

Building a Patent Commons: Experiences with Patent Oppositions in India

Enabling Innovation for Global Health
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Tahir Amin

Director and Intellectual Property Solicitor

I-MAK

tahirmamin@gmail.com



INITIATIVE FOR MEDICINES ACCESS & KNOWLEDGE

Background

1 January 2005, India required to amend its Act under TRIPS and re-introduces patent protection on medicines. Parliament gives assent to the amendments on 4 April 2005. Some key amendments:

- New forms of known substances are not inventions unless they result in an enhancement of the known efficacy of the existing substance. Salts, esters, polymorphs, isomers, combinations and other derivatives etc considered to be the **same substance** unless they differ significantly in properties with regard to efficacy (section 3(d)).
- Act permits **any** person to oppose a patent before its grant under various grounds (section 25(1)) - under the 1970 Act pre-grant opposition limited to any 'person interested'.
- Act introduces post grant opposition for the first time for '**any person interested**' (section 25(2)).



Opening the Mailbox and Access to Patent Information

- First pharmaceutical product patents from mailbox published in the Official Patent Office Journal on 21 January 2005 as required under s145 (and s11A(5)).
- Publications in PDF format only, limited information and not text searchable. Key data missing e.g priority date.
- Patent specifications and information on patent application status/examination reports not freely available. E.g s144 - examination reports of examiners are not open to public inspection or publication.



Opening the Mailbox and Access to Patent Information

(21) Application No. 563/KOL-NP/2003 A (22) Date of filing of : 02/05/2003 application
(54) Title of the Invention : "NITROSO DIPHENYLAMINE DERIVATIVES"

(51) International classification : C07C 233/80 (30) Priority Data : (31) Document No. 00/12749 (32) Date : 05/10/2000 (33) Name of convention country : FR (66) Filed U/s 5(2) :NIL (61) Patent of addition to application No. NA (62) Filed on :NA (63) Divisional to Application No. :NIL (64) Filed on :NA	(71) Name of the Applicant : MERCK PATENT GMBH., OF FRANKFURTER STRASSE 250, 64293 DARMSTADT, GERMANY. (72) Name of the Inventors : 1. LARDY, CLAUDE, 2. NIOCHEM JEAN-YVES, 3. CAPUTO, LIDIA, 4. DECERPRIT, JACQUES, 5. ORTHOLAND, JEAN-YVES, 6. FESTAL, DIDIER, 7. GUERRIER, DANIEL.
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(57) Abstract : The present invention relates to a compound of formula (I) in which X, A, T, Y, G and R are as defined in Claim (1)



Opening the Mailbox and Access to Patent Information

PUBLICATION UNDER SECTION 43(2) IN RESPECT OF THE GRANT OF PATENT

Notice is hereby given, that any person interested in opposing the following patents under Section 25(2) may, at any time within one year from the date of this issue, give notice to Controller of Patents at the appropriate office on the prescribed Form 7.

SN	APPLICATION NO.	TITLE OF INVENTION	NAME OF THE APPLICANT	PATENT NO	APPROPR-IATE OFFICE FOR THE FILING OF OPPOSITION
1.	533/BOM/1999	A CONTAINER COMPRISING TWO CHAMBERS ADHERED TO EACH OTHER	HINDUSTAN LEVER LIMITED	196535	Mumbai
2.	536/BOM/1999	A DRYING APPARATUS, A DRYING APPARATUS ASSEMBLY, AND A METHOD FOR DRYING	DAITO SEIKI CO., LTD.,	196536	Mumbai
3.	543/BOM/1999	AN INSTRUMENT FOR MEASUREMENT OF SLOPE	SHRI VIVEK RAMESH DUDHE	196537	Mumbai
4.	578/BOM/1999	GARBAGE DUMPER PLACER	SHAFEE ABDUL RAHIM MANIAR AND OTHERS	196538	Mumbai

Extract of Granted Patents from Indian Patent Office Journal 23.12.2005



Opening the Mailbox and Access to Patent Information

- 3rd party intervention to aid transparency:

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What:

india.bigpatents.org is the first site to provide a complete, searchable (and free!) version of post-TRIPs Indian patent applications and issued patents.

Who:

india.bigpatents.org was created by [Professor Bhaven Sampat](#) of the [International Center for Health Outcomes and Innovation Research \(InCHOIR\)](#) and the [Department of Health Policy and Management](#) at Columbia University, together with Patrick Crosby of [XB Labs, LLC](#) and [bigpatents.com](#). The Ford Foundation generously provided material support for data collection and software development, and Sarah Allenby provided excellent research assistance.

Why:

After becoming a signatory to the TRIPS agreement last year and enactment of Patents (Amendment) Act in 2005, India has become the flavour of the season. But India's patent infrastructure is still in its infancy.

The [Indian Patent Journal] has been online only for about a year now ... However, this has not made the search any easier ... there is no indexing... one has to search each issue manually from cover-to-cover if one needs to check on a patent application.

The need of the hour is to have all the approved patents and published applications digitised so that they can be accessed as easily as people access the US or EU patents.

From "[The Patent Challenge](#)", Express Pharma, 13-16 July 2006.

A modern patent system requires modern data infrastructure. Searchable data on Indian applications and patents are critical to ensuring that the patent system promotes the development of new technologies, facilitates the diffusion of these technologies, and issues high-quality patents.

How:

The bulk of the data was parsed from the Indian patent journals, beginning with those published in January, 2005, using proprietary algorithms developed by [XB Labs](#). Data not parsable via programming were hand coded by [Digital Divide Data](#), a non-profit social enterprise offering data



Opposition Procedure in Practice

- Disparities in practice between four patent offices - lack of clear patent office examination guidelines.
- Ambiguous procedural rules with respect to right to receive patent applicant's response to pre-grant opposition and whether hearing is *ex parte* or *inter partes* (r.55).
- Lack of skilled examiners with adequate understanding of patent law and limited resources.



Successes of Pre-grant Opposition to Date

- Has made the patent process more 'democratic' by allowing any party to intervene prior to grant of a patent. At least 150 pre-grant oppositions filed to date.
- Assists under resourced/skilled patent offices/examiners with respect to finding relevant prior art and understanding of pharmaceutical industry practices for extending the patent life cycle of known compounds to prevent generic entry e.g salts and polymorphs.
- Some successes to date:
 - Novartis's application for Gleevec (imatinib mesylate) refused.
 - GSK withdraws application for Combivir (Lamivudine+Zidovudine)
 - Pre-grant opposition against Viread (Tenofovir Disoproxil Fumarate) resulted in Gilead offering 11 voluntary licenses to Indian generic companies.
 - Cipla successfully opposes Wockhardt's application for Nadoxin (benzoquinolizines) a tropical cream formulation for treating mupirocin-resistant bacterial infections.



Resources Required for Oppositions

- Human resources to check publications and status of applications including travel expenditure for 4 patent offices.
- Printing and photocopying facilities.
- Access to databases and textbooks - commercial patent databases, scientific journals, industry textbooks and journals.
- Access to pharmaceutical chemists with industry know how and knowledge of properties of drugs being opposed.
- Independent laboratories to carry out tests on claimed inventions e.g. salt selection cases, synergy in combination patents, bioavailability and stability tests.
- Opposition fees for post grant opposition (albeit nominal for natural persons e.g Rs 1,500) and costs awarded to the applicant if unsuccessful.
- Patent attorneys/lawyers willing to act in the public interest - lawyers fees.



The Future of Pre and Post Grant Opposition

- Lack of Transparency - over 9,000 mailbox applications for pharmaceutical products, not including new applications. A greater role for the Right to Information Act?
- Lack of skilled lawyers/pharmaceutical chemists available to file oppositions in the public interest. Is the opposition model sustainable - approximately 20 pre-grant opposition decisions have been appealed?
- How will the patent office interpret 'any person interested' for the purpose of post grant opposition?
- How will the patent office and courts develop legal standards for patentability? Patents are being granted for products that fall within s3d.
- Pressure from USTR on India to remove pre-grant opposition.
- How will the changing landscape for India's domestic industry affect the patent law and opposition systems?



Other Suggestions

- Guidelines on pharmaceutical patenting practices to assist examiners in patent offices (e.g *Prof. Carlos Correa - Guidelines for the Examination of Pharmaceutical Patents - (ICTSD/WHO)*).
- The need for examiners to have access to key databases and resources in order to carry out effective examination.
- Develop new tools to assist examiners, lawyers and civil society to challenge/scrutinise patents.
- Training materials for lawyers/NGOs in developing countries, including developing IP law and public health clinics to foster a new environment for public interest lawyering.
- Strengthen the International Preliminary Examination Report (IPER) mechanism for applications filed under the Patent Cooperation Treaty so as to reduce burden on developing country offices with no examination capability and deter applicants pursuing weak patent applications. This could involve WIPO accepting third party submissions E.g Morocco and South Africa may only rely on IPER's.



THANK YOU

