum Wages Act, 1948, Maternity Benefit Act, 1961, Payment of Bonus Act, 1965 and Payment of Gratuity Act, 1972.

**Employees’ Compensation Act, 1923 and the Rules framed thereunder (previously known as Workmen’s Compensation Act, 1923) (“EC Act”)**

The EC Act provides for payment of statutory compensation to an employee (and its dependants) by the employer in case of personal injury or death due to an accident arising during the course of employment. The EC Act provides for a Schedule which sets out the categories of persons covered under the EC Act including but not limited to persons employed: (i) in any occupation involving the handling and manipulation of radium or X-ray apparatus or contact with radioactive substances; (ii) as drivers; (iii) as watchmen in any factory or establishment; and (iv) employed in the manufacture or handling of explosives in connection with employer’s trade or business, etc. The EC Act also specifies incidents for which the employer is required to pay compensation such as death, permanent/temporary partial or total disablement of an employee resulting from an injury during the course of employment.

**Minimum Wages Act, 1948 and the Rules framed thereunder (“MW Act”)**

The MW Act provides for payment of wages to specified employees on the basis of minimum rates as prescribed by the appropriate Government (Central or State, as the case may be) from time to time. The MW Act defines the term “employee” to mean, *inter alia,* “any person who is employed for hire or reward to do any work, skilled or unskilled, manual or clerical, in a Scheduled Employment in respect of which minimum rates of wages have been fixed” and also includes “an employee declared to be an employee by the appropriate Government”.

The term “Scheduled Employment” includes employment in construction and/or maintenance of roads or in building operations, employment in an oil mill, employment
in tanneries and leather manufacturing, etc. While the pharmaceutical industry is not expressly included within the meaning of “Scheduled Employment”, it is noteworthy that the State Governments are empowered to expand the ambit of the said term.

Under the MW Act, the appropriate Government may fix and notify: various details such as the (a) minimum rate of wages for Time work; (b) minimum rate of wages for piece work; (c) minimum rate of remuneration, i.e., a ‘guaranteed time rate’, for employees employed on piece work for the purpose of securing to such employees a minimum rate of wages on a time work basis; and (d) minimum rate (whether a time rate or piece rate), i.e., ‘overtime rate’ in respect of any overtime work performed by the employees. Pursuant to such notifications, an employer is required to pay to every employee (engaged in a Scheduled Employment), wages at a rate which is not less than the minimum rate of wages fixed by the appropriate Government for that class of employees.

Maternity Benefit Act, 1961 and the Rules framed thereunder (“MB Act”)

The MB Act applies to factories, mines, plantations and other shops and establishments in which 10 or more persons are employed or were employed on any day of the preceding 12 months. The MB Act mandates payment of maternity benefits to every female employee in an establishment, provided that such female employee has worked for at least 80 days in the 12 months immediately preceding the date of her expected delivery.

Under the MB Act, the employee is entitled to maternity leave/benefit for a maximum period of 12 weeks, of which not more than 6 weeks should precede the expected date of her delivery. The MB Act also provides for leave entitlements during certain circumstances/conditions arising on account of the pregnancy (such as any illness, premature birth of child or miscarriage).

A unique feature of the MB Act is that a female employee on maternity leave is protected from: (a) being discharged or dismissed while on maternity leave; (b) being given a notice of discharge/dismissal during such leave; and (c) the terms and conditions of her service being varied to her detriment during such a period.

Payment of Bonus Act, 1965 and the Rules framed thereunder (“Bonus Act”)

The Bonus Act applies to every factory and other establishments employing 20 or more persons on any day during an accounting year. It also applies to all employees earning a salary of not more than Rs. 10,000 per month. If the Bonus Act is applicable to an establishment, the employer is required to pay a minimum bonus (even if she/he suffers losses during the accounting year) of 8.33% of the salary or wage earned by the employee during an accounting year or Rs. 100, whichever is higher. However, no bonus is required to be paid by a new establishment in the first 5 accounting years if there is no profit.

The employer to which the Bonus Act applies must also comply with various formalities including maintenance of records and filing of returns.
Payment of Gratuity Act, 1972 and the Rules framed thereunder ("Gratuity Act")

The Gratuity Act applies to every establishment in which 10 or more persons are employed or were employed on any day of the preceding 12 months. An employee is entitled to payment of gratuity on termination of his/her employment (in case of: (a) superannuation; (b) retirement or resignation; or (c) death or disablement due to accident or disease), provided she/he has rendered continuous service for not less than 5 years (except in the case of death or disability where the entitlement to gratuity does not depend on the number of years of service).

The employer is required to pay an amount equal to 15 days’ wages based on the rate of wages last drawn by the employee towards gratuity for every completed year of service (with part of a year in excess of 6 months counted as 1 year), subject to a maximum limit of Rs. 10,00,000. However, in case of termination of the services of an employee for any act, wilful omission or negligence causing any damage or loss to or destruction of property belonging to the employer, the gratuity shall be forfeited to the extent of the damage or loss so caused.

Every employer to whom the Gratuity Act applies is also required to comply with various formalities mentioned under the Gratuity Act including filing of notices.

Uniform Code of Pharmaceuticals Marketing Practices ("Code")

The Code\(^2\) has been recently issued by the Department of Pharmaceuticals, Government of India ("DoP\(^\)”) and has been made applicable to the pharmaceutical industry on a trial basis for a period of 6 months with effect from January 1, 2015. The Code sets out certain guidelines for observance of high standards of ethical conduct and behaviour while promoting and providing information about pharmaceutical drugs including specific guidelines for ‘medical representatives’ while promoting sales of a drug. These medical representatives are strictly prohibited from employing any coercive or disguised means of making payments in order to obtain interviews with the healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of drugs.

As per the notification, the DoP has indicated that it will review the Code upon the completion of the 6 month trial period. Further, it has also been stated that in the event that the Code has not been implemented by pharmaceutical companies in the prescribed manner, then the DoP may also consider making the Code a statutory code for its effective and compulsory implementation.

Key Issues faced by employers in the pharmaceutical industry

Trade Unions

Increase in unionisation of employees at the industry and national level has also seen a rise in the number of compliances on account of employers, while dealing with their workforce, especially in case of change of service conditions, transfer of employees and termination/mass-retrenchment of employees, etc. Employers are increasingly cautious

of their manner of dealing with unions and approach sensitive issues with the unions based on sound strategy.

In various sectors, in dealing with instances of termination, employers are increasingly adopting the method of mutual discussions and dialogue with the concerned employees/union/representative(s) before taking any decisions/carrying out any changes to service conditions in order to mitigate resistance and/or opposition to the extent possible. While this has increased the time period of decision making, taking the representatives of the employees into confidence and/or adopting a process of mutual negotiation and discussion has been seen to promote harmonious relations between the employer and their employees. There are also instances of unions resorting to violence when companies/industries have initiated talks on possible change in ownership/management leading to change in service conditions of the employees, such as an incident at the Mumbai plant of Pfizer Inc. in August 2014 where certain management decisions had led to aggression amongst the employees and the factory had to be locked down to ensure safety of the management and avoid damage to property. Given the rise of such incidents, employers have started taking steps for protection of management and property to avoid grave loss and damages.

Restrictive Covenants

Employers have become increasingly aware of the need for adopting watertight contracts and agreements between themselves and the employees in order to clearly set out terms and conditions of employment, protect confidential information and the violation of the same and set out such terms of employment which may be in addition to what is set out under company policies. For this purpose, contracts typically contain 3 key restrictive covenants including: (a) non-compete; (b) non-solicit; and (c) confidentiality/non-disclosure, each of which is discussed in greater detail below.

- Non-compete clauses in a contract are enforceable during the currency of a contract. However, non-compete clauses operational beyond the tenure of employment have been held to be unenforceable and violative of Section 27 of the Indian Contract Act, 1872. Nevertheless, it is a common market practice to include such clauses for the purposes of deterrence. As an alternative, employers often opt to place an employee on 'garden leave', in order to safeguard its interests, especially when the separating employee has occupied a key (managerial) position in the company.

- Non-solicit clauses on the other hand, are enforceable during the course of employment and beyond the term of employment under certain circumstances. However, the validity of such a clause varies from case to case and is at the discretion of the court. Typically, employers enforce these conditions for a period of 6 to 12 months beyond the tenure of employment.

- Confidentiality and non-disclosure clauses are incorporated in employment contracts in order to safeguard the company’s trade secrets, financial and business information which invariably become known to employees and stand a chance of

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becoming known to their competitors. Therefore, employers generally include such a clause to include various factors such as: (i) nature of information which may be considered as confidential information; (ii) jurisdictional limits of the restrictive covenant; and (iii) time period of such restriction (which is generally an indefinite period). However, it is essential to keep in mind that, in the event a breach of confidential information is disputed in courts, the burden of proof would lie on the employer. Further, information relating to routine day-to-day affairs and which is available in public domain would not fall within the protected ambit of confidential information.

Conclusion
The pharmaceutical industry, as any other labour intensive industry, has seen various ups and downs and with the intention to resolve and mitigate disputes between employers and their employees. The government, in conjunction with the legislature, has sought to codify the laws in relation to employees in the pharmaceutical industry and also provide them with all the employment benefits available to other employees in most other industries.
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