

Rejected in India:

WHAT THE INDIAN PATENT OFFICE GOT
RIGHT ON PHARMACEUTICALS PATENT
APPLICATIONS (2009–2016)

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Contents

Executive Summary	5
1. Introduction	9
2. Methodology	11
3. Data	14
4. Analysis	16
4.1. Grounds of Rejection	20
4.2. Patentable Invention	20
4.3. Statutory Exceptions to Patentability	21
4.4. Section 3(d)	23
4.5 Rejections due to Applicant’s Inaction	25
5. Conclusions	26
An Overview of the Rejection Process	28
Glossary of Sections Quoted	29
End Notes	32

Executive Summary

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Executive Summary

Introduction

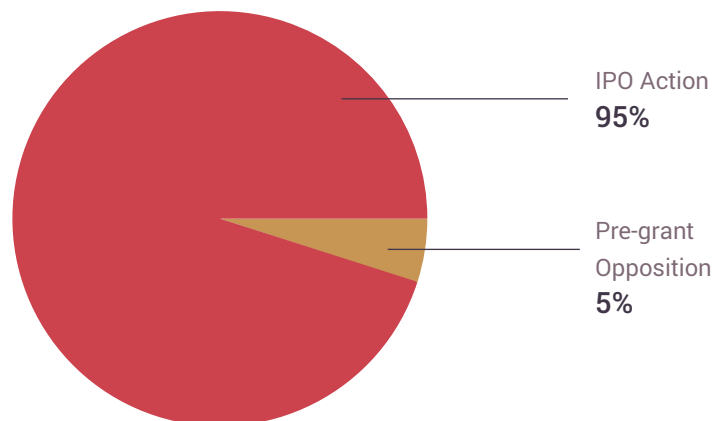
This report identifies the 1723 pharmaceutical patent applications that were rejected by the Indian Patent Office (IPO) between January 2009 and January 2017. The pharmaceutical applications covered include those rejected solely by the IPO as well as those rejected by the intervention of third parties in the form of pre-grant oppositions.

The Role in Rejections: IPO vs. Pre-grant Opponent

Pre-grant oppositions account for only a minor fraction of rejections (5%). Most applications (95%) were rejected solely by the IPO.

Most of the pre-grant oppositions (72%) were initiated by a single entity. The concern that pre-grant opponents indulged in serial oppositions to abuse the process turned out to be untrue.

Rejection Distribution: Office Actions vs. Pre-grant Oppositions



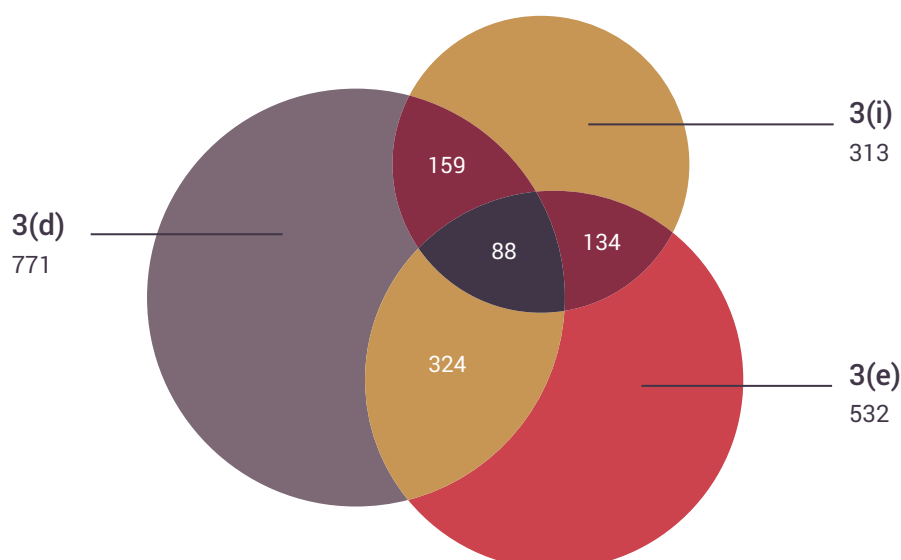
The Most-Used Grounds of Rejections

	Grounds of Rejection (under different sections)							
	2(1)(j)	2(1)(ja)	10	8	16	59	77	3
No. of Applications	945	466	386	186	118	75	4	1113

Chief amongst the grounds for rejection was the basic criterion of patentability (Section 2(1)(j) & 2(1)(ja)) which requires an invention to be novel, involve an inventive step, and to have industrial applicability to be patentable. 77% of applications were rejected because they failed to satisfy this basic criterion. These applications were predominantly rejected due to lack of an inventive step. Over one-third of orders for rejection in this category make a particular reference to a new definition of inventive step (Section 2(1)(ja)), which introduced a heightened standard of patentability in India.

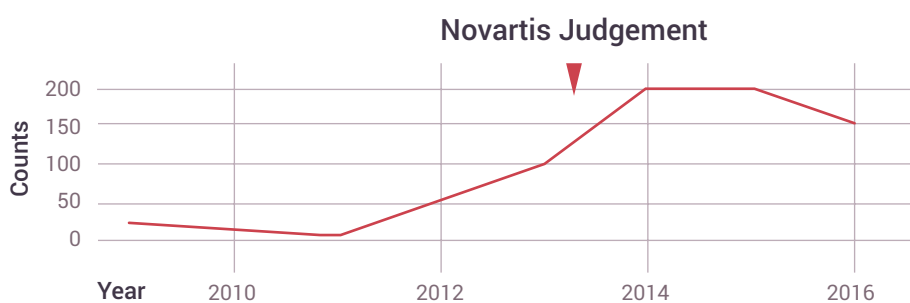
Impact of Section 3(d)

Statutory exceptions to patentability also featured prominently in the reasons for rejection, with around 65% of rejections citing Section 3 as a ground for rejection. Various sub-sections under Section 3 were often cited in combination, with exceptions to patenting new forms of known substances (Section 3(d)), mere combinations of known drugs (Section 3(e)), and methods of treatment (Section 3(i)) being the most commonly cited grounds in this category.



Section 3(d) was raised in 69% of the cases where the exceptions to patentability were cited indicating its use as a policy tool by the IPO in rejecting applications that fell within the exceptions.

Section 3(d)



Application of Section 3(d) after Novartis

The increased application of Section 3(d) by the IPO soon after the Novartis case could be due to the legal certainty provided by the decision of the Supreme Court in upholding the rejection of a patent application rejected under that section.

Uncontested Objections

The applicant is given an opportunity to be heard before a final rejection of an application. During the hearing, the applicant may make arguments to contest the Controller's decision or amendments to the application in order to circumvent objections raised. However, in a majority of cases (61%), the applicants did not avail this option, choosing instead to let the objections remain uncontested.

1.

Introduction

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1. Introduction

To understand how the Indian Patent Office (also known as the Intellectual Property Office or IPO for short) had examined patent applications involving pharmaceuticals, we analysed a set of orders passed by the IPO while rejecting patent applications. The IPO is not normally obliged to give a written opinion when it rejects a patent. But some provisions of the Patents Act, 1970 require the Controller to give a hearing to the party, in case the Controller chooses to exercise his discretion. For instance, rule 129 of the Patents Rules, 2003 requires the Controller to give an applicant or a party, a hearing before exercising any discretionary power. Moreover, the Controller is obliged to give a written opinion on the rejection when the ground/proceeding on which the patent application is rejected can be appealed to the Intellectual Property Appellate Board (IPAB). Section 117 A (2) provides the instances in which the order of the Controller can be appealed to the IPAB. In all the above instances the Controller will be required to give a written opinion. We analysed the orders passed by the IPO when it rejected patent applications, the copies of which were hosted on the IPO website. We wanted to study how the IPO had rejected patent applications pertaining to pharmaceuticals, to understand the role played by the Patent Office in safeguarding the interests of the public in rejecting applications for medicines and drugs which do not satisfy the conditions of patentability. To do this, we identified patent applications for pharmaceuticals based on the International Patent Classification (IPC) codes (A61K, A61P, C07C and C07D) for the years 2009-2016.¹ When the IPO rejects an application, it is done under section 15 or under section 25(1) of the Patents Act, 1970. Section 15 rejections are done by the IPO on its own without the involvement of third parties, whereas section 25(1) rejections result from a pre-grant opposition filed by an opponent or opponents.

2.

Methodology

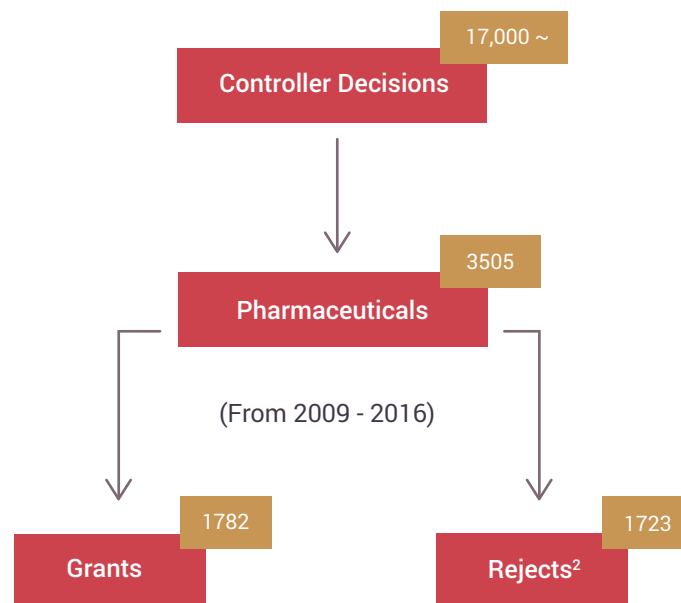
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2. Methodology

Our analysis is based on data freely available at the website of the Indian Patent Office (IPO). Since we were particularly interested in rejections accompanied by a written opinion, we accessed these from the IPO's archives of the Controller's decisions.² Before issuing an order of rejection, the Controller sends the First Statement of Objection (similar to Office Actions at the USPTO) and gives adequate opportunity for the patent applicant to overcome the objection. The Controller also calls for a hearing of the applicant or the parties before passing an order of rejection.

Classification based on IPC Code¹ & Applicant Information



¹ IPC Code - A61K, A61P, C07C & C07D.

² Based on IPO database

We retrieved all decisions issued over a span of 8 years (January 2009-January 2017), yielding more than 17,000 decisions from all branches of the Patent Office (Chennai, Delhi, Kolkata, Mumbai). Not all decisions end in a refusal to grant, and

we proceeded to cull the dataset to include only those decisions culminating in a rejection. This was carried out by reading the final decision of the Controller pertaining to a patent application that has been rejected. We proceeded to refine our dataset of rejections based on several criteria. We cleaned up the list to remove both duplicates and incomplete entries. We also noticed that the details of the IPC class were not entered uniformly for all the patent applications. There were entries without the IPC code which had to be manually checked with the IPO database. Even when we had manually checked the missing IPC codes using the corresponding patent application number, we found that the IPC details were not updated in the IPO database.³

The IPO classifies all applications based on both an internal classification scheme based on the field of invention (F11 for Pharmaceuticals), as well as the International Patent Classification (IPC) scheme. We focused our attention on applications relating to pharmaceuticals, readily identifiable by their IPC classification⁴ under the following categories – A61K, A61P, C07C and C07D. Since C07C and C07D include a broad class of non-pharmaceutical compounds as well, applications in this category were reviewed further to identify those pertaining to pharmaceuticals.

In some cases, the data on the IPO website lacked information about the IPC classification. In such cases, the identity of the applicant also helped ascertain if the application might pertain to pharmaceuticals. Entities which were known to be pharmaceutical companies formed the basis for identifying several applications as pharmaceuticals, especially in cases where the IPC classification was found missing.

A subsequent analysis was carried out on the contents of the decision. This was done by reading each decision and sifting through the contents to retrieve key details. These details would often be supported by a reference to particular provisions of the Patents Act, 1970, and broadly include:

- (i) Grounds of rejection – Lack of novelty, lack of inventive step (Section 2(1)(j), 2(1)(ja)), absence of enabling disclosure (Section 10(4)), foreign filing (Section 8), divisional application (Section 16), etc.;
- (ii) Exceptions to patentability – Under different sub-sections of Section 3; and
- (iii) Opposition – Whether the decision came about as a result of opposition (under section 25).

All decisions were indexed based on reference to particular details in the order of rejection, and this was analysed further to understand the rationale behind rejections at the IPO. All the Controller's decisions pertaining to patent applications are available at the IPO website.⁵ The website allows searching of patents based on different criteria: by Patent number, Application number, Applicant Name, Section, Decision date and Opponent.

3.

Data

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3. Data

Based on the aforementioned IPC codes, we were able to identify 1723 applications where the IPO had given a written order of rejection during the period between January 2009 and January 2017.⁶ The data pertaining to the applications were collected from the IPO website, where the Controller's decisions are uploaded. The decisions were searchable based on the decision date.⁷

The application numbers were identified from the Controller's decision. The decisions were downloaded between the periods January 2009 and January 2017.⁸ The decisions pertain to either grants or rejections. The Patent application number was searched on the INPASS database⁹ of the IPO to check whether the application resulted in a grant. Only those applications which did not materialise into grants were considered for the study. Thus, the decisions of the Controller refusing to grant an application were analysed. This data set also included some cases where the IPO refused to grant the patent due to objections beyond patentability and exceptions to patentability, such as not obtaining the approval of the National Biodiversity Authority in cases that attract the Biological Diversity Act, 2002.¹⁰ Thus, we have considered an application as a reject where the status of the application was shown as "Application Refused" in the IPO website.

4.

Analysis

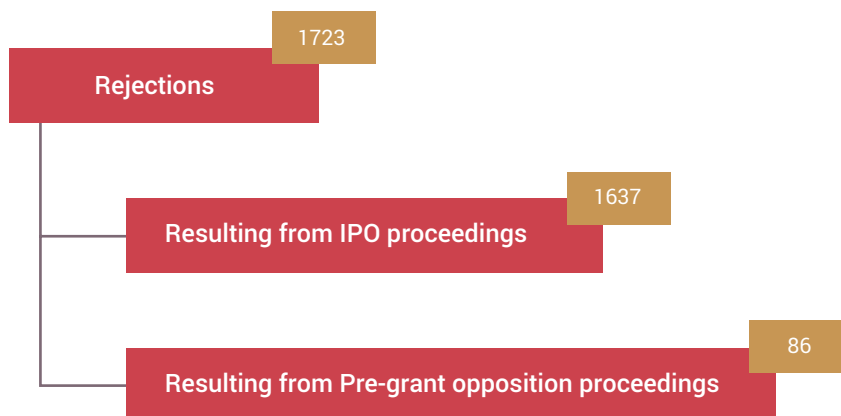
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4. Analysis

Of the 1723 applications under study, 86 applications resulted in a rejection due to an intervention by a third party, i.e. Pre-grant opposition. The remaining 1637 applications were rejected due to objections raised by the IPO itself.

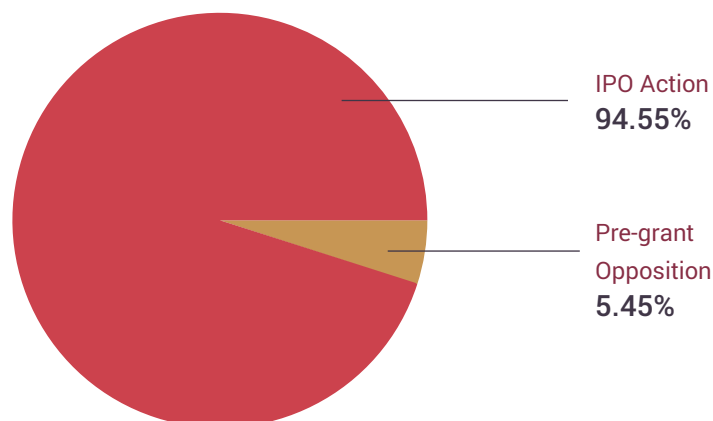
Type of Rejection Proceeding



The majority of the rejections came due to the objections raised by the IPO alone. This is largely due to the practice of looking into third party objections after the patent applicant overcomes the objections raised by the IPO. Hence, in most cases that ended up in a rejection, the patent applicant was not able to overcome objections raised by the IPO. The rejections by the IPO are raised mostly in section 15 proceedings, which accounts for 1637 rejections. Section 15 is not quoted in isolation, and is often used in conjunction with other sections. At times, the IPO calls for a hearing (under section 14), requesting the applicant for clarifications. In cases where the applicant fails to clarify the objections raised under section 14, the Controller rejects the application under section 15. In 54 cases, the Controller rejected the application solely based on section 16, i.e. the

application did not qualify as a divisional application under the Act. Section 16 was otherwise quoted along with other sections in 117 cases.

Rejection Distribution: Office Actions vs. Pre-grant Oppositions



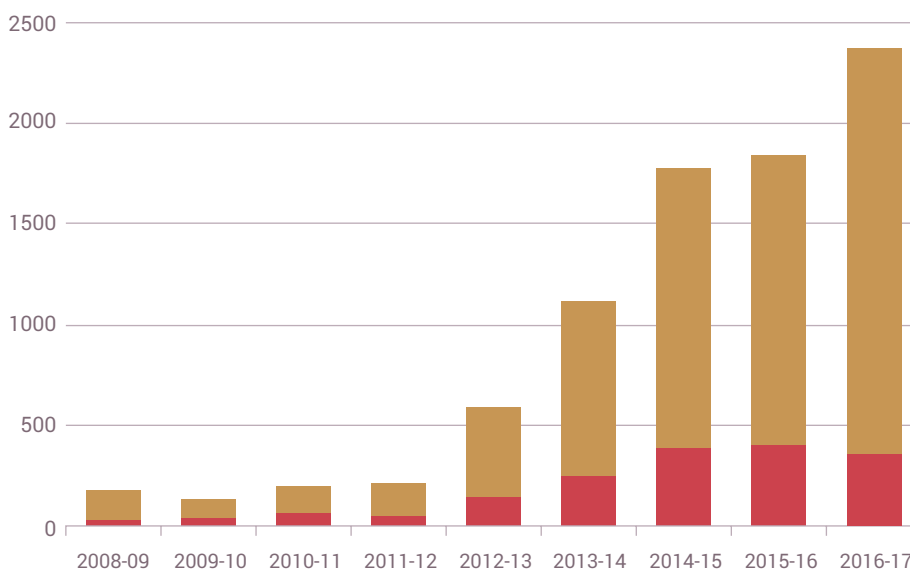
With regard to third party objections, of the 1723 applications, there were 86 rejections based on pre-grant opposition filed by a third party under section 25(1). In 945 cases, the applications were rejected under section 2(1)(j) as the applications did not qualify as an invention (as defined under the Act). In 1113 cases, the applications were rejected due to the objections under section 3. Pre-grant oppositions are normally initiated by a single party. We did not find enough evidence to substantiate the existence of serial oppositions filed one after the other to delay the grant of a patent.¹¹ In most cases, the opposition was filed by one opponent. In 5 cases, there were oppositions filed by 2 or more opponents. Whenever the opposition is initiated by a third party, there is usually a tendency to supply the IPO with more prior art information than what the IPO would do in the course of raising the preliminary objections (through the First Statement of Objections).

In practice, the pre-grant opposition is considered only after the application is 'found to be in order for grant'.¹² In other words, the Controller looks into the pre-grant opposition file only after the First Statement of Objections (earlier known as the FER or First Examination Report) is communicated to the applicant and the applicant has complied with all the objections raised by the Controller. Thus, the prior art documents introduced by the opponent and relied by the Controller in rejecting the patent application are most likely to be documents which were not initially considered by the Controller. We found that the pre-grant opponent performs a vital function of supplying information to the IPO leading to rejection of patents.

In some cases, the applications were rejected without the intervention of the Controller. Such applications were either rejected: (1) as the applicant did not

file a request for examination and hence the Controller treated the application as withdrawn under section 11B(4) which occurred in 20 cases; or (2) in 8 cases the application was rejected as deemed to have been abandoned as the applicant did not comply with the timelines as prescribed in section 9 or section 21.

Rejections Trends: Pharma vs. Others



Legend:

- Others
- Pharma

Figure – Rejections Trends:

There has been a steady increase in the number of pharmaceutical patent applications being rejected, mirroring the overall trend of rejections across all categories of patent applications.

4.1. Grounds of Rejection

Of the 1723 cases, in 1323 cases the Controller rejected the applications citing section 2(1)(j) or section 2(1)(ja), stating that application did not disclose an invention as defined under the act. This was the most frequently used provision for rejecting applications.

	Grounds of Rejection (under different sections)							
	2(1)(j)	2(1)(ja)	10	8	16	59	77	3
No. of Applications	945	466	386	186	118	75	4	1113

4.2. Patentable Invention

To be a patentable invention under the Patents Act, the application has to demonstrate the requirements of patentability mentioned in section 2(1)(j), i.e., that the “invention” which covers a process or a product is new (Novelty), involves an inventive step and is capable of industrial application. In some cases the Controllers had also referred to section 2(1)(ja) that defines an inventive step. The new definition of an inventive step which was introduced by the 2005 amendment to the Patents Act reads, “a feature of an invention that involves technical advancement as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.” The new definition introduces two new requirements, (1) technical advancement and (2) economic significance as additional requirements along with the requirement of not being obvious to a person skilled in the art for proving an inventive step. Of the 1323 cases, in 466 cases (35%) the Controllers made reference to the new definition of the inventive step in section 2(1)(ja). The Controllers’ mention of the new definition indicates the reliance on the two new requirements. Scholars have identified this new definition as the heightened standard of inventiveness.¹³ The reliance on the new definition shows that the IPO has been employing the new standard and has been using the same in rejecting applications.

4.3. Statutory Exceptions to Patentability

After section 2(1)(j) and section 2(1)(ja), we found that the objections to patentability contained in section 3 were used widely by the patent office in rejecting applications.

We found that section 3 was used in 65% of cases either singly or in combination with other sections to reject the patent applications. Out of the total number of 1723 applications, 1113 applications were rejected by citing section 3 as an objection.

Section 3 has many sub-sections. Section 3(d) which deals with patentability of known substances was used, either alone or in combination with other sections in 771 cases (69%) when a section 3 argument was raised. In combination with other subsections like section 3(e) and section 3(i), section 3(d) was used in 36% of cases where an objection of section 3 was raised.

Table - Section 3 distribution:

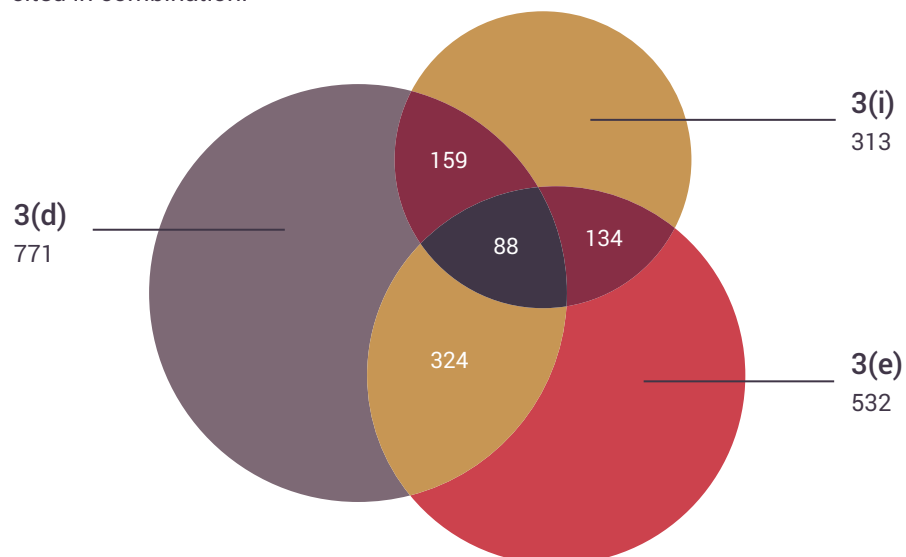
The table depicts the number of citations for each sub-section of Section 3

Year	3(b)	3(c)	3(d)	3(e)	3(f)	3(i)	3(j)	3(k)	3(m)	3(n)	3(p)	No. of applications refused on Section 3
Upto Mar 2009	0	0	21	6	0	2	0	0	0	0	0	23
Apr 2009 - Mar 2010	0	0	24	7	0	3	1	0	0	0	0	32
Apr 2010 - Mar 2011	0	0	14	17	0	6	0	0	0	0	0	30
Apr 2011 - Mar 2012	0	0	7	5	0	1	0	0	0	0	0	10

Year	3(b)	3(c)	3(d)	3(e)	3(f)	3(i)	3(j)	3(k)	3(m)	3(n)	3(p)	No. of applications refused on Section 3
Apr 2012 - Mar 2013	0	2	48	35	0	31	0	0	0	0	4	76
Apr 2013 - Mar 2014	1	2	100	65	2	44	7	2	0	0	20	151
Apr 2014 - Mar 2015	1	1	202	128	2	93	8	0	0	6	5	266
Apr 2015 - Mar 2016	2	2	201	131	2	78	8	3	2	1	13	281
Apr 2016 - Jan 2017	2	5	154	136	3	55	7	0	0	0	9	244
	6	12	771	532	9	313	31	5	2	7	51	1113

Figure - Section 3 combinations:

Sections 3(d), 3(e), and 3(i) were cited most often overall, and these were often cited in combination.



4.4. Section 3(d)

Of the 771 cases where an argument on section 3(d) was raised, in 381 cases the application or the specification was amended. Since an argument on section 3(d) is a substantive argument which requires the exercise of discretion on the part of the Controller, the applicant needs to be heard before an order of rejection is passed. In all the 771 cases, the applicant would have received a hearing notice. But in 479 cases the applicant either did not attend the hearing or the applicant withdrew the application which can be treated as instances where the application did not proceed, based on an objection raised under section 3(d).

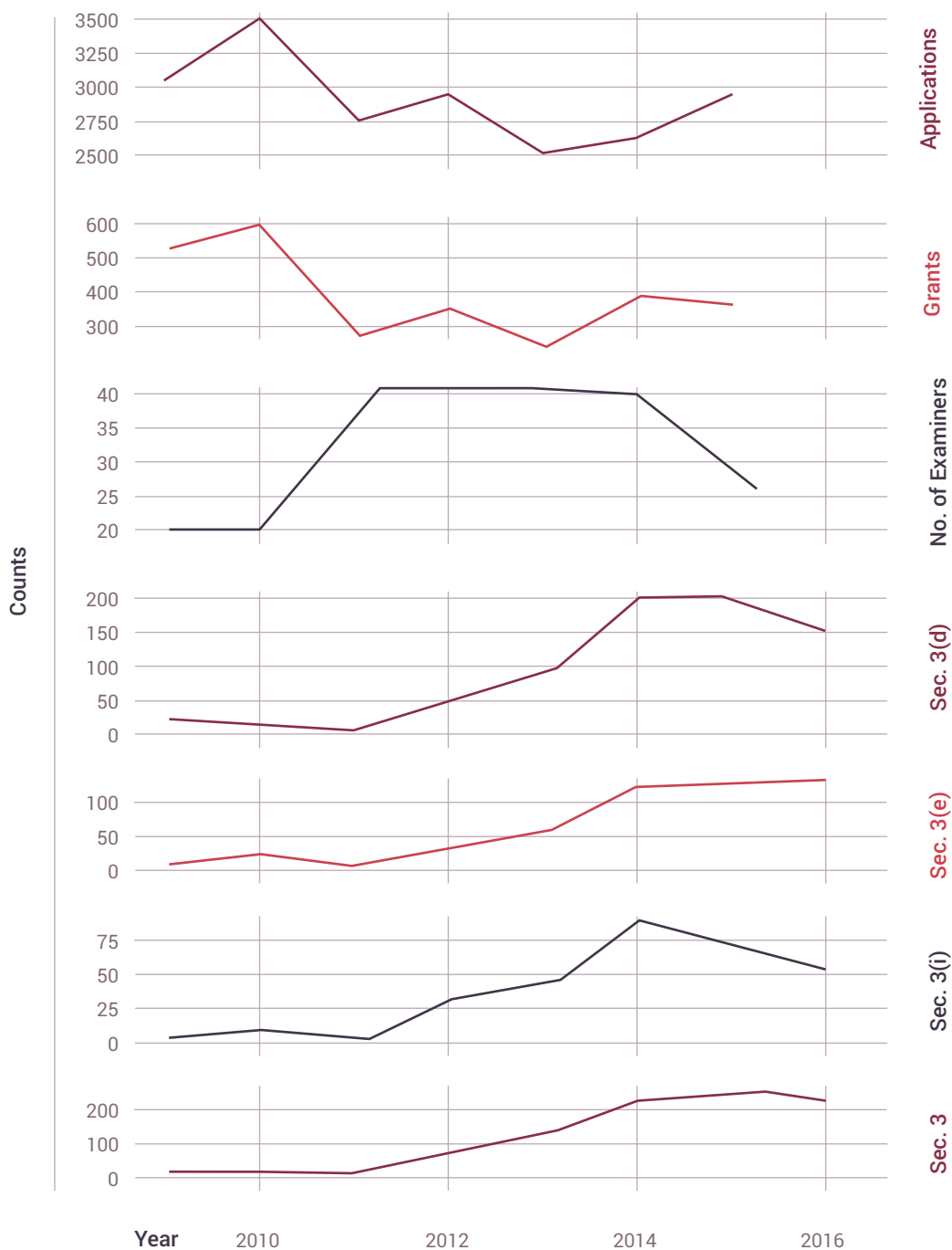


Figure - Trends timeline:

The number of applications, grants, examiner numbers and Section 3 citations were compared from 2009-16. This data was retrieved from our analyses (for section 3 and subsections), as well as information available in the IPO's annual reports¹⁴ (applications, grants, examiner counts). Examiner numbers here reflect the number specialised in chemistry, the group likely to evaluate pharmaceutical patent applications.

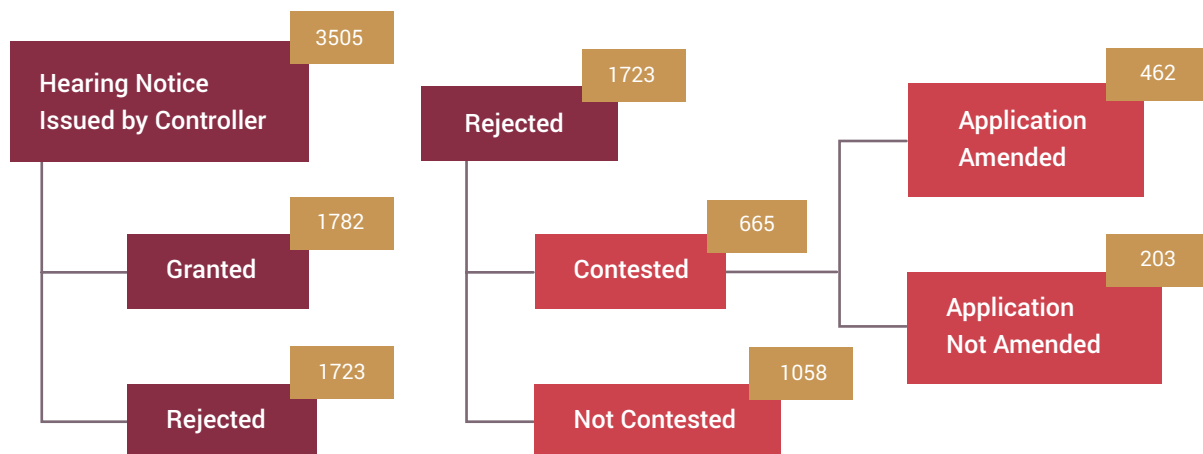
The number of section 3(d) citations in the Controller's decision shows a marked increase in the years between 2013 and 2016. In comparison to two other frequently cited subsections of section 3 [3(e) & 3(i)], there is a relative increase in the number of citations for Section 3(d).

The increase in the 3(d)-citation frequency is not surprising. In April 2013, the Supreme Court's decision in *Novartis AG vs. Union of India* upheld the rejection of Novartis' patent application by the IPO using section 3(d).¹⁵ Following this landmark decision, patent applications dealing with new forms of known substances would also need to submit data pertaining to enhanced therapeutic efficacy of the compound they sought a patent for. The increase in the rejections using section 3(d) after the Novartis Case could be due to this interpretation of 3(d) given by the Supreme Court. Moreover, the decision coming from the highest court in India, could have removed ambiguities surrounding its legal validity and could have emboldened the IPO to use the provision more often.

4.5. Rejections due to Applicant's Inaction

Often, it is possible to overcome some objections raised by the IPO by amending the specification. Although applicants sought this measure in 856 cases, the amendments however failed to circumvent the reason for the rejection. The Controller also allows applicants to present their arguments against objections raised either in writing, or in a hearing that presents an opportunity to present their case in person. In 665 cases, the applicant attended the hearing.

Progress of Application After Issuance of Hearing Notice



In some cases, an applicant may choose to abandon or withdraw their application. Abandonment, as was seen in 6 cases, may also result as a failure to comply with timelines stipulated by the IPO. Withdrawals may be made by a written request to the Controller, which were used in 20 cases.

5.

Conclusions

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5. Conclusions

In 95% of the cases, the IPO rejected the pharmaceutical patent application on its own. The rejection of a pharmaceutical patent application by the intervention of a pre-grant opponent (third party) happened only in 5% of the cases.

In cases where divisional applications were used by applicants for pharmaceutical patents to circumvent office objections, the IPO was able to identify them and reject them in 54 cases.

Amongst the grounds of rejection, the patentability criteria, i.e. that the invention should be new, involve an inventive step and should be capable of industrial application, was the most frequently used ground for rejection. The exceptions to patentability grounds in section 3 were the second most frequently used grounds for rejection.

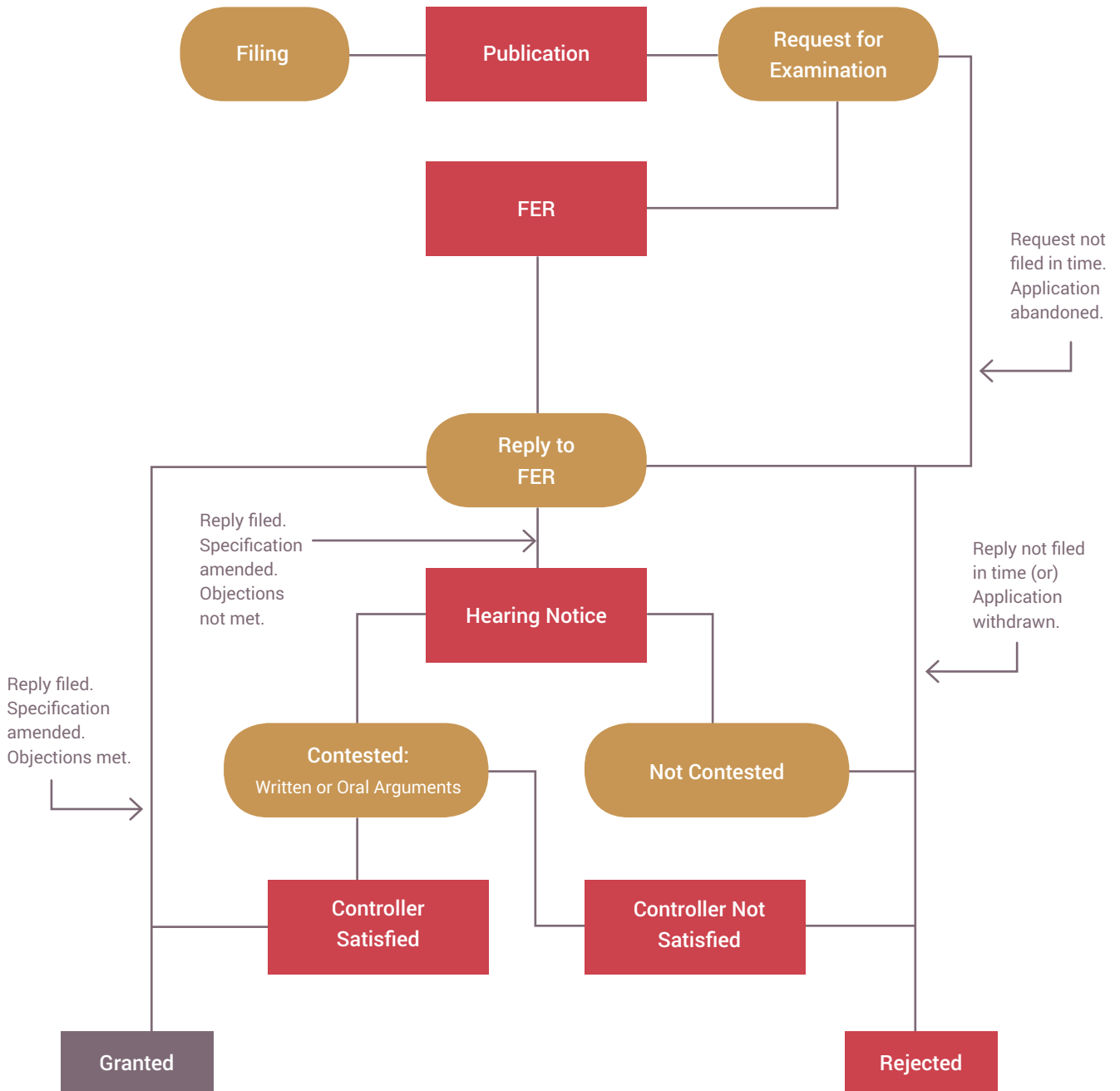
With most of the pre-grant oppositions initiated by a single entity, there was no data to substantiate the concern that pre-grant opponents indulged in serial oppositions and abused the process.

In 35% of the cases where the IPO rejected an application under the patentability criteria, it referred to the new definition of the inventive step in its decision. This indicates that the IPO has consistently applied the heightened standard of inventive step which was introduced in 2005 by amending the definition of inventive step to include technical advancement and economic significance.

More than half of the applications were rejected using one of the grounds of exceptions to patentability. Section 3(d) was raised in 69% of the cases where the exceptions to patentability were cited. This indicates the use of section 3(d) as a policy tool by the IPO in rejecting applications that fell within the exceptions.

The increase in the application of section 3(d) soon after the Novartis Case could be due to the legal certainty provided by the decision of the Supreme Court in upholding the rejection of a patent application rejected under that section.

An Overview of the Rejection Process



Labels:



Office Actions



Applicant Actions

Glossary of Sections Quoted

Section 2(1) (j):- Definition of 'Invention' as given in Patent Act, 1970

A new product or process involving an inventive step and capable of industrial application.

Section 2(1)(ja):- 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 the invention not obvious to a person skilled in the art

Section 3:- Deals with statutory exceptions to patentability

3(b):- an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.

3(c):- the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature.

3(d):- the mere discovery of a new form of 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 uses for a known substance or of the mere use of known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

3(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.

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

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

3(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;

3(k):- a mathematical or business method or a computer program per se or algorithms;

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

3(n):- a presentation of information

3(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.

Section 8:- Under this section, an applicant needs to make a disclosure before the patent office about the foreign patent applications involving same or substantially the same invention as before the controller herein within the prescribed time. The applicant also needs to give an undertaking by stating that, he would keep the Controller informed in writing about the status of such foreign applications till the date of grant of patent in India.

Section 10(4):- It refers to complete specification.

It should have full description of the invention and its operation or use and methods by which it is to be performed;

It should have the best method of performing the invention which is known to the applicant, for which he is entitled to claim protection;

It should end with a claim or claims defining scope of the invention for which protection is claimed;

It should be accompanied by an abstract to provide technical information on the invention. However, the Controller may amend the abstract for providing better information to third parties.

Section 11B (4):- Deals with withdrawal of patent application

In case the applicant or any other interested person does not make a request for examination of the application for a patent within the specified period, the application shall be treated as withdrawn by the applicant.

Provided, the applicant may, at any time after filing the application but before the grant of patent, withdraw the application by making a request in the prescribed manner; and

In a case where secrecy direction has been issued under section 35, the request for examination may be made within the prescribed period from the date of revocation of the secrecy direction.

Section 14:- Consideration of the report of examiner by the Controller.

If the report of the examiner is adverse to the applicant or requires any amendment of the application, the specification or other documents to ensure compliance with the provisions of the Patent Act or of the rules, the Controller, before proceeding to dispose of the application in accordance with the provisions of the statute shall communicate as expeditiously as possible to the applicant along with required details and if so required shall give the applicant an opportunity of being heard within the prescribed period.

Section 15:- It deals with power of the Controller to refuse the patent application.

Under this section, if the Controller is not satisfied with a patent application due to non-compliance with requirements of the Act, he may refuse the application or seek amendments before he proceeds with the application, and refuse the application on failure to do so.

Section 16:- Deals with power of the Controller to make orders respecting division of application.

Under this section, any time before the grant of the patent, if the applicant so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, he may file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.

Such application shall not include any matter not in substance disclosed in the complete specification filed in pursuance of the first-mentioned application.

The Controller may require such amendment of the complete specification filed in pursuance of either the original or the further application as may be necessary to ensure that neither of the said complete specifications includes a claim for any matter claimed in the other.

Section 21:- Provides time for putting application in order for grant

As per this provision, a patent application is deemed to be abandoned unless within the prescribed period, the applicant has complied with all the requirements as mandated by the Indian Patents Act, 1970. That is, objection raised by the Controller against the application needs to be addressed by the applicant within the prescribed time.

Section 25(1):- This section makes provision for third parties to file their opposition against the patent application before the concerned Patent Office. This opportunity is given, when an application for a patent has been published but a patent has not been granted.

End Notes:

¹Under the International Patent Classification (IPC) maintained by the WIPO, pharmaceutical patents applications may fall under the following IPC classes: A61K (Preparations for Medical, Dental, or Toilet Purposes), A61P (Specific Therapeutic Activity of Chemical Compounds or Medicinal Preparation), C07C (Acyclic or Carbocyclic Compounds), and C07D (Heterocyclic Compounds).

²The decisions are available at the link <http://ipindiaservices.gov.in/patentdecisionsearch/patentsearch.aspx> (last accessed on 10 August, 2017).

³For instance, the search of the well-known patent application number 1602/MAS/1998 pertaining to Novartis's anti-cancer drug Gleevec (which has the IPC classification A61K as ascertained from corresponding international applications) does not give any detail with regard to the IPC code on the IPO website. Only the decision rejecting the patent application can be found on the website.

⁴The International Patent Classification (IPC), established by the [Strasbourg Agreement 1971](#), provides for a hierarchical system of language independent symbols for the classification of [patents](#) and utility models according to the different areas of technology to which they pertain. Source – <http://www.wipo.int/classifications/ipc/en/>.

⁵<http://ipindiaservices.gov.in/patentdecisionsearch/patentsearch.aspx>

⁶Though the website has entries before 1st January 2009, since the objective of the study was to look at decisions of pharmaceutical patents granted after 2005 we had to eliminate few decisions before 1st January 2009. There were 10 decisions between 1st January 2005 and 31st December 2008. Of the 10 decisions, 3 decisions pertain to proceeding under section 25(1) of the Act before the Patents amendment act, 2005. 5 decisions pertain to the proceedings under section 15. The remaining 2 were decisions on section 21. Copies of the decisions were uploaded only for 7 cases, in the other 8 cases no files were uploaded. Of the 10 decisions, 2 decisions resulted in the rejections of the patents.

⁷However, we noticed that the website shows the decisions only on the basis of the date on which the decisions were uploaded. This caused a mismatch between the date of the decision and the date on which the decision was uploaded.

⁸The decisions till 17th January 2017 were considered in the study.

⁹<http://ipindiaservices.gov.in/publicsearch>

¹⁰For instances patent application no. 881/CHENP/2008, was kept in abeyance by the Controller subject to the applicant getting approval of National Biodiversity authority.

¹¹*Dr. Snehalata Gupte v Union of India*, Delhi High Court, Order dated 15th July, 2010 noting the practice.

¹²Section 43 (1)

¹³Josef Drexler & Nari Lee, 33-34, Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective, (Edward Elgar Publishing Ltd) (2013).

¹⁴Information for the year 2016-17 was unavailable from the IPO, since the annual report for the period had not been published yet.

¹⁵MIPR 2013(1) 0313 (SC).

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Rejected in India:

WHAT THE INDIAN PATENT OFFICE GOT RIGHT ON
PHARMACEUTICALS PATENT APPLICATIONS (2009–2016)

Dr. Feroz Ali, Dr. Sudarsan Rajagopal, Mohamed Mustafa
and Chinnasamy Prabhu

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