Post-TRIPS Thrust Triggers for Indian Pharmaceuticals in the IP Context

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The impact of the transition of Indian patent regime from pre-TRIPS to post TRIPS and the post-2005 product patent regime is discussed sequentially with evaluation thereof. Contrary to general perception and negative expectations, India appears to have driven through the anticipated ‘rough weather’, most successfully and creditably, largely thanks to the lawmakers making best use of the flexibilities permitted in TRIPS. The intervening Doha Declaration, wherein, the open unanimous admission of sovereign rights to incorporate measures for protecting public health and nutrition was adopted, also came in good time. With the entrepreneurial enthusiasm, due diligence and newly acquired patent proficiency, the Indian pharmaceutical industry has moved on to a globally dominant position at least as the leader of generic medicines. The early patent litigations have alerted and awakened the domestic pharmaceutical industry to take preventive or defensive measures as well as to go on the offensive where the patents are vulnerable. The awareness and practice of the new patent regime has helped Indian pharmaceutical companies to successfully redirect themselves to regulated markets with largest number of USFDA and EMA/EDQM approved manufacturing sites and large DMF/ANDA filings and approvals. The R&D allocations and IP protection by Indian pharmaceuticals has also gone up creditably, even though early drug initiatives have not borne fruits yet. With increased Government funding and participation, the Indian pharmaceutical industry appears to be gearing up for entering the drug discovery band wagon too. The provisions adopted in the amended Patents Act, 1970 and decisions thereof, including the latest grant of the first compulsory licence, appears to be drawing considerable global attention and fair appreciation, for its equitable balance of rights and obligations.

Keywords: TRIPS, pharmaceuticals, patent, Gleevec, licence

Post-TRIPS analysis of pharmaceutical patents has to necessarily begin with pre-TRIPS scenario. Consequent to the 1970 amendments, introducing Section 5 to exclude pharmaceuticals, food and chemicals from product patent protection and more importantly introducing the erstwhile Section 86 dealing with ‘Licence of Right’, the research community in India and globally, not only in pharmaceuticals but also generally in all fields surprisingly lost all interest in patenting in India. This period (post 1970) also coincided with India, shedding its Nehruvian basic scientific research philosophy to replace it with Indira Gandhi’s applied research strategy for self-reliance and import substitution.

The provision for ‘licence of right’ endorsement was equivalent to an automatic compulsory licence for non-working. These restrictive conditions for research and patenting virtually destroyed all interest in patenting for the research community, during 1970 to 1995. However, APIs (active pharmaceutical ingredients, i.e., bulk drugs) and formulations (dosage forms) in pharmaceutical industry grew by leaps and bounds during the same period.

**IP in India and its Transition**

In the early seventies, even though the head office for patent was in Kolkata and the head office for TM was in Mumbai, the Controller General of Patents had his office jointly with the Registrar of Trademarks. While the Trademark Registry used to be vibrant, even in the 1970s, the Patent Office was only involved in policy matters due to the low level of patenting in India.

Post Uruguay Round, during Dunkel Draft negotiations and the TRIPS accession, the level of awareness and proficiency in India on patents had been dismally low. Indian negotiators as well as concerned Ministry were taken by surprise even though a couple of industry leaders and a handful of IP advisors came forward to caution the Government on wrong moves and to advise appropriately on key transitional proposals, involving industrial properties (renamed as intellectual properties) which got incorporated into GATT to form WTO.

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Till 2005, patent related publications were dependent on the Gazette of India. Printing of gazette and the delayed availability was a major constraint. All publications for patent applications, grants and related information were later transferred to the Official Journal of the Patent Office from 21 January 2005. Since then, on every Friday of the month, the Journal publishes various proceedings relating to patents as required under Section 145 of the Patents Act 1970. This and other publications and announcements on the website of the Indian Patent Office have been very useful to inventors, IP owners, IP users and practitioners.

Unlike most countries of the world, India has multiple Patent Offices (in Delhi, Mumbai, Chennai and Kolkata). This has led to non-uniform procedures and diverse approaches (often contradictory) to the implementation of the policy and the provisions of the Patents Act, 1970. While no one was interested in patents in the pre-TRIPS era, the sudden rush for patents post-1995 (including EMRs) led to practices which were not commensurate to expectations. However, drastic revamping of Indian Patent Office, with higher transparency has led to high quality good governance.

Post-TRIPS Challenge: Legal Perspective

Performance of the Indian pharmaceutical industry in post-TRIPS period has been analysed by Kiran and Mishra. Drafting of needful amendments were the biggest challenge for India post TRIPS accession. A close scrutiny of the broadly negotiated and unanimously concluded TRIPS document was undertaken in the light of the decision at the highest national echelons to comply with TRIPS on a ‘need based’, ‘phase-wise’ basis and on the basis of evaluation of the flexibilities and stretchabilities of the TRIPS provisions, in national interest.

To send the right messages to the international community on India’s willingness to comply with TRIPS, the 1st amendment was promulgated as an ordinance on 1 January 1995, in compliance of the transitional provisions under Article 70 and more particularly 70.8 of TRIPS. This ordinance provided among others, for filing of Mailbox applications (also nicknamed ‘black-box application’, since substantive examination of the Mailbox applications would have been done only on the introduction of a full-fledged product patent regime) from 1 January 1995 onwards and to apply for EMR (exclusive marketing rights) by complying with the provisions as prescribed under newly inserted sections under the 1st amendment. Chapter IV-A and Sections 24A to 24F relating to EMR became extinct on introduction of product patent regime, thereafter in 2005. While a few EMR applications were either rejected or stayed in legal proceedings subsequently, EMR was granted for ‘Gleevec’ (imatinib mesylate) and injunction obtained from the Madras High Court by Novartis, though the product patent application was rejected post 2005, consequent to pre-grant oppositions.

While the 1st and 2nd amendments to Patents Act, 1970 were in progress and while India acceded to Paris Convention and Patent Co-operation Treaty (PCT) on 7th December 1998, a few EMRs were granted as per the erstwhile Chapter IV A and Section 24A to 24F. The first (and the last) EMR was for Gleevec granted to Novartis and injunction was also granted against generic companies who were manufacturing Imatinib tablets in India by Chennai High Court. A similar grant of EMR to CIALIS (Tadalafil) of Eli Lilly was successfully challenged and revoked in Kolkata High Court. Many EMR applications were still in pipeline which got extinguished when the 2005 product patent regime emerged.

The ordinance of 1 January 1995 for the 1st Amendment lapsed, since the Bill for first amendment was defeated in the Parliament. India was dragged to the DSB (Dispute Settlement Board) of the WTO for non-compliance with TRIPS by EU and US. Consequently, India was directed to comply with TRIPS by WTO and the 1st Amendment Act of 1999 to the Patents Act, 1970, to usher in the transitional provisions effective 1 January 1995 (retrospectively), was unanimously passed in the Indian Parliament in 1999.

2nd Amendment of 1999/2003

Compared to the 1st amendment, which was first promulgated as an ‘overnight’ ordinance, extensive multi-centric road-shows all over India were organized to elicit views and suggestions for finalising the second amendment. The Draft Bill was left open from 2002 and came into effect in May 2003. Related draft Rules were also made public for receiving opinion and suggestions. Consequent to the passing of the 2nd Amendment Bill 2002 and the related Patent Amendment Rules, 2nd amendment came into effect on 20 May 2003.

The 2nd Amendment and Rules thereunder were elaborate and made sweeping changes to the original 1970 Patents Act. The 2003 amendments brought in the following important provisions and changes:
(1) Patent term was made uniformly 20 years from the date of application (date of filing) replacing the term of 7 years for pharmaceuticals, food and chemicals and 14 years for others.

(2) Examination request was made compulsory (within 36 months which was later amended in 2005 to within 48 months of priority date).

(3) Provision for publication of patent application ‘as applied’ was introduced.

(4) Definition of invention was amended to comply with Article 27(1) of TRIPS. Inventive step was defined for the first time as per TRIPS, which controversially got further amended in the 3rd (2005) amendment.

(5) Amendments were done to Section 3 (inventions not patentable) to make it more restrictive. Amendment introducing explanation to Section 3(d) was introduced in Parliament during the 3rd amendment.

(6) Most importantly, sweeping amendments were done to Chapter XVI on Compulsory Licences and Working of Patents. The controversial ‘Licence of Rights’ provision was deleted.

(7) PCT and Budapest Treaty related sections were introduced for the first time.

(8) Microorganisms became patentable, as per TRIPS Article 27(3)(b).

(9) Reversal of Burden of Proof (Section 104-A) was introduced, as required under TRIPS.

(10) Appellate Board for Patents was introduced under Chapter XIX (which came into effect much later in 2007).

(11) Qualification for patent agents was amended restricting to only science, engineers, and technology graduates to be patent agents.

(12) Additional exceptions (Section 107A), penalties and many other amendments were introduced to comply with TRIPS and to balance the rights and obligations.

**3rd Amendment of 2005**

TRIPS compliance with regard to the introduction of product patent regime remained pending till 24 December 2004 and involved extensive debates as to when India should introduce product patent regime. Many experts predicted doom if the patent regime were to be introduced early (in 2000) and many professed EMR to be more damaging (in absence of substantive examination) than product patents. There were two schools, one suggesting an early end to the transitional (EMR) provisions (by 2000) while the other school suggested full utilization of the pipeline (up to 2005) for transition. India was eligible for 5+5 (5 years being developing country and additional 5 years, since there was no product patent regime prior to TRIPS) years. Eventually, India opted for full 10 years and implemented the product patent regime from 2005 onwards.

However, consensus on the draft for 3rd amendment was not reached till December 2004. On 24 December 2004, the 3rd amendment ordinance was promulgated and the corresponding Rules were notified two days later. The Bill was extensively debated in Parliament and was facing defeat, when the Government brokered smooth passage of the 3rd amendment Bill with retrospective effect from January 2005 by accepting *in toto* the amendments suggested by the opposition parties.

The following important amendments (amongst others) suggested by Opposition parties in the Parliament were accepted:

(1) Section 2(1)(j)(a) for inventive step (one wonders how the amendment has helped).

(2) Definition of medicines or drug (which was a good one, compared to the newly inserted definition for a pharmaceutical substance) was deleted.

(3) The definition of ‘new invention’, which was introduced, was meaningless and irrelevant since there was no mention of ‘new invention’ anywhere else in the Act.

(4) More importantly, (continuing to be most controversial but relevant to India) Section 3(d) was amended to add an ‘explanation’ to Section 3(d) defining ‘same substance’ and qualifying the need to ‘differ significantly in properties with regard to efficacy’. The dispute relating to Section 3(d) is now pending in the Supreme Court of India with specific reference to Gleevec.

(5) Another amendment introduced in the Parliament was to re-introduce pre-grant opposition in addition to post-grant opposition (which was a modified version of the earlier post-acceptance opposition). Pre-grant opposition inserted as Section 25(1) continues to be used to curb frivolous patenting largely by the pharmaceutical sector, post the TRIPS transition, in addition to post-grant opposition under Section 25(2). Prior to the 3rd amendment, there was only the provision for
opposition, post-acceptance. No patent application was published as applied. Applications used to be examined, granted with claims amended if needed and the application used to be published as accepted, inviting oppositions if any. In the Bill presented to Parliament, the provision of the post-acceptance opposition as existed in the original Patents Act, 1970, was proposed to be replaced only by a post-grant opposition. This proposal received strong criticism and objections both outside and inside the Parliament. The Indian Parliament insisted that provision for both pre-grant opposition by any person and post-grant opposition only by 'any interested person' must be reinstated in the 3rd amendment draft before passing the Bill in the Parliament, which was done.

In addition to the above amendments, proposed and accepted in Parliament, while passing the 3rd Amendment Bill, Section 5 (originally introduced on 1970) was omitted, opening up the doors for a full-fledged product patent regime. While a couple of Indian pharmaceutical companies had initiated intensive research programs, including drug discovery research initiatives, from the early 1990s, most leading Indian companies started taking active interest in research and patenting, post-2005.

**Pre-grant Oppositions**

One of the earliest and most debated pre-grant opposition was on Gleevec for which an EMR had been granted earlier. A few pre-grant oppositions were heard relating to Gleevec patent applications, one after the other at the Chennai Patent Office and the product patent application for Gleevec was rejected leading to relief for the cancer patients and uproar from Novartis and others. The Gleevec decision as well as the Section 3(d) provision were challenged in High Court of Madras (Chennai).

While a well-reasoned order was passed by the Constitution Bench of Madras High Court upholding the constitutional validity of Section 3(d), the order of the Controller rejecting the patent application was sent back to the IPAB (Intellectual Property Appellate Board). The IPAB upheld the rejection which was appealed by Novartis. The Gleevec case is currently drawing international as well as domestic attention. The Supreme Court of India where the appeal is being heard is expected to pass orders around July 2012.

As per the Annual Report of the Patent Office, only about 50 to 150 pre-grant oppositions are being filed annually, which amounts to 0.2 to 0.3 per cent of annual patent applications.

**Post-grant Oppositions and Revocations**

Compared to pre-grant oppositions, post-grant oppositions in pharmaceutical patents were relatively few. A well-spoken order was issued by the Chennai Patent Office in a post-grant opposition to Eli Lilly's Pegasys. The opposition was filed by Wockhardt and an NGO, Sankalp Rehabilitation Trust. Although, the Opposition Board had recommended revocation of the patent, through a well-reasoned order, the Controller upheld the validity of the patent and rejected the post-grant oppositions.

Another post-grant opposition relating to Valcyte (Valganciclovir) of Roche also received attention for altogether different reasons. The Patent Controller, who had granted the patent, heard the post-grant opposition and revoked the product patent claims and directed for amendment restricting to single process patent claim. Even though, revocation petitions were filed in IPAB, there have been few decisions besides Gleevec, related to pharmaceutical patents in the recent past from the IPAB. There have also been a few counterclaims for revocation under Section 104 of The Patents Act, 1970, related to the infringement suits filed against generic manufacturers by overseas pharmaceutical giants.

**R&D Trends**

Indian pharmaceutical industry started increasingly investing in R&D, post-TRIPS. While the early thrusts by a couple of Indian pharmaceutical companies into drug discovery research did not yield promising results, formulation development work and new drug-delivery systems (NDDS) showed better performance results leading to commercialization, licensing and increased DMF/ANDA registrations and exports. A very significant fall-out of the post-TRIPS, upgradation of the Indian pharmaceuticals continues to be the higher level of co-operation and collaboration with big pharmaceutical companies, leading to contract research (more by way of product development) and contract manufacturing with process development. Recently, an Indian pharmaceutical company, Piramal Healthcare has announced acquisition of US healthcare data services firm, Decision Resources Group to revamp the drug
discovery program. A few contract drug discovery initiatives such as, Advinus and Suven also merit mention.

Patenting Trends

Post-TRIPS, post-PCT, the international filings have gone up by leaps and bounds. While overseas pharmaceutical patent filings have increased by nearly 100 fold, the patent filings by Indian pharmaceuticals has also shown promising trend as can be seen from the data on the website of the Indian Patent Office. Overseas national phase filings through PCT route has also increased substantially in recent times.

On perusal of the Annual Reports published by the Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, for the years 1992 to 2010, it can be safely concluded that filing and grant of patent applications is on the rise (Table 1).

It is interesting to note the trends in 1998/99 and 2009/10. On 7 December 1998, India became signatory to Paris Convention and PCT. Consequently, there was a rush of national phase filings in the 3rd quarter and 98/99. Thereafter, there was a lull in 1999-2000. The trend between 2008-2009 and 2009-2010 in reduction in grant of patents is due to more stringent examination and hearing procedures and consequent reduction in filing of frivolous patent applications. This trend is also seen in the dip in revenue generated lately, as seen in Table 2.

As per Annual Report of 2008-2009 and 2009-2010, the top 10 Indian applicants for patents from pharmaceutical industry are shown in Table 3.

As per annual report of 2009-2010, the distribution of patent applications filed from 2005 to 2010 under various fields of inventions is shown in Table 4.

There is likelihood of some overlap between chemical and pharmaceutical patent applications. Computer and electronic applications include software (embedded or otherwise) patent applications also. Overseas judgements on need for utility in every genomic or biotech patent applications may have led to a dip in PCT (or Convention) based national phase biotech patent applications. A very detailed study on Indian pharmaceutical industry in India after TRIPS was conducted by Prof Sudip Chaudhuri.8

Pharmaceutical Pricing Trends Post-TRIPS

While there have been serious concerns over likely adverse trends in prices of medicines post-TRIPS, these have substantially been belied. The National Pharma Pricing Activity (NPPA) under the Department of Pharmaceuticals (DOP) tightened the pharmaceutical price control regulations under direct monitoring by the Supreme Court, prompted by a few NGOs. However, prices of a few newly patented drugs, especially for cancer treatment and treatment of HIV/AIDS went up dramatically. The technology savvy generic pharmaceutical industry led by Cipla, (Natco) and others revived their reverse engineering skills, developed technology (home-grown know-how) for manufacturing and formulating these bio-equivalent medicines and commenced marketing them at a fraction of the innovators prices, based on imports. These led to infringement litigations, many of which are currently ongoing in India.
While the Doha Declaration on Public Health and Nutrition and the need for affordable access to lifesaving essential medicines were largely applauded as a major breakthrough; the acceptance of Articles 7 and 8 of TRIPS and the implementation of the Doha Declaration, took a backseat consequent to the failure of the Doha Round of World Trade Organisation (WTO). The Patents Act, 1970 incorporated Section 92A to implement the Doha provisions of compulsory licensing for exports against overseas compulsory licences, however, the rules were not amended thereafter to facilitate the Section 92A provisions of compulsory licensing for exports. WTO had come up with a procedure through WIPO, for implementation of Doha provisions. These procedures were drastically cumbersome and had remained untested, also due to subsequent failure to conclude the Doha Round.

The unanimous admission that public health related flexibilities are available to sovereign WTO member countries, was a major success of Doha. However, the euphoria of Doha Declaration evaporated when the TRIPS Council came out with a detailed procedure for operation of compulsory licence for export. The salient features of implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health are as follows:

- Definition of ‘pharmaceutical product’, ‘eligible importing member’ and ‘exporting member’
- Procedures to be adopted by exporting member jointly with eligible importing member, such as:
  - notification to TRIPS Council specifying (a) name and quantity of pharmaceutical product or medicine
  - certification of eligibility (LDC or no local manufacturing facility/capacity)
  - patent status (granted) in the importing and exporting countries.

Further it is stated that the compulsory licence be granted with specific conditions (mainly to ensure non-diversion to other markets).

Table 3 — Top 10 Indian applicants for patents from pharmaceutical industry

<table>
<thead>
<tr>
<th>Name of applicant</th>
<th>Position (no of patent filings) 2009-2010</th>
<th>Position (no of patent filings) 2008-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>AurobindoPharma Ltd</td>
<td>6th (22)</td>
<td></td>
</tr>
<tr>
<td>Avesthagen Ltd</td>
<td>3rd (66)</td>
<td></td>
</tr>
<tr>
<td>Cadila Healthcare Ltd</td>
<td>4th (57)</td>
<td></td>
</tr>
<tr>
<td>Cipla Ltd</td>
<td>3rd (21)</td>
<td></td>
</tr>
<tr>
<td>Concept Medical Research Pvt Ltd</td>
<td>6th (10)</td>
<td></td>
</tr>
<tr>
<td>Dr Reddy’s Labs</td>
<td>1st (147)</td>
<td></td>
</tr>
<tr>
<td>Envision Scientific Pvt Ltd</td>
<td>9th (07)</td>
<td></td>
</tr>
<tr>
<td>Hetero Research Foundation</td>
<td>4th (11)</td>
<td></td>
</tr>
<tr>
<td>Ind-Swift Laboratories Ltd</td>
<td>9th (19)</td>
<td></td>
</tr>
<tr>
<td>Jubilant Organosys Ltd</td>
<td>8th (21)</td>
<td></td>
</tr>
<tr>
<td>Matrix Labs Ltd</td>
<td>5th (54)</td>
<td></td>
</tr>
<tr>
<td>Orchid Chemicals &amp; Pharma Ltd</td>
<td>6th (22)</td>
<td></td>
</tr>
<tr>
<td>Panacea Biotech Limited</td>
<td>10th (15)</td>
<td></td>
</tr>
<tr>
<td>Ranbaxy Labs Ltd</td>
<td>2nd (101)</td>
<td></td>
</tr>
<tr>
<td>Rubicon Research Pvt Ltd</td>
<td>7th (08)</td>
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</tr>
<tr>
<td>Stempeutics Research Pvt Ltd</td>
<td>7th (08)</td>
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</tr>
<tr>
<td>Sulur SubramaniamVanangamudi</td>
<td>4th (11)</td>
<td></td>
</tr>
<tr>
<td>Sun Pharma Advanced Research Co Ltd</td>
<td>9th (07)</td>
<td></td>
</tr>
<tr>
<td>Wockhardt Research Centre</td>
<td>2nd (33)</td>
<td></td>
</tr>
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</table>

Source: www.ipindia.nic.in

Table 4 — Patent applications filed under various fields of inventions between 2005 and 2010

<table>
<thead>
<tr>
<th>Year</th>
<th>Chemical</th>
<th>Drugs</th>
<th>Food</th>
<th>Biotechnology</th>
<th>Engineering and computer related</th>
<th>General</th>
<th>Other fields</th>
<th>Total</th>
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<td>2005-2006</td>
<td>5810</td>
<td>2211</td>
<td>101</td>
<td>1525</td>
<td>11708</td>
<td>3150</td>
<td>24505</td>
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<tr>
<td>2006-2007</td>
<td>6354</td>
<td>3239</td>
<td>1223</td>
<td>2774</td>
<td>13729</td>
<td>1621</td>
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<tr>
<td>2007-2008</td>
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<td>233</td>
<td>1950</td>
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<tr>
<td>2008-2009</td>
<td>5884</td>
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<td>276</td>
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<td>885</td>
<td>34287</td>
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</tr>
</tbody>
</table>

Source: www.ipindia.nic.in

**Doha Declaration and its Aftermath**

While the Doha Declaration on Public Health and Nutrition and the need for affordable access to lifesaving essential medicines were largely applauded as a major breakthrough; the acceptance of Articles 7 and 8 of TRIPS and the implementation of the Doha Declaration, took a backseat consequent to the failure of the Doha Round of World Trade Organisation (WTO). The Patents Act, 1970 incorporated Section 92A to implement the Doha provisions of compulsory licensing for exports against overseas compulsory licences, however, the rules were not amended thereafter to facilitate the Section 92A provisions of compulsory licensing for exports. WTO had come up with a procedure through WIPO, for implementation of Doha provisions. These procedures were drastically cumbersome and had remained untested, also due to subsequent failure to conclude the Doha Round.

The unanimous admission that public health related flexibilities are available to sovereign WTO member countries, was a major success of Doha. However, the euphoria of Doha Declaration evaporated when the TRIPS Council came out with a detailed procedure for operation of compulsory licence for export. The salient features of implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health are as follows:

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  - notification to TRIPS Council specifying (a) name and quantity of pharmaceutical product or medicine
  - certification of eligibility (LDC or no local manufacturing facility/capacity)
  - patent status (granted) in the importing and exporting countries.

Further it is stated that the compulsory licence be granted with specific conditions (mainly to ensure non-diversion to other markets).

These cumbersome procedures and conditions make compulsory licence under Para (6) of Doha Declaration, almost impossible. Canada (through Canada’s Access to Medicines Regime) took 2 to 3 years to clear the grant of export to Rwanda, in
Africa, a combination anti-HIV drug, in spite of permitted by the patentee to do so. This explains the complexity of the cumbersome procedures. Since the Doha Round was not completed and adopted, these procedures have not been legalized and are, therefore, not binding on member countries. India needs to finalize a simpler procedure in the Patent Rules to support the operation of Section 92(A) of its Patents Act, 1970.

**Patent Infringement Litigation**

Dubey *et al.* have analysed the performance of Indian pharmaceutical industry pre and post-TRIPS era. While there have been many patent infringement suits between Indian pharmaceutical companies post-2005, the limelight has been hogged by the ‘nib’ patent wars, the Imatinib (Gleevec) litigation leading the pack. Erlotinib, Sorafenib and Dasatinib are subject matters of ongoing litigation on both infringement-related injunctions and damages, as well as patent-regulatory linkages. While patent-regulatory linkage was contested by Indian pharmaceutical companies successfully from High Court to the Supreme Court, a few cases still languish for final orders in the High Courts. Astellas, a Netherlands based subsidiary of a Japanese group, has sued Microlabs for infringement of the Indian patent, while both Mylan (Matrix) and Microlabs have moved the IPAB for revocation of the granted patent of Astellas for fast-disintegrating tablets of amoxycillin trihydrate.

**The Gleevec case - The Epic Patent War in India**

The Gleevec case of Novartis which was being heard in Supreme Court of India has been re-scheduled for final hearing on 10 July 2012. The case can be traced back to an Indian patent application no 1602/MAS/1998 filed by Novartis in India on 17 July 1998. This patent specification claimed β-crystalline form of imatinib mesylate and distinguished the physical properties of the β-crystalline form as superior to that of the α-crystalline form. The claims were amended to focus on β-crystalline form even though a separate divisional application no 799/CHE/2004 was filed thereafter specifically claiming α-crystal form. Both the patent applications were subjected to pre-grant opposition. The β-crystalline form was opposed at the pre-grant stage by Cipla, Ranbaxy, Natco, Sunpharma and Cancer Patients Aids Association among others. The Indian patent application of Novartis claimed a Swiss priority while Switzerland had not been granted convention status by India, on the date of filing the divisional application.

Further, the imatinib base and salts thereof were extensively discussed in pre-1995 in an EP patent no EP0564409 which had the earliest priority of 3 April 1992 and was published on 6 October 1993 (hereinafter the 1993 patent). In the 1993 patent there were two important disclaimers by Novartis, one was that any mention of salts has to be read as base and vice versa (any reference to the free compounds should be understood as including the corresponding salts, where appropriate and expedient). All references to the base had to be expressed in the form of salt since the base was insoluble and could be not subjected to pharmacological and clinical test. Amongst potential salts described were methanesulfonic salts (mesylate) and benzene sulfonic salts (besylate). A second disclaimer clearly stated that the formation of salt was customarily known and was prepared by conventional processes (acid addition salts can be convened into the free compounds in a customary manner). Further, the use of the base and the salt for treatment of cancer was specifically claimed in the 1993 patent.

Pre-grant oppositions against the patent application claiming the β-crystalline form also laid specific emphasis on Section 3(d) of the Patents Amended Act, 1970. The basis was an amendment to Section 3(d) proposed in the Parliament while passing the 3rd amendment Bill. This amendment introduced an explanation to the section, clarifying what physical form came under the ambit of same substance, namely, ‘which does not result in the enhancement of known efficacy of the substance’. The ruling party and the opposition came to compromise accepting the two major and few minor amendments including the 3(d) amendment. The patent application for the α-crystalline form of imatinib mesylate was also rejected consequent to a pre-grant opposition thereafter.

Novartis filed appeals in the Madras High Court challenging both the constitutional validity of Section 3(d) as well as decision of Patent Controller rejecting the β-crystalline form. The hearing at the Madras High Court extended through 2006-2007. A well-reasoned order was passed by the Madras High Court upholding the constitutional validity of Section 3(d). Even though there was no specific provision in the Patents Act, 1970 for appealing against the rejection through pre-grant opposition under Section 25(1), the Madras High Court converted the appeal into a Section 15 application and proceeded with the hearing.
In the meantime, a technical member (patents) to IPAB was appointed and the same was notified on 2 April 2007. Consequently, the Novartis appeal and many other appeals which were pending in the High Court were transferred to the IPAB. Novartis objected to the technical member, who was an ex-Controller General of Patents, hearing the appeal on the ground that he was an interested party. A special technical member was appointed only to hear the Novartis Appeal. This appointment was done by the Supreme Court to whom Novartis had appealed. Madras High Court has been the subject of multiple appeals on Gleevec by Novartis. A detailed sequence of events in Gleevec case is narrated in Table 5. The IPAB upheld the decision of the Patent Controller which was further appealed to the Supreme Court by Novartis. On 9 August 2012, the final hearing in this matter began in the Supreme Court of India. A judgement is awaited before end of July 2012.

The Gleevec case is indeed an epic case for the following reasons.

Generic manufacturers produce generic forms of Gleevec at around 10 per cent of Gleevec price, post rejection of the Gleevec (β-crystalline form) patent application in India. Decision in favour of Novartis in the Supreme Court could lead to monopoly for Novartis in Gleevec, grinding to halt all generic production and thus, adversely impacting affordable access to this important cancer drug. The Supreme Court’s order on Section 3(d) could also affect the status of various other molecules where the patent applications were rejected earlier.

A sequence of events (Table 5) in the Novartis’ Gleevec case is as follows:

Pending prayers in the Supreme Court on the SLP by Novartis are as follows:

- (i) Grant special leave to appeal against the order dated 26 June 2009 passed by the IPAB, Chennai in

Table 5 — Sequence of events in the Gleevec (β-crystalline form) patent application

<table>
<thead>
<tr>
<th>Event</th>
<th>Relevant dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filing of EMR application no EMR/01/2002</td>
<td>27 March 2002</td>
</tr>
<tr>
<td>Grant of EMR for Gleevec by Patent Office</td>
<td>10 November 2003</td>
</tr>
<tr>
<td>Grant of injunction against Indian generic manufacturers of Imatinib</td>
<td>January 2004</td>
</tr>
<tr>
<td>Refusal to grant injunction by Delhi High Court</td>
<td>December 2004</td>
</tr>
<tr>
<td>Commencement of the product patent regime and passing of the 3rd Amendment to the Patents Act, 1970 with Section 3(d)</td>
<td>1 January 2005</td>
</tr>
<tr>
<td>Pre-grant oppositions by generic manufacturers &amp; Cancer Patients Aid Association</td>
<td>July 2005 to November 2005</td>
</tr>
<tr>
<td>Hearing of pre-grant oppositions at Chennai Patent Office</td>
<td>14/15 December 2005</td>
</tr>
<tr>
<td>Decision rejecting Gleevec application by Chennai Patent office</td>
<td>25 January 2006</td>
</tr>
<tr>
<td>EMR extinguished by rejection of product patent application</td>
<td>25 January 2006</td>
</tr>
<tr>
<td>Writ petitions by Novartis in Madras High Court</td>
<td>May 2006</td>
</tr>
<tr>
<td>- Against rejection of patent application</td>
<td></td>
</tr>
<tr>
<td>- Against Section 3(d)</td>
<td></td>
</tr>
<tr>
<td>Conversion of writ petition to appeal on its rejection during the hearing at Madras Patent Office</td>
<td>February 2007</td>
</tr>
<tr>
<td>IPAB comes into force</td>
<td>April 2007</td>
</tr>
<tr>
<td>Technical member (ex-CG of Patent Office) appointed</td>
<td>2 April 2007</td>
</tr>
<tr>
<td>Notification transferring all pending appeals in High Court (other than counterclaims) to IPAB</td>
<td>3 April 2007 (effective 2 April 2007)</td>
</tr>
<tr>
<td>Transfer of Gleevec appeal against rejection to IPAB by Madras High Court</td>
<td>4 April 2007</td>
</tr>
<tr>
<td>Order issued by Madras High Court on writ petition challenging the constitutional validity of Section 3(d)</td>
<td>6 August 2007</td>
</tr>
<tr>
<td>Questions on impartiality of the technical member – before the IPAB</td>
<td>July 2007</td>
</tr>
<tr>
<td>Petition dismissed by IPAB</td>
<td>July 2007</td>
</tr>
<tr>
<td>Appeal against IPAB dismissal (technical member) by Novartis to Madras High Court</td>
<td>August 2007</td>
</tr>
<tr>
<td>Madras High Court allows a 2-member IPAB bench to hear the Appeal (as proposed by DIPP)</td>
<td>November 2007</td>
</tr>
<tr>
<td>Appeal of Natco to Supreme Court against 2-member IPAB bench</td>
<td>December 2007</td>
</tr>
<tr>
<td>Stay issued by Supreme Court as requested by Natco</td>
<td>January 2008</td>
</tr>
<tr>
<td>Call for suitable candidates’ list by Supreme Court for technical member to hear Gleevec case in IPAB</td>
<td>October 2008</td>
</tr>
<tr>
<td>Supreme Court appoints special technical member to hear Gleevec case in IPAB</td>
<td>November 2008</td>
</tr>
<tr>
<td>IPAB hears the appeal and passes order rejecting the appeal and upholding rejection of the Gleevec patent application by Patent Controller</td>
<td>26 June 2009</td>
</tr>
<tr>
<td>Next hearing at Supreme Court No 7</td>
<td>10 July 2012</td>
</tr>
</tbody>
</table>


Judge made Compulsory Licence

In an application for interim injunction relating to infringement of patent granted for Erlotinib (Tarceva®), single bench of Justice S Ravindra Bhat in the Delhi High Court rejected the application in the interest of third party – public health.

This could be interpreted as first Judge made compulsory licence in India. This order of single bench was challenged in a division bench of Delhi High Court who not only upheld the order of the single bench but also imposed costs at Rs 5 lakhs on Roche for not disclosing the contents of the complete specification and facts concerning the pending (divisional) application for polymorph B. This was further challenged unsuccessfully by Roche. The hearing between Roche and large number of generic manufacturers with respect to the infringement suit involving infringement of Erlotinib patent are in progress in Delhi High Court.

Judgement on Date of Grant of Patents

While a pre-grant opposition could be filed any-time before grant of patent, a post grant opposition could be filed anytime within one year from the date of publication of grant. The ‘date of grant’ of a patent became a subject matter in a bunch of patent disputes in the Delhi High Court. Due to the lapse in the time between the actual grant of a patent and the issuance of the patent certificate, several oppositions during this period became controversial. Consequently, Justice Muralidhar directed the Controller of Patents to:

- list cases for pronouncement of orders under ‘cause list’,
- bar a pre-grant opposition once a final order granting patent is passed. However, a review petition under Section 77 (1) (f) read with Rule 130 may be filed by those who are parties to the order of the Controller,
- pass the ‘final order’ saying that ‘the patent is hereby granted’ only after all amendments have been carried out by the applicant to the satisfaction of the Controller and
- digitally sign and publish the ‘final order’ granting the patent.

Further, it was clarified that ‘date of grant’ for pre-grant opposition is the date of allowance recorded in the file wrapper or examination records. ‘Date of grant’ for post-grant opposition was confirmed as the date of publication of grant in the official Patent Office Journal.

Intellectual Property Appellate Board (IPAB)

Even though, the creation of an Intellectual Property Appellate Board (IPAB) had been on the anvil from 2003 (post the second amendment), IPAB commenced its operations only from 2 April 2007. Multiple options for patent benches in IPAB and separate patent (and trademark) benches in all cities with patent offices will be a welcome step to expedite the hearings and judgements as well as improve the functioning of the IPAB. The performance of IPAB during its first five years has not been upto expectations and has fallen short of the objectives. However, lately there have been attempts to revamp the IPAB by appointing a recently retired Judge of the Madras High Court as its Chairman. IPAB has commenced touring and conducting hearing at all the jurisdictions. However, the need for further reforms in IPAB is due, to improve case disposal which can be done by having IPABs in all individual jurisdictions under the overall supervision of the Chairman located at Chennai.

Compulsory Licence

While provisions for a grant of compulsory licence were substantially restricted in the post-TRIPS (amended) Patents Act, 1970 (such as omission of licence of rights and restriction of royalty to 3 per cent, etc. present in the pre-amended version), there were no compulsory licences granted against pharmaceutical patents in India till 2012. Provisions for compulsory licence exist in most patent laws overseas. Even in USA, a provision for compulsory licence for government use exists (outside the 35 USC which is US Patent Code) in 28 USC 1498. Many developing countries have been using compulsory licensing provisions for affordable access to lifesaving medicines while India had never put this provision to test, primarily because of the delay in grant of pharmaceutical patents. In March 2012, the first compulsory licence was granted in India for Sorafenib (Nexavar).
The Controller countered every objection raised by the patentee (Bayer) in a reasoned order. The compulsory licence was granted to the applicant (Natco) under specific terms and conditions. A sale price of Rs 8,800 per month (as against Rs 2,80,000 of Bayer) and royalty rate of 6 per cent on net sales (in view of low volume of sales of this product) were fixed. This first compulsory licence granted in India has been subject of global deliberations and debate. Incidentally as on date, this order has been challenged in the IPAB by the patentee, Bayer Corporation.

Post-TRIPS Thrust Triggers

Even after 15 years of TRIPS transition, the debate continues as to whether TRIPS and the IP patent scenario post-TRIPS triggered further growth of the Indian pharmaceutical industry or not. Abundant doomsday predictions, ever since the commencement of the Uruguay Round, disappointingly for some, did not come true. In the overall analysis, the Indian pharmaceutical industry woke up, took note of the new rules of the game, prepared themselves and commenced to master the IP/patent based international trade regime.

Post-TRIPS, there have been major thrust in the Indian pharmaceutical industry, some of which are as follows:

1. Increased patent awareness and proficiency creation
2. ‘Patent-expiry’ based thrust of generic pharmaceutical companies into the markets of developed countries such as USA and EU
3. Increase in domestic as well as overseas patenting activities by Indian pharmaceutical companies
4. Steep increase in USFDA, EDQM, EMA (EU) inspections and approvals to Indian pharmaceutical companies, lifting India to 2nd position after USA
5. Large DMF and ANDA filings as well as increase in 505(b)(2) filings and Para IV patent challenges in USA, prior to patent expiries.
6. Larger outlay in R & D expenditure by Indian pharmaceutical companies
7. Increase in funding by agencies including Government departments such as DST, DBT and others for pharmaceuticals research

Although, early results have not been very encouraging, the initiation of ‘new drug discovery’ programmes by larger Indian pharmaceutical companies is a major thrust area, post-TRIPS.

The transition from a ‘no product patent’ to the 10 year EMR pipeline and onward to a full-fledged TRIPS compliant product patent regime could not have been smooth had it not been for the agility with which the Act and the Rules were re-drafted and the amendments adeptly handled by law-makers and rule-drafters. The transition from ‘licence of right’ (automatic compulsory licence) to the new regime was expected to exhaust the options for the generic industry. With the support of the law-makers, the entrepreneurial pharmaceutical industry picked up the gauntlet and took full advantage of the new globalized and harmonized regime to enter new markets including advanced regulated markets and developing countries which had non-tariff regulatory barriers. The speed with which Indian pharmaceuticals became globally harmonized in the regulatory and intellectual property field have baffled most India watchers.

While a few of the amended provisions in the Patents Act, 1970 were criticized globally as non-TRIPS compliant, it is heartening to note that many overseas actions and judgements, have been influenced by the equitable balance of rights and obligations emphasized in the Indian patent law. WHO, WIPO and even US and EU patent procedures (including the new America Invents Act of 2012) appear to be appreciating the Indian patent law.

The new regime brought with it an eagerness to comply with the new global regulatory framework based on advanced GMP (good manufacturing practices), GLP (good laboratory practices) and GCP (good clinical practices) as well as new drug discovery Initiatives. The awakening effect on Indian pharmaceutical industry, post-TRIPS could easily be identified as a ‘thrust trigger’.

References
1. www.ipindia.nic.in (1 May 2012).
3. Preliminary examination used to be conducted on patent applications, immediately on filing, for errors or omissions and a preliminary publication was done in the Gazette within a week of application including provisional, giving details of the title and the applicant along with application number. This practice was discontinued from 20 May 2003, post-second amendment.
Pharmaceutical patent applications used to be examined and granted on fast track, since these patents had only 7 years patent term prior to TRIPS and Patents Act amendments.


Spicy IP, a blog by Prof Shamnad Basheer extensively covers all IP litigations in India.


For an overview of FDA India office activities and recent initiatives of FDA, http://www.ipapharma.org/events (1 May 2012).

