Chapter

Case Study on Rejected Patents in India

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Abstract

India is a country that has understood the importance of strong patent systems for the growth of industry and commerce to bring it at par with the modern world. As per WIPO statistical database September 2018, 45,379 patent applications were filed in India. Out of which, 12,387 applications were granted and 29,789 applications were withdrawn or abandoned by the applicants. About 3203 patents were rejected on the ground of non-fulfillment of patentability criteria by the invention, that is, Novelty, non-obviousness and Industrial applicability or non-patentability criteria mentioned under Sections 3 and 4 of Indian Patent Act. In this chapter, the authors have discussed few of the cases of rejection under the Indian Patent Act.

Keywords: Indian Patent Act, refused U/S 15, novelty, non-patentable, inventions

1. Introduction

The three patentability criteria for any inventions are novelty, non-obviousness and industrial applicability. Few inventions fulfilled all three patentable criteria but still not patentable based on morality, public order or human rights considerations of each country. The Indian patent rights provide mutual benefits to the patent holder and user of patented medicine by considering socio economical welfare of the society [1–5].

As per the Indian Patent Act, Section 2 describes patentability criteria, whereas Sections 3 and 4 describe non-patentable inventions [6, 7].

2. Statistical database of patent filling in India

India has stringent patenting system, policies and enforcement system to protect IPR laws. Due to the TRIPs Agreement and amendments in the Indian Patent Act, technological innovations are encouraged and protected in India [8, 9]. As per Indian Patent Act, Section 15 deals with the power of the controller to refuse applications for grant of patent [10, 11].

As per WIPO statistical database September 2018, 45,379 patent applications were filed in India. Out of which 12,387 applications were granted and 29,789 applications were withdrawn or abandoned by the applicants. About 3203 patents were rejected on the ground of non-fulfillment of patentability criteria by the invention i.e. novelty, non–obviousness and industrial applicability or non-patentability criteria mentioned under Sections 3 and 4 of Indian Patent Act [12]. Indian Patent office rejected 1723 pharmaceutical patent applications between January 2009.
and January 2017. Among them, 945, 466 and 1113 patents were rejected based on Sections 2(1)(j), 2(1)(ja) and Section 3, respectively. Ground for patents rejection may be one or more for one case [13]. As per Annual report of IPR 2017–2018 in India, number of patent applications examined, number of grant of patents and disposal of applications increased by 108.2, 32.5 and 57.6%, respectively as compared to 2016–2017 [14].

Sections 2 and 3 were the major reasons for the rejection of patents filled in India hence some case studies related to rejected patents are discussed in this chapter.

3. Case studies of rejected patents as per Section 2 of the Indian patent act

Section 2 describes the patentability criteria of inventions.

Section 2(j) Inventions means a new product or process which involves an inventing step and having industrial applicability;

Section 2(ja) Inventive step means invention should show technical advancement in comparison with the existing knowledge or having economic significance or both and invention must not be obvious to a person skilled in the art;

Section 2(1)(ac) “capable of industrial application”, in relation to an invention, means that the invention is capable of being made or used in an industry [15, 16].

Case 1: Patent application entitled “Powder Formulation for Valganciclovir”

Patent application detail of case 1 is given in Table 1. The solid-state of valganciclovir hydrochloride exhibits acceptable physical, chemical, and light stability when stored under ambient conditions. The applicant prepared a liquid dosage form of valganciclovir hydrochloride for the pediatric patient as well as for patients who require flexibility. However, short-term stability data indicated that a liquid dosage form would be unstable for the anticipated shelf life of the product.

The applicants, therefore, focused on powder dosage forms, for later constitution with water, to provide reasonable shelf life for valganciclovir hydrochloride and the resulting (constituted) liquid dosage form. The formulation procedure was changed from a dry mix granulation to a wet mix granulation. Because valganciclovir hydrochloride is readily soluble under acidic conditions, a solid pharmaceutical dosage form must contain an organic acid present in an amount sufficient to solubilize and stabilize the valganciclovir hydrochloride in a predetermined amount of water for the proposed shelf life of the resulting (constituted) liquid dosage form. Hygroscopic organic acids were found to degrade the solid valganciclovir hydrochloride pharmaceutical dosage forms. Therefore, the applicant’s claimed for a solid pharmaceutical dosage form which needs to be reconstituted in water before giving by the oral route. The product contained a therapeutically effective amount of drug (valganciclovir hydrochloride) and non-hygroscopic organic acid present in an amount sufficient to stabilize the drug in a predetermined amount of water. They claimed non-hygroscopic organic acid from the group consisting of fumaric acid, succinic acid, and adipic acid and amount of that acid was selected such to lower the pH of the constituted solution of valganciclovir hydrochloride to 3.8 or below.

The patent examiner argued that stability of valganciclovir below pH 3.8, using organic acid i.e. citric acid, is already reported in the prior art. Thus, there is no technical advancement achieved from the present invention. As the patent did not involve any inventive step, it was refused as per Section 15 on the ground of Section 2(1)(ja) of the Patent Act [17]. Examination report of the case can be studied in detail from Dynamic Patent Utilities: The Controller’s Decision mentioned on website of Indian patent.
4. Case studies of rejected patents as per Section 3 of the Indian patent act

Section 3 of Indian Patent Act describes non-patentable inventions.

Section 3(a). An invention which is frivolous or which claims anything obviously contrary to well established natural laws [16];

Example: Machine that gives more than 100% performance, A perpetual motion machine of the first generation which claimed to produce work without energy input which is contrary to law of thermodynamics (law of conservation of energy - energy can be neither created nor destroyed. It simply changes from one form to another).

Case 2: Patent application entitled “Gravity wheel—a perpetual motion machine”

This invention claimed to produce a powder delivery wheel, which is a perpetual motion machine working by gravitational force. This machine was claimed to be never stopped except human means. The claimed machine was a stationary engine of the unlimited size which was capable of continuous power output from gravity force and the gravity force can be universally available in any planet. The patent was abandoned under Section 21(1) on the ground of Section 3(a) as its performance was contrary to the law of thermodynamics. The patent application detail of case 2 is given in Table 2 [17–19].

Section 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 [16];
Example: The Oncomouse, genetically modified to develop cancer for the purposes of medical research is not patentable because cancer can be transmitted to the public [20, 21].

Companies developing animal models are arguing for patenting of animal models as 1. Microorganisms are now patentable, 2. Animal models are very close to human disease and hence contribute significantly to the process of drug discovery, and 3. The patents provide a means of compensation for investment of millions of dollars in research which in turn stimulates further research and eventually better treatments. However, based on ground of morality and reproducibility the patent applications on animal models are not granted [22–24].

Case 3: Patent application entitled “Electro-Mechanical Sexual Stimulation Device”

Patent application detail of case 3 is listed in Table 3.

This patent deals with sexual stimulating vibrator and its intended use or commercial exploitation which is contrary to public order or morality hence the patent was rejected based on ground Section 3(b).

Claims 1 and 17 have been drafted as separate independent claims although they belong to the same category of claims. Said claims, therefore, lack clarity and conciseness under Section 10(5) of the Act.

Claims lack Novelty and/or Inventive step of u/s 2(1)(j) of the Patent Act. The problem with the present invention is the fact that its distinguishing features depend on relative dimensions, i.e. they depend on the anatomy of the users.

Patent drafting errors in abstract and drawing were also mentioned in the report.

Applicant or applicant’s agent neither appeared for the hearing on the scheduled date nor filed any written submission in response to the hearing notice [17].

Section 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 [16];

Example: Newton’s Laws, Discovery of micro-organism, Raman effect and Theory of Relativity [25].
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Case 4: Patent application entitled “Gene Family (LBFL313) Associated with Pancreatic Cancer”

Patent application detail of case 4 is given in Table 4.

The invention relates generally to the changes in gene expression in human pancreatic adenocarcinoma. The invention relates specifically to a human gene

Table 3.
Patent application detail for case 3 for electro-mechanical sexual stimulation device.

Table 4.
Patent application details for case 4—gene family (LBLF313) associated with pancreatic cancer.
family which is differentially expressed in cancerous pancreatic tissues compared to corresponding non-cancerous pancreatic tissues.

The hearing was offered on 10th April, 2014 intimating the following outstanding objections:

1. The applicant used 777 base pairs and in prior art it was 764 base pairs. The claimed sequence ID having extra 13 base pairs but the applicant does not show any advantages due to these extra 13 nucleotide base pairs. Further, it is very much possible that the 764 base pairs may retain the natural property.

2. Objection 2 of FER is not met as amended claim 6 (Production of Polyclonal Anti-LBFL313 Antibody) is directed to a host cell, which is not allowable u/s 3 (j) of the Act.

3. Objection 3 of FER is not met as the amended claims 1–4 & 7–8 are not patentable as the subject matter of claim 1–4 are directed to isolated nucleic acid/PP sequence from human genomic DNA, which is considered to be an isolated non-living substance occurring in nature, is not allowable to be patented under the provision of Section 3(c) of the Act in the absence of any clear cut recombination in these molecules. The same observation applies to the subject-matter of claim 7–8, which encodes polypeptides from the isolated nucleic acid of claims 1 i.e. sequence ID No-2. It already stated that said nucleotide sequence is isolated from nature, the polypeptide, which encodes by them, would be available in the source from which the said nucleic acid is isolated. Consequently, the subject-matter of claims 7–8 also falls within the scope of Section 3 (c) of the Act.

4. Amended claims 7 and 8 does not sufficiently define the invention, Claims should contain all the essential feature of the polypeptide which refers by its amino acid sequence ID, not by its nucleotide sequence ID. As stated above the said claim should be defined by its essential technical features, if any, otherwise it is not acceptable in the present form.

5. While filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, not to add subject matter, which extends beyond the content of the application as originally filed.

6. In reply to the hearing notice, the Applicant’s agent submitted a faxed letter dated 9th April, 2014 with the following statement: “We have been informed by our client that they are not interested in pursuing this application further and accordingly we will not be attending the hearing scheduled for April 10, 2014.” Considering the Applicant’s interest of not to pursue the instant application, it is hereby decided that the requirements communicated in the hearing notice are still outstanding and hence, the application was refused for grant of a patent [17].

Section 3(d). Section 3(d) of the Patents Act 1970 was as follows: The simple discovery of any new attributes or new utility for a known substance or of the mere utilization of a known method, machine or apparatus except if such known method results in a new product or employs at least one new reactant;

Section 3(d) of the Patents Act 1970 was amended in 2005 as follows: the simple discovery of a new form of a known substance which fails to result in the improvement of the known efficacy of that substance or the simple discovery of
any new attribute or new utility for a known substance or of the mere application of a known method, machine or apparatus unless such known method 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 anticipated to be the same substance, unless they vary significantly in properties with consideration to efficacy [26, 27].

Case 5: Patent application for the “beta crystalline form of the imatinib mesylate salt” by Novartis

As per Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, India has started providing product patent After 1 January 1995 [28, 29]. Novartis filed patent applications of pharmaceutically acceptable salts of a drug - “imatinib” and the patents were granted in the USA. After this Novartis filled patents application which claimed for “beta crystalline” form of imatinib mesylate and a patent was granted in the USA and other countries. The Indian Patent Office rejected the patent based on the ground of failure to promise novelty and non-obviousness. They said it is a modified version of an existing drug hence on the ground of Section 3(d) the patent cannot be granted. Novartis argued that beta crystalline form is a polymorph of imatinib mesylate and it showed better flow property, improvement in thermodynamic stability, reduced hygroscopicity and augmented bioavailability. At last, the Supreme Court declared that although the beta crystalline form of imatinib mesylate enhanced the bioavailability of the drug, it did not prove enhancement of efficacy hence it was found to be non-patentable under Section 3(d) in India [30, 31].The same product patent was granted in USA but rejected in India as patentability criteria have been provided in TRIPS but their interpretation may vary from country to country [32]. In India, the many aspects of intellectual property rights are dealt with in particular legislations enacted by the Parliament [33].

In 2015, the patent of BoehringerIngelheim Pharma GmbH & Co for drug “Spiriva®” was granted even after pre-grant opposition by one domestic firm. Cipla proceeded for post grant approval and the patent was revoked [34].

Section 3(d) has created a significant impact in determining the patentability of pharmaceutical derivatives in India [35]. Indian Patent Office opposes the concept of “evergreening” which is a practice of inventors of patented products for extending their monopoly period by various strategies (for example over associated delivery systems, or new pharmaceutical mixtures, etc.) [36, 37].

Section 3(e). A product obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance [16];

Case 6: Patent application entitled “Sterile Pharmaceutical Composition”

Patent application detail of case 6 is given in Table 5.

The applicant’s claim 1 includes a sterile pharmaceutical composition including a water-insoluble anticancer agent and a pharmaceutically acceptable carrier, albumin. The ratio (w/w) of albumin to the anticancer agent was 1:1 to 9:1. The applicant claimed that the size of particles was less than 200 nm. Claims 2 to 12 were dependent claims which depend on claim 1.

The opposition was filed by M/s Natco Pharma Ltd., Hyderabad. Based on submitted documents and hearing from both the parties, the patent application was refused under Section 15 based on ground section u/s 2(1)(j), u/s 3(e) and u/s 10 of the Patents Act, 1970 on 24/07/2009.

The applicant filed an appeal in ‘Intellectual Property Appellate Board’ (IPAB) against the said decision. The Hon’ble IPAB again reconsiders the case on dated 20/01/2014.
Second representation was considered by Assistant Controller as revised fresh representation and not the continuous hearing as the applicants have amended the claims 1 day before the hearing and opponent came to know it on the day of hearing (09/04/2009).

After hearings, the patent was refused on the ground of u/s 2(1)(j), 3(d) and 3(e) of the Patents Act, 1970. The specifications were also insufficient so rejection was also on the ground of u/s 10 of the Patents Act, 1970 [17].

**Case 7: Patent application entitled “Gel Useful for The Delivery of Ophthalmic Drugs”**

Patent application detail of case 7 is reported in Table 6. The application was rejected by Indian Patent Office of Sigma-Tau Industrie Farmaceutiche Riunite S.P.A of Italy as it does not mate the requirements of Section 2(1)(j), Section 3(d), Section 3(e) and Section 3(n) of the Patents Act, 1970. The claims were aimed at a solid powder comprising a mixture of (a) a carboxy vinyl polymer as a gelling agent; (b) a buffer; (c) a saccharide, (d) one or more drugs used for the treatment of diseases of the eye. However, the Controller was dissatisfied by applicant’s reply to the FER and sustained objection therein and gave the applicant’s a chance to be heard.

The Controller sustained the objections that the amendments to claim 1 did not hold as per Section 59 (1) read with Section 57(2) of the Patent Act; revised claims were not novel, obvious and did not comprise an inventive step w.r.t. cited prior art documents; the revised claims were unacceptable under Section 3(d), Section 3(e) and Section 3(n) of the Patents Act, 1970 and last of all a few of the claims were ambiguous.

After conducting trial, the Controller accepted the agent’s submissions that the amended claim 1 contained by the scope of the firstly filed PCT claims and hence was in consonance with the provisions of Section 59(1) and 57(2) of the Indian Patents Act. Further, claims remonstrated under Section 3(n) were also deleted.

With reference to Section 2(1)(j), the Controller in his verdict stated that the composition of the ophthalmic preparation (solid powder) of the claimed invention was not novel since all the ingredients were unveiled in the prior art, hence, the product did not meet the criteria as a “new” product. Further, the inventive step is missing in the drug delivery system claimed as no therapeutic efficacy.
was exhibited. Creating a drug delivery system (powder or gel) of different well-known components and verifying release rate of drug (amount of drug released after 30 min to 6 h) are regular experimentation carried out by medicinal chemist or trained artisan. The rejection was on the basis of Section 2(1)(j). Merely showing enhancement in bioavailability and retention time of the drug system was not adequate to evade the requirements of Section 3(d) and data indicative of the therapeutic efficacy was needed for the product. In absence of such data, the drug delivery system as claimed was precluded under Section 3(d) [17–38].

Section 3(f). The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way [39];

Section 3(g). Omitted by the Patents (Amendment) Act, 2002.

Section 3(g) was as follows: ‘a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus, or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture’. Omission of this section widens the scope of patentability [40].

Section 3(h). A method of agriculture or horticulture(Note: But Agricultural Equipment are patentable) [16].

**Case 8: Patent application entitled “Process for the Production of Recombinant Proteins Using Carnivorous Plants”**

Patent application detail of the case is given in Table 7. The applicant claimed that carnivorous plant can be used as a medium for the production of the protein of interest. The applicant claimed a process in which plant was genetically modified by transformation and protein was expressed in the digestive secretion of the genetically modified plant. Hence, this patent application was refused under Section

| Application status                | Application Refused U/S 15 |
|----------------------------------|---------------------------|
| Application number               | 1314/KOLNP/2009           |
| Application type                 | PCT NATIONAL PHASE APPLICATION |
| Date of filing                   | 08/04/2009                |
| Applicant name                   | SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A. |
| Title of invention               | GEL USEFUL FOR THE DELIVERY OF OPHTHALMIC DRUGS |
| Field of invention               | PHARMACEUTICALS           |
| PCT international application number | PCT/EP2007/062929         |
| PCT international filing date    | 28/11/2007                |
| Priority date                     | 22/12/2006                |
| Request for examination date     | 19/11/2010                |
| Publication date (u/s 11a)       | 29/05/2009                |
| Reply to fer date                | 13/05/2015                |

Table 6.
Patent application details for case 7 – gel useful for the delivery of ophthalmic drugs.
Based on ground of Section 3(j). Cultivation of plant, growing of the plant, harvesting of fluid from the trap was considered as a method of agriculture hence it was also not a patentable invention as per Section 3(h) [17].

Section 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 [16];

**Case 9:** Patent application entitled “Method for Hybrid Gastro-Jejunostomy”

Table 8 enlists patent application detail of case 9.

The invention is related to methods for joining one piece to the tissue to another piece of tissue. In one embodiment, the method can include inserting an applicer device having an actuation portion into a first body lumen through a natural body orifice, forming a first opening in a first piece of tissue within the first lumen and a second opening in a second piece of tissue defining a portion of a second lumen adjacent to the first piece of tissue, and inserting the applicer device through the first and second openings such that the actuation portion is between the first and second piece of tissue. The method can further include deploying a fastener into the first and second pieces of tissue through the actuation portion of the applicer device, thereby joining the first and second pieces of tissue to form an anastomosis between the first and second lumens.

The patent controller said that as claims 1–10 recite “A method for joining tissue”, which is a surgical method. The subject matter is excluded from patentability according to Section 3(i) of the prevailing Act [17, 41].

Section 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 [16];
Example: Clones and new varieties of plants, a process for the production of plants or animals, if it consists entirely of natural phenomena such as crossing or selection i.e., essentially biological process are not patentable. However, processes or methods of preparing genetically modified organisms are patentable [42, 43].

Case 8 has covered the case study of rejection of patent as per Section 3(j).

Section 3(k). A mathematical or business method or a computer program per se or algorithms [16];

Example: Computer program by itself or as a record on a carrier (Note: Combination of hardware and software is patentable).

In India, the Patent Amendment Act 2005 sought to introduce software patents. The amendment proposed in the Patent Amendment Act 2005 for Clause 3(k) was, “a computer program per se other than its technical application to industry or a combination with hardware; a mathematical method or a business method or algorithms.” However, this amendment was rejected by the Indian Parliament, which chose to retain Clause 3(k) as it is [44–46].

**Case 10: Patent application entitled “Chaos Theoretical Exponent Value Calculation System”**

Patent application detail of case 10 is provided in Table 9.

The Appellant’s invention is about the system which can analyze a time series signal using a method based on Chaos Theory and calculation of a chaos theoretical exponent value (CTEV). The conventional CTEV system was not calculating the temporarily changing dynamics as a significant value. In the present invention, the inventor proposed a system which can process at a high speed and on a real-time basis to calculate a CTEV even from a time series signal which includes noises. The average CTEV can also be calculated in a shorter time of two decimal orders or more.

As per First Examination Report (FER) of the Patent Office, the invention was not found to be patentable on the ground of clause (k) of Section 3 and Section 2(1) (j) of the Indian Patent Act, 1970. A response to the first examination report (FER) was filed by the applicant on 9th April 2008. The Deputy Controller rejected a patent under Section 15 by declaring that the invention still falls under Section 3(k) of the Patents Act.
The Manual of Patent Office Practice and Procedure provides a reason as to why mathematical or business methods are not considered patentable. “Mathematical methods” includes mental skill as they are not patentable. Mathematical methods are used for writing algorithms and computer programs for different applications are also not patentable although the applicants may argue that the said invention is of technical advancement, not the mathematical model [17, 47, 48].”

Section 3(l). A literary, dramatic, musical or artistic work or any other esthetic creation whatsoever including cinematographic works and television productions [16] (Note: These subject matters fall under the copyright and related right protection);

Example: Prepare a drama from a book.

The patents protect ideas, not just expressions of them.

Section 3(m). A mere scheme or rule or method of performing mental act or method of playing a game;

Example: Method for solving a crossword puzzle, Method of learning a language

Section 3(n). A presentation of information;

Example: Spoken words, symbols, diagrams [49].

Section 3(o). The topography of integrated circuits [50];

Three-dimensional configuration of the electronic circuits used in microchips and semiconductor chips is not patentable because protection of Layout Designs of Integrated Circuits is governed separately under the Semiconductor Integrated Circuit Lay-out Designs Act, 2000 [51].

Section 3(p). An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of a traditionally known component or components.

Use of turmeric, neem, tulsi, etc. is not patentable as it is traditionally known. Although, if someone develops a medicine from tradition plant, for example. Ointment having an active ingredient that is an extract from leaf of the plant, is patentable [52].

Case 11: Patent application entitled “device used for manually hauling agricultural produce”
One device to collect agricultural produce was patented by DhanpatSheth. He made this device so flexible that it can fit to persons of varying height and size. Initially this patent was granted but afterward it was revoked as Nil Kamal Plastic Crates Ltd. sui him in Himachal Pradesh High Court. The patent was revoked on the ground of lack of novelty (Section 2(1)(ja)), mere duplication of traditionally known component known as “Kilta” (Section 3(p)) and mere replacement of raw material as plastic has been used in the patented product whereas bamboo was used in kilta [Section 3(d)] [53].

5. Non-patentable inventions as per Section 4 of Indian Patent Act

No patent shall be granted in respect of an invention relating to atomic energy falling within sub-section (1) of Section 20 of the Atomic Energy Act, 1962 (33 of 1962) [54–57].

6. Conclusions

The patent is granted to the inventor to encourage innovations by providing exclusive rights to the owner for the limited period of time and to reveal his invention for propagation of knowledge and welfare of the society. Intellectual property protection is of larger importance to the researcher and research industries as the research and development process is expensive and time-consuming. In the present chapter, the authors have used a case study approach to explain patentability criteria and non-patentable inventions as per the Indian Patent Act. By disseminating the knowledge on patentability and non-patentability criteria, the author will guide the researchers for answering the question of whether the research which they are doing is patentable or not? It will save time, money and manpower for the patent drafting, application, and examination process as well as promote researchers for doing patentable research.

Conflict of interest

The authors declare no conflict of interest.

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