

From Transparency to Quality: *Bridging the Gap Between Access to Knowledge and Medicines*

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INITIATIVE FOR MEDICINES ACCESS & KNOWLEDGE

The Need for Transparency

- In the developing country context, to assess patent quality there first needs to be transparent patent publication, examination and grant systems.
- This requires searchable electronic patent office databases that provide free access to complete patent specifications for examined and granted patents, including examination file wrappers/file histories.
- Without transparency, mechanisms such as pre/post grant opposition(or observations/opinions) to aid patent quality cannot work effectively.



The Need for Transparency

- India operates a pre-grant and post opposition system but the lack of transparency and access to patent information from the patent office hinders its effectiveness for several reasons:
 1. The Patent Office does not provide a searchable electronic patent database, but only PDF files of individual published applications for opposition or grant.
 2. The publications only provide basic details of the application or granted patent and not the full specification. Often, even the basic data is missing e.g priority data.



The Need for Transparency

(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)



The Need for Transparency

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



The Need for Transparency

- Intervention by Prof. Bhaven Sampat of Columbia University and Patrick Crosby of XB Labs (with assistance from Ford Foundation) to create a searchable database, BIG PATENTS INDIA <http://india.bigpatents.org/>.

India BigPatents -- Home

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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



The Need for Transparency

3. Copies of the patent specifications and information on the status of applications have to be requested from the patent office on payment of a fee.
4. Examination reports of examiners are not open to public inspection or publication unless court specifies the need for legal proceedings (s144 - Indian Patents (Amendment) Act 2005).



Improving Pharmaceutical Patent Quality

- Creating patentability standards that consider pharmaceutical industry practices/techniques for extending patent life of known substances as not being inventive/obvious e.g section 3d Indian Patents Act lists the various substances/forms of a known substance e.g salts, esters, polymorphs, isomers as not being inventions without showing a significant difference in properties re efficacy.
- E.g Lopinavir crystalline forms (European Application No. 01924250) claiming greater than 90% purity. Abbott Laboratories argued that there could be no reasonable expectation of success for obtaining the crystalline forms. The application was rejected on the ground that it lacked inventive step/unexpected advantages over Abbott's earlier patent for the amorphous form.



Improving Pharmaceutical Patent Quality

- 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.
- 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.



Improving Pharmaceutical Patent Quality

- Pre Grant Opposition mechanisms can assist under-resourced examiners and strengthen examination by allowing third parties to submit evidence. Makes the patent system more 'democratic'.
- E.g. Examination reports for Tenofovir Disoproxil Fumarate at the PCT level, European Patent Office and USPTO failed to cite key prior art literature relating to salt selection practices e.g. *P. Gould - Salt Selection for Basic Drugs, International Journal of Pharmaceutics (1986)*. See also recent case Pfizer Inc. v Apotex (CAFC), 2007 relating to the drug Norvasc®.



Improving Pharmaceutical Patent Quality

- Predicate patent terms on patent quality, e.g. X years for new inventions such as new chemical entities, X-Y for incremental modifications demonstrating therapeutic benefit.
- “Reverse damages”: award penalties against a patent holder whose patent is successfully opposed or subsequently invalidated and which has kept competitors off the market. E.g. Pfizer v Apotex. This could deter applicant’s from making applications for non-meritorious patents that impact the cost of access to medicines. Also creates a ‘shared burden’ between the Applicant, patent office and courts.



THANK YOU

