Case law clearing up patent law issues

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IP PRACTICE NEW DELHI . INDIA

not just patent law issues, even the offices got cleared up..

India, patents, the shift in policy – black, white and grey

The 1994 Ordinance*[1] articulates it this way:

Amend the patent law to meet India's obligations under TRIPS/WTO;

While doing so, safeguard its interests;

In formulating policy, adopt measures consistent with TRIPS/WTO, but necessary to protect public health and nutrition;

And also to promote public interest in sectors of vital importance to India’s socio-economic and technological development.

*1_New Delhi, the 31st December, 1994/Pausa 10, 1916 (Saka)
THE PATENTS (AMENDMENT) ORDINANCE, 1994
No. 13 OF 1994

patent policy - black, white and grey

Transition from the 1911 law to the 1970 law and rules

Two committees:
1948 Oct – 1949 Aug (Dr. Bakshi Tek Chand & Mr. K. Rama Pai) Outcome: compulsory licensing provisions, mainly.

1957 Apr – 1959 Sept (N. Rajagopala Ayyangar & Dr. S. Venkateswaran) Outcome: the 1970 Act with limited term process patent for food, drug, medicine.

1970 law & rules
the pre-WTO era

The 70s, 80s and 90s – India's experiment with a 'government – license based market economy' – patent policy and law aligning with the pre-economic liberalisation era (prior to 1991)

The new economic policy of 1991 (gradual liberalisation towards free and fair market economy, by privatisation of public sector companies & by removing FDI restrictions) – didn't really touch the patent law.

WTO/TRIPS 1995-2005
changed the policy

TRIPs driven transition was significant: 1994 Ordinance, 1998 Paris Convention accession, 1998 PCT accession, 1999 Ordinance, the 1999 Act, 2001 Budapest Treaty accession, the 2002 Act, the 2004 Ordinance, the 2005 Act.

The whole debate on pharma/chemical product patents, EMRs, Mailbox, CLs, a Joint Parliamentary Committee, setting up of IPAB, Patent office modernization, the Glivec saga, the Delhi HC decisions on pharma patents, ISA/IPEA, new patent manual, outsourcing search, to the most recent/India's first CL application Nexavar (Sorafenib) of Bayer by Natco.

patent policy & law: the grey areas

TRIPS+ was a no, no.

TRIPS^{-} is something that the policy makers wanted, but also wanted to avoid a TRIPS non-compliance and an eventual dispute at WTO/DSB.

This lead to tweaking the law to 'soften up' the 'pharma product patent' regime, while ensuring Indian generic's interests. Means 'no' to patent term extension strategies (if at all that is possible in Indian law/the so called "evergreening"), while letting generic pharma companies' around patented drug molecules

Section 3(d) as an additional test of inventive step through the non-statutory subject matter route.

More statutory exceptions.

No new use claims.

Inventive step definition was played with/tech. advancement & economic significance.

'New invention'. Unsure of its implication, though.

Expanded CL provisions.

Pre and post grant oppositions.
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Do we see more office actions with 3(d) based claim rejections?

Pre-grant used to delay prosecution.

Conversion of new use claims into kit type claims or even product claims – all stopped?

Do we see more claim rejections based on the amended definition of inventive step?

CL – need to wait and watch what the CG says in the Natco-Nexavar case.

On 3(d) the Glivec saga is on. Now at the SC.

on patent prosecution..

Local working– is it really possible to submit correct and complete data?

Information disclosure – can a patent applicant comply with this obligation easily? what is the use of this data?

Foreign filing permission – lack of clarity on who is an Indian resident?

Deemed abandonment – un-substantiated abandonment orders instead of refusal to grant, is the practice changing?

Right of hearing – in pre-grant oppositions, as well as before the Controller passes any adverse order?

Prosecution deadlines – are they sacrosanct?

And

Notes on claims/examination practices.

local working

Patentees must Working Statement every year explaining if the invention is worked in India on commercial scale.

The Working Statement (to be filed in Form 27) must state, if the invention is worked or not, if not; the reasons thereof, if worked the quantum and value in INR of the product manufactured in India or imported.

The Working Statement must include licensing details, if any and a statement if the requirements of the public has been met partly, adequately or fully.

The statement must be filed before March 31 every year. No official fee.

Consequences of refusing or failing to furnish Working Statement is a punishable offence and the fine can be up to INR 10,00,000 (US$20,000).

FORM 27

THE PATENTS ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003

Statement regarding the working of the patented invention on commercial scale in India

[See section 146(2) and rule 131(1)]

No Fee

1. Insert name, address and nationality.

In the matter of Patent No.....of .....

I/We[1] .....
.....
.....

2. State the year to which the statement relates

The patentee (s) or licensee (s) under Patent No..... hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year[2].....

3. Give whatever details are available.

(i) The patented invention:
{ } Worked { } Not worked [Tick (✓)mark the relevant box]

(a) if not worked: reasons for not working and steps being taken for working of the invention.

(b) if worked: quantum and value (in Rupees), of the patented product:

i) manufactured in India

ii) imported from other countries. (give country wise details)

(ii) the licenses and sub-licenses granted during the year;

(iii) state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price.

The facts and matters stated above are true to the best of my/our knowledge, information and belief.

Dated this ..... day of .....200 .....

4. To be signed by person(s) giving the statement.

Signature[4] .....

To
The Controller of Patents
The Patent Office
at .....

Note: (a) Strike out whichever is not applicable.".

deemed abandonment

Writ Petition: Telefonaktiebolaget LM Ericsson *v*. Union of India & Ors *(W.P(C) 9126 of 2009) (*Delhi High Court).

Indian patent examiners rarely issued reasoned orders rejecting patent applications.

Even if an applicant files response to the office actions on time, meet the examiner multiple times, explain the invention, enter claim amendments, advance argument and do everything possible to get an application granted, the Controller would issue an Abandonment Letter. Often a one-liner.

Abandonment Letter means, a letter to the applicant stating that under Section 21 of the Patents Act, it has been found that the applicant has failed to comply with the requirements imposed by the Act within the prescribed period, and as such the application is deemed to have been abandoned. This order under Section 21 is non-appealable (to IPAB).

What the Controller should be doing is to issue a reasoned order under Section 15 refusing to grant a patent setting out the reasons thereof.

The Court set aside the order, compared Section 21 and 15, and directed the Patent Controller to pass a reasoned order.

national phase entry deadline –not to be missed..

Writ Petition: Nokia Corporation *v* Deputy Controller of Patents *(W.P. (C) 2057 of 2010): Case concerns* missed national phase entry deadline.

Whether the Controller has discretionary powers (under Rules 137 and 138) to 'condone' the delay in filing a national phase patent application after the 31 months' deadline?

The Petitioner missed the deadline.

The Controller's position was that a delay caused due to a docket error does not fall under the category of condonable delays.

The Controller interpreted the rules in light of Article 48 (Delay in Meeting Certain Time Limits) and Rule 82 (Irregularities in the Mail Service) of PCT Regulations to conclude as above. Controller's position was that a petition seeking exercise of his discretion under Rule 138 must be filed before the end of the prescribed time period.

In this case the petition seeking extension of time should have been filed within the 31 months' timeline. The Petitioner appealed before the Single Bench of the Madras High Court, which asked the Controller to re-consider the case. But, the Controller has now preferred an appeal!

RFE deadlines too..

Indian patent law is among the world's most stringent and has hard hitting deadlines. Many deadlines are non-extendible, hence sacrosanct. You miss them, your application is killed.

Writ Petition: Nippon Steel Corporation *v* Union of India *[W.P (C) 801 of 2011]*, (Delhi High Court). Docketing error.

The Court made some interesting analysis in this case that reiterates the criticality of error free docketing

The patent agent of Nippon, inadvertently missed the deadline to file a Request for Examination for one of its patent applications. This was a PCT National Phase case claiming priority from a Japanese patent application. Under India's patent rules 24 B, a Request for Examination (RFE) must be made within 48 months from the date of priority or the date of the filing of the application whichever is earlier.

The due date for filing the Request for Examination for this case was 9th February 2010. This was missed.

The case got killed.

right of hearing

Writ Petition: Universidad Politechnica De Valencia *v.* Union of India & Ors (W.P No. 1435 of 2007; Bombay High Court).

The application was deemed abandoned without even giving the applicant a fair hearing.

The issue before the Court included:
Whether the action of the Controller in denying the applicant a hearing on the ground that the request for hearing was not made before the mandatory 0 days period prior to the 12 month's deadline equitable?

Court held that Section 21 requires a judicious exercise of discretion on the part of the Controller and this exercise of discretion has an inbuilt element of hearing, as recognized under section 80 of the Patents Act.

information disclosure

A patent applicant must:

(a) File a statement of corresponding applications (Form 4) containing:

(i) country name
(ii) application date
(iii) application number
(iv) status
(v) publication date &
(vi) grant date

(b) File an *undertaking* to keep the Controller informed of the above details within 6 months from the date of application (same Form 4) .

(c) Submit details of such corresponding applications if the Controller requires within 6 months thereof.

foreign filing permission

Indian residents wanting to file foreign application(s) must obtain a Foreign Filing Permit, if no Indian application is filed within 6 weeks prior to such foreign application(s).

This rule applies even if an inventor named in the application is an Indian resident.

This rule does not apply to an application first filed outside India by a person not resident in India.

Controller will grant such Foreign Filing Permit within 21 days. Relevant form is Form 25.

The official fee is INR 4000 (US$ 40).

Non-compliance of this provision is an offence punishable with upto 2 years of imprisonment or fine or both.

date of grant of a patent

Writ Petition: Dr. Snehlata C. Gupte *v*. Union of India & Ors *(W.P. (C) No 3516 and 3517 of 2007*.

Case sought to set right the delay/time-gap between the date of putting an application in condition for grant and the actual date of grant.

Those who are familiar Indian patent practice would know that at times it can take many months to get a Letter of Patent after putting the application in condition for grant. And there has been no certainty regarding the actual date of patent. This decision clears the ambiguity concerning the date of patent.

Held: the date of grant of a patent is the date on which the Patent Controller passes an order to that effect and records it on the relevant file. Patent must be granted once it is found that either the application has not been refused under Section 25(1) r/w rule 55 (6) (Pre-grant Opposition).

patentability criteria

Definition of ‘inventive step’:

“a feature of an invention that involves **technical advance** as compared to the existing knowledge or having **economic significance or both** and that makes an invention **not obvious** to a person skilled in the art”.

The Examiners however confine to the test of obviousness.

The Patents Act did not contain a definition of novelty. Now includes a definition of **“new invention”**:

“any **new invention** or **technology** which has **not** been **anticipated by publication** in any document or **used** in the country or **elsewhere in the world** before the date of filing of patent application with complete specification, i.e., the **subject matter has not fallen in public domain** or that it does not form part of the **state of the art**”.

The Examiners however use the test of anticipation by previous publication, prior public working or public knowledge to determine novelty.

CHAPTER II

INVENTIONS NOT PATENTABLE

3. What are not inventions.—The following are not inventions within the meaning of this Act,—

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

[1][(b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;]

(c) the mere discovery of a scientific principle or the formulation of an abstract theory [2][or discovery of any living thing or non-living substances occurring in nature];

[3][(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.

Explanation.—For the purposes of this clause, 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;]

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

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1. Subs. by Act 38 of 2002, sec. 4, for clause (b) (w.e.f. 20-5-2003).
2. Ins. by Act 38 of 2002, sec. 4 (w.e.f. 20-5-2003).
3. Subs. by Act 15 of 2005, sec. 3, for clause (d) (w.r.e.f. 1-1-2005). (*See* Annexe)

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

[1][***]

(h) a method of agriculture or horticulture;

(i) any process for the medicinal, surgical, curative, prophylactic [2][diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals [3][***] to render them free of disease or to increase their economic value or that of their products.

[4][(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(k) a mathematical or business method or a computer programe *per se* or algorithms;

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;

(n) a presentation of information;

(o) topography of integrated circuits;

(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.]

notes on claim/examination practices..

multiple independent claims are often objected. Even if unity of invention is proved.

the age old practice has been to allow one independent claim (product claim) followed by one process claim. This practice is now changing. Also the Examiners used to insist that claim 1 must recite all the inventive features. Typically, the Examiners used to prefer a broadly worded (narrow in scope) first claim followed by a chain of dependent claims. And an omnibus claim supported by a statement of invention in the specification. The new Manual says, no more omnibus claims.

transitional elements such as 'further comprising' can invite rejection on grounds of lack of unity.

dependent claims must be directed at qualifying the integers recited in the first claim. According to many Examiners, all dependent claims must literally fall within the coverage of the main claim.

though no express statutory limitation – too many claims are not allowed. Often the number of claims will range between 15 – 25.

there exist lack of uniformity in the practices followed by various examination units. A lot would depend upon the personal approach of a controller. The manual and the Patent Office Practices (PoP) seek to change it.

examination practices

first examine to determine if the subject matter is patentable under section 3 (whether it is statutorily excluded from patentability).

if not excluded, examine the application to determine patentability of the claimed invention. Carry out an independent search, rather than relying solely on the ISR. Indian Examiners do cite prior art references not found in the ISR. This trend is new.

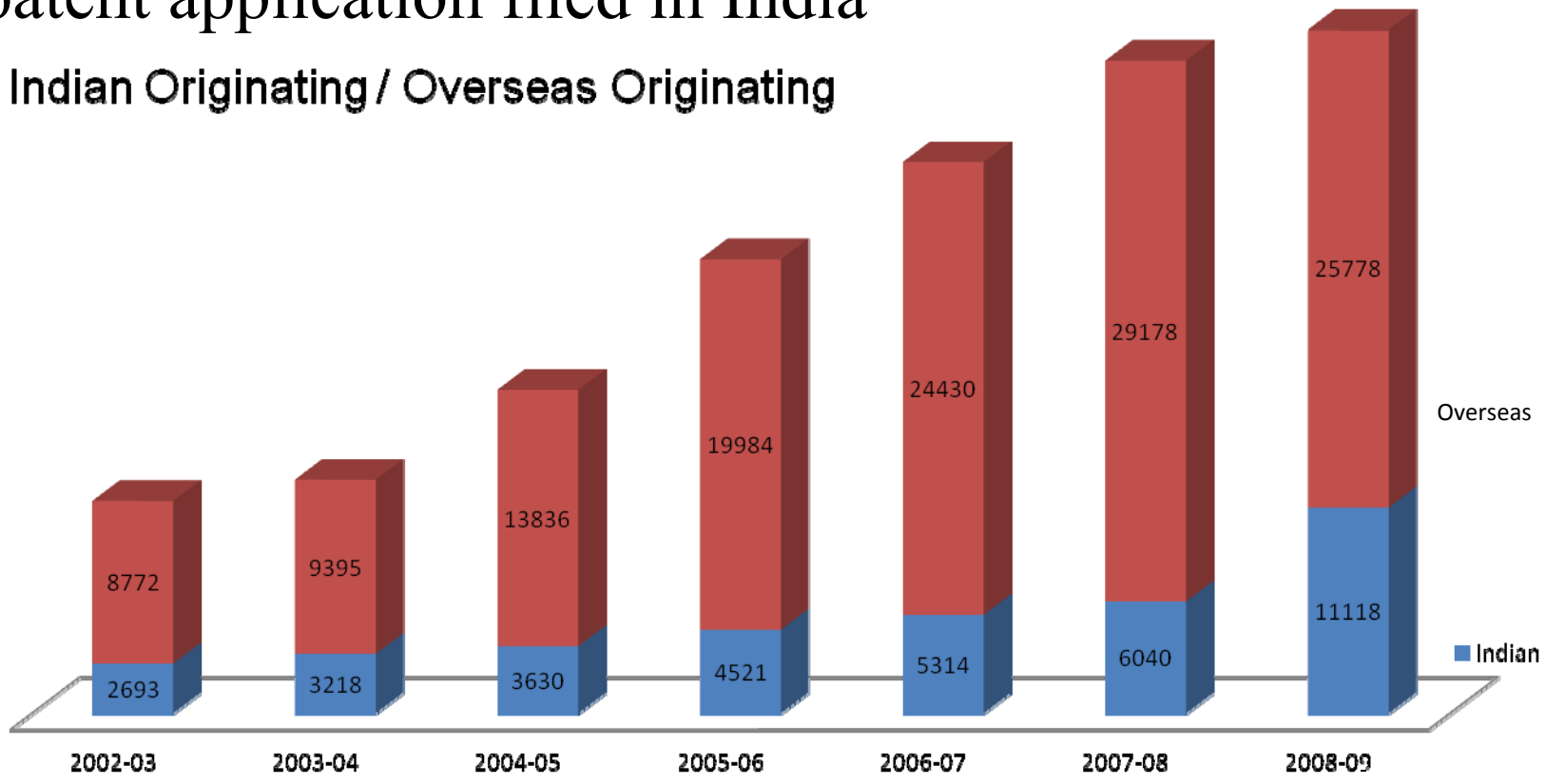
examination to determine compliance with Section 10 of the Act follows – claims – clarity, succinctness, claim format, types, support, unity/double patenting, consideration of the amendments, if any and so on.

the new rules prescribe timelines for examiners to make their reports to the controller.

also, now file history is beginning to get published. Hence examiners/controllers are more cautious/conscious.

over to some statistics before we end..

patent application filed in India



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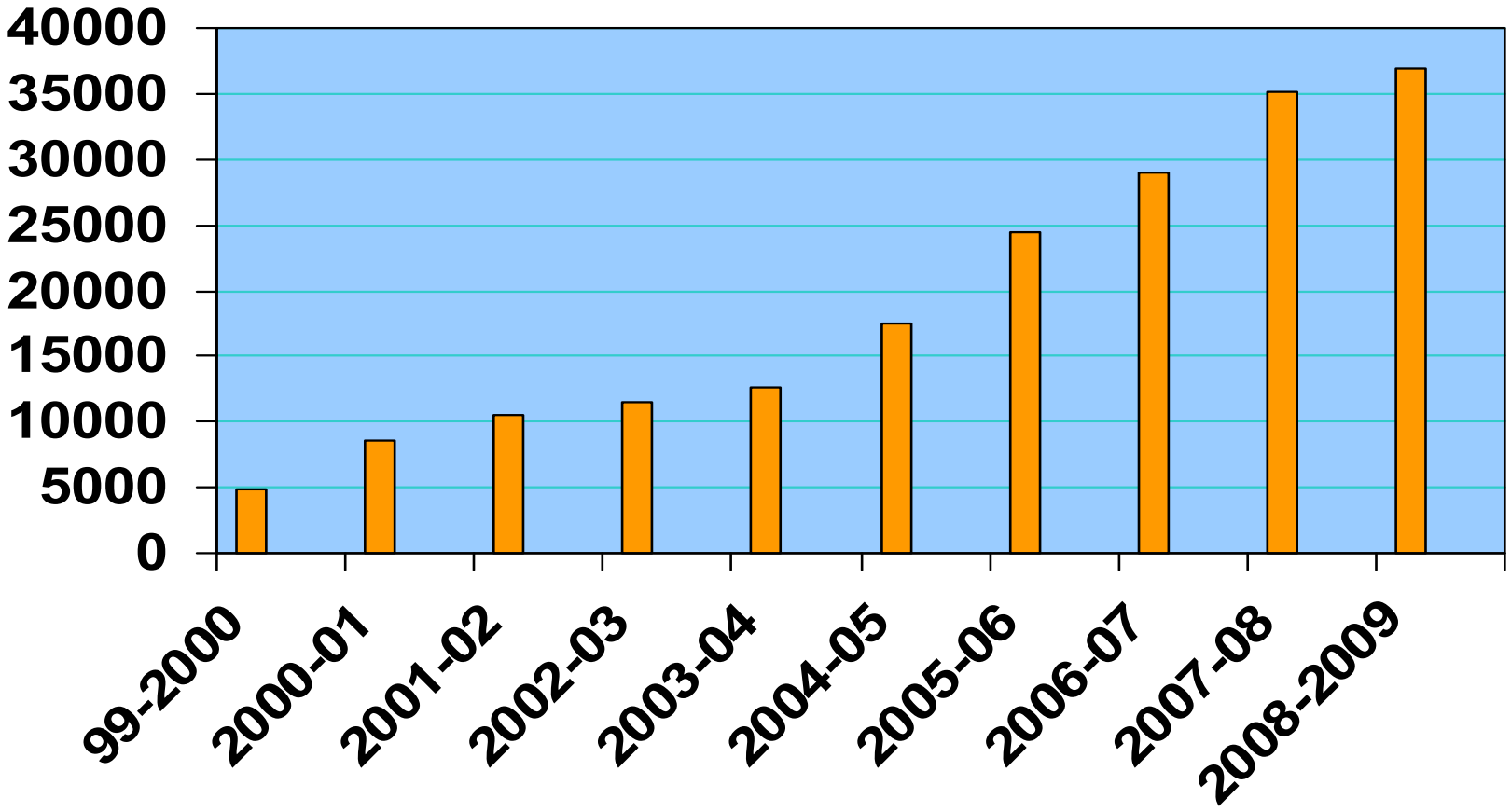
Source: Indian IP Office Journal

patent application filed in India



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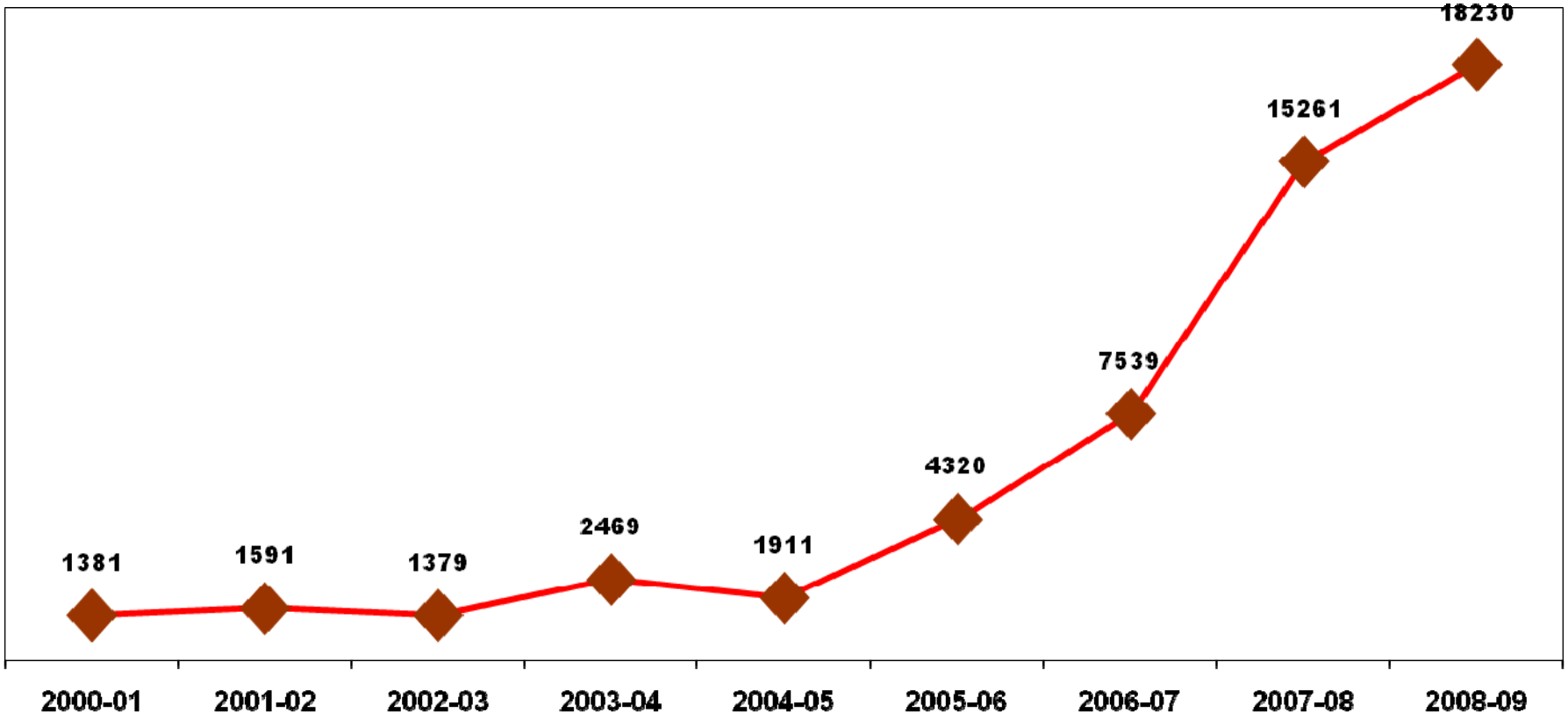
Source: Indian IP Office Journal

technical area-wise filing trend

Field of the invention	No of applications
Chemicals and agrochemicals	6503
Drugs and Pharmaceuticals	7407
Computer science and Electronics	8386
Electrical	2210
Mechanical	6424
General	2486
Polymer and Textile	1447
Metellurgy	334
Microbiology	119
Total	**35316**

Source: Indian IP Office Journal

patent grant trend



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Source: Indian IP Office

MAIL BOX APPLICATIONS

	No of applications	Patent granted		
		Indian	Foreign	Total
Pharmaceuticals	7945	260	1616	1876
Agrochemicals	973	23	176	199
Total	8918	283	1792	2075

Source: Indian IP Office

PHARMACEUTICALS PATENTS

Year	Applications filed	Patent granted
	Total	Total
2005-06	2211	457
2006-07	3239	798
2007-08	4267	1469
2008-09	2674	1166

Source: Indian IP Office

PHARMACEUTICAL CASES: PRE GRANT OPPOSITIONS

As on March 31, 2009

	Filed	disposed	Pending
Total	393	118	337

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Source: Indian IP Office

PHARMACEUTICAL CASES: POST GRANT OPPOSITIONS

As on March 31, 2009

	Filed	disposed	Pending
Total	149	27	122
Pharmaceuticals	52		

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Source: Indian IP Office

PATENT APPLICATIONS/OPPOSITIONS IN PHARMACEUTICALS*

January 1, 2005 – March 2009

	No. Applications	Pre-grant	Post- grant
Total number of cases in all areas	126344	455	149
Pharmaceuticals	12391	312	52

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Source: Indian IP Office

When it comes to law, and legal systems, there will always be some grey areas, Indian patent law is no exception. courts will continue to fill in..

Thank You

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