Draft Guidelines

for Examination of Patent Applications

in the Field of Pharmaceuticals

2026

भारत सरकार

वाणिज्य और उद्योग मंत्रालय

कार्यालय महानियंत्रक एकस्व अभिकल्प एवं व्यापार चिन्ह

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Introduction

1.1. Pharmaceutical patenting is an extremely important aspect of India's Patent system. At the time of Independence, India's patent regime was governed by the Patents and Designs Act, 1911, which had provisions both for product and process patents. It was felt that there was a need for a change in the existing patent law since it had not helped in the promotion of scientific research and industrialization in the country.

1.2. Immediately after independence, a committee headed by Justice Bakshi Tek Chand, a retired judge of the Lahore High Court, was constituted to undertake a comprehensive review of the working of the Patents and Designs Act, 1911 (during 1948–1950).The Committee submitted its interim report on August 4, 1949 and the final report in 1950 making recommendations for prevention of misuse or abuse of patent rights in India. The Committee also recommended that the Patent Act should contain a clear indication that food and medicine and surgical and curative devices were to be made available to the public at the affordable price while giving reasonable compensation to the patentee. Based on the recommendations of the Committee, amendments were made in the Patents and Designs Act, 1911, first in 1950 (by Act XXXII of 1950) in relation to working of inventions, including compulsory licensing and revocation of patents, and then in 1952, (by Act LXX of 1952) to provide for compulsory license for food and medicines, insecticide, germicide or fungicide, and for the process for producing substance or any invention relating to surgical or curative devices.

1.3. Subsequent to that, another Committee under Justice Ayyanger (1957-59) was constituted. Justice Ayyangar's report specially discussed (a) patents for chemical inventions and (b) patents for inventions relating to food and medicine. After thoroughly examining the contemporary law of patents governing inventions on chemical substances of different countries, the Committee recommended that only process claims be allowed. For foods and medicines, the Committee recommended that inventions related to foods and medicines including insecticides and fungicides should not be patentable as such and processes for their productions should alone be patentable.

1.4. On the basis of these reports and other deliberations, the Patents Act 1970 was enacted and came into force from 1972. The Patents Act 1970 allowed process patents for drugs, foods and products of chemical reactions but no product patents were allowed for inventions related to such substances [erstwhile Section 5 of the Patents Act 1970]. The definition of "Drugs" included pesticides and insecticides. Also, the term of patents, for processes related to drugs and foods, was reduced to a maximum of seven years as

opposed to fourteen years for the general category patents. During the period 1970-1994, the Indian pharmaceutical industry became nearly self- sufficient and one of the largest exporters of generic medicines. A large number of developing countries depend upon the supply of cheaper generic medicines from India.

1.5. The 1990s marked the beginning of a new era in the world economy. From the Uruguay round of General Agreement on Tariffs and Trade, emerged the World Trade Organization (WTO), which also integrated Intellectual Property Rights (IPR) laws in international trade in a comprehensive manner. The WTO agreement, of which India is a signatory, came into force from 01.01.1995. TRIPs (Trade Related Aspects of Intellectual Properties) agreement (Annexure 1C of the WTO agreement) under Article 27, required introduction of both product and process patents in all fields of technology including drugs, foods, products of chemical reactions and micro-organisms.

1.6. To introduce product patents, TRIPS under Article 65, allowed a ten years transition period for developing countries which did not have product patenting. However, for such developing countries including India, an interim measure was required to be adopted for pharmaceutical and agrochemical product related applications. Article 70.8 of TRIPS stipulated that such countries were required to introduce mail-box provisions for receiving applications claiming products in the relevant field. Also, Article 70.9 mandated that Exclusive Marketing Rights (EMR) were to be made available for such applications subject to certain conditions for a term of five years from the date of grant of such rights or till the grant or rejection of patents claiming such products.

1.7. Accordingly, after the WTO agreement, the Patents Act 1970 was amended in a phased manner in 1999, 2002 and 2005 in conformity with the TRIPs agreement.

1.8. In 1999, mail-box and EMR provisions were introduced in India with a retrospective effect from 01.01.1995. Erstwhile Section 5 of the Patents Act 1970 was bifurcated to create a new Section 5(2) (mail-box provision) to receive applications claiming pharmaceuticals and agrochemicals products and a new chapter IVA was introduced to deal with EMR applications.

1.9. By the 2002 amendments, the term of all patents was uniformly made twenty years.

1.10. After the introduction of product patenting in 2005, mail-box and EMR provisions [Section 5 and Chapter IVA of the Patents Act 1970] were deleted and consequently product patents have been made available for inventions related to pharmaceuticals, agrochemicals, foods and products of chemical reactions since 01.01.2005.

1.11. While introducing the amendments, utmost care was taken to protect the public health and nutrition. Also, provisions for both pre- and post-grant opposition were engrafted in the Patents Act.

1.12. Other than the WTO agreement, India is signatory to various international agreements which, inter alia, have bearing on patenting in pharmaceuticals. These include the Paris Convention (since 1998), Patent Cooperation Treaty (since 1998) and Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (since 2001), Convention on Biological Diversity (since 1992). The amendments of the Patents Act 1970 were also calibrated to recognize India's accession to these treaties.

1.13. In the wake of the public health crisis afflicting many developing and least- developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, the ministerial conference of WTO adopted 'The Doha declaration on TRIPS and Public Health' (2001). The Doha declaration provided a mechanism for compulsory licensing to supply medicines to countries with insufficient or no manufacturing capacities. The declaration also explicitly stressed that the TRIPs Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. Consequently, a provision (Section 92A) was introduced in the Patents Act for Compulsory Licensing for the purpose of export of pharmaceuticals products to any country having insufficient or no manufacturing capacity.

1.14. Convention of Biological Diversity (CBD) acknowledged the sovereign right of the nations on their genetic resources and mandated that the access to the genetic resources and any intellectual property derived therefrom should be subject to the benefit sharing accrued from such access. The CBD also warranted that the member states should protect their traditional and indigenous knowledge.

1.15. In consequence of the CBD, India passed the Biological Diversity Act, 2002 which has been amended further through Biological Diversity (Amendment) Act, 2023 which provides a mechanism for access to the genetic resources and benefit sharing accrued there from. Section 6 of the Biological Diversity Act, 2023 came into force on 3rd August, 2023, and prescribes that obtaining IPRs from the utilization of biological resources in India is subject to the approval/registration of the National Biodiversity Authority (hereinafter referred to as NBA). To facilitate this access and benefit sharing and in order to prevent any unauthorized use of the biological resources of India, in 2005 suitable amendments were already made in Section 10 of the Patents Act, 1970, wherein

disclosure of the source and geographical origin of the biological material was made mandatory in application form for patent when the said material was used in an invention.

1.16. Pharmaceutical patenting in India is of utmost concern not only to the people of India, but also for the world community as India has emerged as "the pharmacy of the world".

With reference to recent global pandemic India is regarded as the vaccine manufacturing hub of the world, contributing 60% to the global vaccine supply. The country has the capacity to manufacture well over 3 billion coronavirus disease 2019 (COVID-19) vaccine doses annually. The ability of the country to produce low-cost COVID-19 vaccines will benefit low-income countries that cannot afford expensive vaccines.

1.17. Hence, Pharmaceutical patenting in India is, therefore, an extremely important and sensitive issue since, while a bad patent is a burden to society, good patents are also essential for promoting innovation and technological development in the country.

In order to achieve these targets, the Patent Office is continuously upgrading its internal resources, revamping its internal work modules or its public interfaces. In an attempt to bring in quality, consistency and uniformity, the office has introduced the guidelines for examination in certain key areas like pharmaceuticals. Further, many of the issues related to the product patenting in the field of pharmaceuticals are now becoming clear through the decisions of the Hon’ble Courts. Therefore, there is a need to update guidelines for examination of pharmaceutical patents, incorporating the analysis of the Courts, with the objective that the guidelines shall help in improvement of the examination standard and shall introduce harmonious practice amongst the technical Officers of the system.

2. Scope of the Present guidelines

2.1 The guidelines as set out below are supplemental to the practices and procedures followed by the Patent Office as published in the "Manual of Patent Office Practice and Procedure", "Guidelines for examination of patent applications in the field of Pharmaceuticals - 2014", "Guidelines for Examination of Biotechnology Applications for Patent - 2013" and "Guidelines for Examination of Ayush Related Inventions-2025". The present guidelines are prepared with the objective that the Guidelines shall help the Examiners and the Controllers of the Patent Office in achieving consistently uniform standards of patent examination. The guidelines set out below contain, where feasible, certain illustrations. These illustrations are not intended to exhaust the manner in which the relevant guidelines are to be applied in practice.

2.2 Examiners are requested to examine applications on a case-to-case basis, without being prejudiced by the specific illustrations being provided herein. In case of any conflict between these Guidelines and the Patents Act, 1970 and the Rules made thereunder, the provisions of the Act and Rules shall prevail. The Guidelines are dynamic and the Patent Office will update the same as and when required.

2.3 The case laws and illustrative examples referenced in the guidelines are intended for the interpretation of the relevant provisions of the Patents Act, 1970, and are inherently dynamic in nature.

3. Relevant Provisions

The following sections of the Patents Act, 1970 (as amended) are emphasized in the context of examination of patent applications in the pharmaceuticals and allied fields:

I. **Patentability**

Section 2 (1)(j): "invention" means a new product or process involving an inventive step and capable of industrial application;

Section 2(1)(ja): "inventive step" means 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 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;

II. **Non –Patentability**

Section 3 specifies that the following are not patentable inventions within the meaning of the Act:

i) **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;

ii) **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;

iii) **Section 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;

iv) **Section 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;

v) **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.

vi) **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;

vii) **Section 3(p):** an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components or components.

III- Disclosure

Section 10(4): Sufficiency of disclosure, the best method of performing the invention and claims defining the scope of invention, and an abstract to provide technical information on the invention.

IV- Unity of Invention

Section 10 (5): Unity of invention and clarity, succinctness and support of the claims.

4. Claims of Pharmaceutical Inventions

4.1 The details of the wording of claims, clarity, support and sufficiency of the disclosure are discussed under the appropriate headings. However, for a better understanding of the issues related to novelty, inventive step and other patentability criteria, a preliminary reference is made hereunder on claims of pharmaceuticals and allied inventions which are usually filed in patent applications of the relevant fields.

4.2 Generally, applications pertaining to pharmaceutical and allied subject-matters comprise the claims relating to the following subject matters, but not limited to:

I. **Product claims:**

i. Pharmaceutical product:

a. New Chemical Entities;

b. Formulations/Compositions;

c. Combinations/ dosage/dose;

d. New forms of known substance such as:

salts, ethers and esters; polymorphs; solvates, including hydrates; clathrates; stereoisomers; enantiomers; metabolites and pro-drugs; conjugates; pure forms; particle size; isomers and mixtures thereof; complexes; derivatives of known substances; and

ii. Kits;

iii. Product-by-process.

II. Claims for process/method of manufacturing;

III. Claims related to new property, new use of known substance or use claims, including second indications;

IV. Claims for method of treatment and/or diagnosis of human beings and animals;

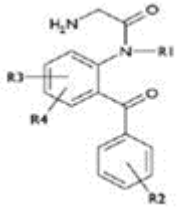
V. Claims related to selection inventions (relating to product and process)

The Guidelines have been designed in such a manner that the explanations given with regard to the separate concepts such as novelty, inventive step, industrial use etc., would be applicable generally to all types of claims given above but where there seems to be a requirement of additional clarification or a different approach, an attempt has been made to explain it separately under the same conceptual head in the context of the pertinent provisions of law.

Markush claims

Patent claims relating to pharmaceutical inventions are often drafted in broad or generic terms to encompass a large family of compounds, which may include thousands or even millions of possible variants. Such claims, commonly referred to as “Markush claims,” generally define a chemical structure in which a plurality of alternative, functionally equivalent chemical groups may be present at one or more positions within the claimed compound. In certain cases, only a limited number of the claimed compounds may have been synthesised and tested, while the properties or activities of the remaining compounds are predicted on the basis of their structural relationship with the tested compounds. Owing to the potentially extensive scope of such claims, the examination of Markush claims may involve complex considerations relating to novelty, inventive step, and industrial applicability across the full breadth of the claimed group of compounds. Such claims may also raise issues concerning whether the disclosure is sufficient to enable the claimed invention throughout its entire scope and whether the claimed alternatives share a common inventive concept or encompass a plurality of distinct groups of inventions. Hence, Markush claims require careful examination to determine compliance with the applicable statutory requirements relating to patentability, sufficiency of disclosure, clarity, support, and unity of invention.

Pharma-Illustrative Examples IE-1:



Wherein, R1 is selected from phenyl, pyridyl, thiazolyl, thioalkyl, alkoxyl and methyl; R2-R4 are methyl, tolyl or phenyl the compounds are used as a pharmaceutical for increasing the oxygen intaking capability of blood.

While examining above said Markush claims, the complete specification should be critically examined whether: (i) it discloses best representatives, as known to the applicant, of the possible embodiments;(ii) such embodiments share a common use or property; (iii) such possible embodiments share common structure; (iv) physical and/ or

chemical properties of best representatives of such embodiments known to the applicant are disclosed; (v) test conducted for the representatives of such embodiments known to the applicant is provided; (vi) in case of product claims at least one process for preparing the compounds has been disclosed enabling the whole scope of the invention.

Furthermore, where any of the requirements specified under points (i) to (vi) are not met, an objection relating to unity of invention or sufficiency of disclosure may be raised, as appropriate, having regard to the facts and circumstances of the application under examination. Compounds may be considered to share a common structure where they contain a common chemical framework represented by the Markush formula. A common structure may also be recognised where the shared structural feature constitutes a structurally distinctive portion of the claimed compounds when considered in light of the prior art. Such a structural feature may comprise a single structural element or a combination of individual structural elements linked together.

5. Prior Art Search

5.1 While conducting a prior art search, the Examiner should design or formulate a comprehensive search strategy by combining various search parameters including keywords, International Patent Classification (IPC), compound searches, etc. A thorough and iterative search should be carried out in patent as well as non-patent databases.

5.2 The compounds can be searched and identified from the various databases by using following methods:

(a) Molecular formula and structural formula searching;

(b) Name searching using IUPAC nomenclature;

(c) Compound searching using CAS Registry Numbers;

(d) Generic name searching (INN); and

(e) Search using International Patent Classification (IPC).

5.3 It is to be noted that quite often the claims of the pharmaceutical compounds involve derivatives of known compounds having established pharmaceutical activities. Also, it has been observed that such pharmaceutical substances have already been assigned generic names (International Non-Proprietary Names, INN). When the patent specification under examination discloses such INNs, the examiner should search the prior art on the basis of such INNs as well.

6. What is an invention: Section 2(1)(j)

6.1 According to Section 2(1)(j) of the Act, an "invention" means a new product or process involving an inventive step and capable of industrial application". An invention will be patentable only if it is new in the light of prior art, or is not anticipated by prior art. From the plain reading of section 2(1)(j), it is amply clear that only products and/or processes for making pharmaceutical compounds are considered to be inventions under the said clause. Sometimes, it is observed that applicants file claims in the following manner:

1. Use of compounds in the treatment of ……
2. A method of treating a cancer cell that is nonresponsive to chloroquine, or salt or prodrug thereof, said method comprising……...

The above two categories of claims are not to be considered as inventions, since the claimed subject matter neither pertains to product nor to process. Further, an objection with regard to Section 2(1)(j) and Section 3(i) would be invoked, respectively.

6.2 Also, it may be noted that sometimes such claimed inventions relate to the second use of already known compounds which have fallen in the public domain. Necessary care may be exercised to examine those cases in the light of Section 2(1)(j) and Section 3. Further, it should be borne in mind that finding the new property of an already known substance does not make the substance novel and/or inventive.

7 Assessment of Novelty:

7.1Section 2 (1)(l) of the Act states that ‘”new invention" means any 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’. For the purpose of ascertaining the novelty during the examination, the prior art is to be construed as prescribed under Section 2 (1)(l) and Section 13 (read with Sections 29 to 34) of the Act.The Manual of Patent Office Practice & Procedure has set out the guidelines for assessment of novelty of inventions (Chapter 9, Para 09.03.02) that may be referred to. Thus Novelty may be ascertained in following way:

An invention as claimed in the complete specification is considered as new (novel), if it is not anticipated by prior published document, where the prior art includes all information and knowledge relating to the invention, which is available in any publication before the date of priority of the patent application.

1. For the purpose of determining novelty, an application for patent filed at the Indian Patent Office before the date of filing of complete specification of a later filed application, but published after the same, is considered for the purposes of prior claiming.
2. A prior art is considered for anticipating novelty if all the features of the invention under examination are present in the single cited prior art document.
3. The prior art should disclose the claimed subject matter of the invention either explicitly or inherently .
4. Mosaicing of prior art documents is not allowed for assessment of novelty.
5. A generic disclosure in the prior art may not necessarily take away the novelty of a specific disclosure. For instance, a metal spring may not anticipate the novelty of a copper spring.
6. A specific disclosure in the prior art takes away the novelty of a generic disclosure. For instance, a copper spring anticipates the novelty of a metal spring.

Further, for assessing Novelty the **SEVEN STAMBHA** Approach as mentioned in **[Lava International Limited Vs TELEFONAKTIEBOLAGET LM ERRICSON, Delhi HC, on 28th March 2024 CS(COMM) 65/2016]**[1]

In Telefonktiebolaget Lm Ericsson (Publ) vs Lava International Ltd on 28 March, 2024, Hon'ble Delhi High Court while proposing a 7-step approach for novelty determination have stated at para 87-88 that:

> *"87.…Taking into consideration the judgements given by various Courts, and the guidance given in the Manual, I have deemed it appropriate to develop a step-wise approach for determination of novelty.*
>
> *88. When assessing the novelty of an invention, a Judge or even a patent examiner ought to follow a systematic approach to ensure a thorough and unbiased analysis of the invention claimed and the prior art cited. Another important aspect of the test for assessment of novelty in an invention is to maintain a distinction between the test of novelty and test for inventive step or lack of obviousness.*
>
> *I am of the view that the following steps, which may be referred to as the **'Seven Stambhas Approach'** serve as guiding Stambhas are referred to as columns or pillars in Indian Architecture principles and provide a clear framework for assessing novelty, reflecting the distinction between novelty and non-obviousness:*
>
> i) ***Understanding of the Claims of the Invention*** *• The determination of lack of novelty should begin with the understanding of the Claims of the invention as it is the Claims that define the boundaries of the invention and what the applicant considers as their novel contribution.*
>
> ii) ***Identify Relevant Prior Art*** *• Collecting the prior art, including any public disclosure, publication, patent, or patent application that predates the filing date of the patent application which is relevant to the Claims of the patent.*
>
> iii) ***Analyse the Prior Art*** *• Conducting a detailed analysis of the identified prior art to ascertain its relevance to the Claims of the invention. This step involves searching and documenting both the similarities and the differences, if any, between the Claims of the invention and the text of the prior art.*
>
> *This step requires comparing the technical details and features of the prior art against those claimed in the invention.*

[1] Lava International Limited Vs TELEFONAKTIEBOLAGET LM ERRICSON [CS(COMM) 65/2016]

iv) ***Determine Explicit and Implicit Disclosures*** *• Examining whether the prior art explicitly or implicitly discloses the same invention. Explicit disclosure means the prior art directly describes the invention claimed. Implicit disclosure refers to whether the prior art describes elements or aspects so similar to the claimed invention that a direct link can be drawn.*

v) ***Assessment material differences while considering the entire scope of the Claims*** *• Identifying the material differences between the claimed invention and the prior art, if any, such that a material difference would indicate that the claimed invention has not been disclosed in the prior art and, therefore, the invention, is novel.*

vi) ***Verifying Novelty in light of Comprehensive Scope and Specific Combination of Claimed Elements*** *• Evaluation of novelty of the invention is carried out in light of the comprehensive scope of its claims, not just individual elements. • The invention is novel only if the combination of claimed elements as a whole has not been previously disclosed.*

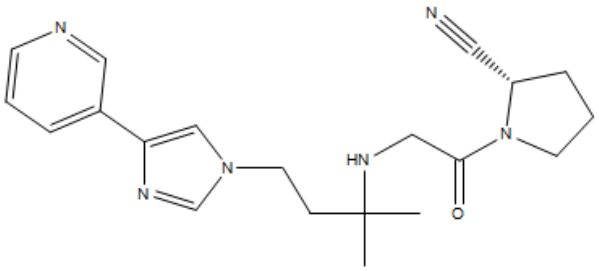
vii) ***Documentation of the Analysis and Novelty Determination*** *• Specify the finding of the examination of novelty, while providing a clear rationale for the said determination. The specific documentation must include references to specific sections of the prior art examined and a reasoning as to how the section affects the novelty of the claims and the inventive concept of the invention.*

• Based on the analysis, issue a formal decision, if the invention or any of its claimed elements is found in the prior art, the invention is not novel. Conversely, if the invention is not disclosed by the prior art, it is considered novel." **[Emphasis added]**

Apart from the above, the novelty criterion is judged under various provisions of the Patents Act and Rules made thereunder and also based on the procedures laid out in chapter 09.03.02 of the Manual.

7.2 **Pharma-IE-2 for determination of novelty**

The invention relates to the fumarate salt of (2S)-1-{[1,1-Dimethyl-3-(4-(pyridin-3-yl))-imidazol-1-yl)-propylamino]-acetyl}-pyrrolidine-2-carbonitrile useful for the treatment of diabetes mellitus, having the structure Prior art specifically discloses methanesulfonic acid salt



of (2S)-1-{[1,1-Dimethyl-3-(4-pyridin-3-yl-imidazol-1-yl)-propylamino]-acetyl}-pyrrolidine-2-carbonitrile.

Further, it discloses "many pharmaceutically acceptable salts" of the said compound and also mentions many salt forming acids, among which fumaric acid was mentioned as one of the pharmaceutically acceptable salt forming acid. However, it does not specifically disclose the fumaric acid salt.

Analysis:

The prior art specifically discloses the methanesulfonate salt of (2S)-1-{[1,1-Dimethyl-3-(4-pyridin-3-yl)-imidazol-1-yl)-propylamino]-acetyl}-pyrrolidine-2-carbonitrile and further teaches that the said compound may be converted into pharmaceutically acceptable salts using a number of salt-forming acids. Fumaric acid is specifically included among the suitable acids identified for this purpose. Although the fumarate salt is not individually exemplified in the prior art but the disclosure, when read as a whole discloses the use of fumaric acid for forming a pharmaceutically acceptable salt of the disclosed compound. Therefore, the fumarate salt claimed in the present application is considered to be implicitly disclosed in the prior art and does not constitute novel subject matter.

7.3 **Combination/Composition Claims**

Claims relating to a combination of two or more known active ingredients may be considered allowable where the applicant establishes that the claimed combination produces an unexpected technical effect, such as a synergistic effect, in the treatment of a disease or such condition. The asserted effect should be supported by appropriate experimental or clinical data demonstrating the effect of the claimed combination in comparison with the effects produced by the individual known active ingredients when administered separately.

Pharma-IE-3 for determination of novelty for combination/composition claims:

Example 1:

Claimed invention relates to a composition for enhancing corneal healing, said composition comprising vitamin A and a sterile buffer administered to the eye.

Analysis:

Prior art discloses the use of the eye-drops to rewet contact lenses, wherein said eye-drops comprising Vitamin A and the sterile buffer.

The claim lacks novelty, as being anticipated by the said prior art, which discloses all the features of claimed composition useful for enhancing corneal healing.

Thus, the claimed subject matter lacks novelty.

Example 2:

Claimed invention relates to a pharmaceutical composition comprising Compound A in an amount of 10–20% w/w, Excipient B in an amount of 30–40% w/w, and Excipient C in an amount of 40–60% w/w.

Analysis:

The prior art discloses a pharmaceutical composition comprising Compound A in an amount of 15% w/w, Excipient B in an amount of 35% w/w, and Excipient C in an amount of 50% w/w.

The claim lacks novelty, as the specific composition disclosed in the prior art falls entirely within the claimed percentage ranges and discloses all the features of the claimed composition. Since each of the claimed numerical ranges is directly and unambiguously anticipated by the prior art, the claimed subject matter lacks novelty.

7.4 Product-by-process claims:

A claim to a product obtained or produced by a process is anticipated by any prior disclosure of that particular product per se, regardless of its method of production. In a product-by-process claim, by using only process terms, the applicant seeks rights to a product, not a process.

Therefore, the patentability of a product by process claim is based on the product itself if it does not depend on the method of production. In other words, if the product-by-process claim is the same as or obvious from a prior product, the claim is

un-patentable even if the prior art product was made by a different process. Accordingly, the product by process claim must define a novel and un-obvious product, and the patentability in such claims cannot depend on the novelty and un-obviousness of the process limitation alone.

Therefore, in product-by-process claims, the applicant has to show that the product defined in process terms, is not anticipated or rendered obvious by any prior art product. In other words, the product must qualify for novelty and inventive steps irrespective of the novelty or inventive step of the process.

In the matter of **Vifor (International) Limited Vs. MSN Laboratories Pvt Ltd & Anr**[2] Para 126 of the Delhi High Court Order opines that:

> *"In our considered opinion, once product-by-process claims are conceptually accepted and acknowledged, it would be wholly incorrect to hold that products must necessarily and invariably be described by their composition and structure. That would go against the very grain of product-by- process claims as understood in patent jurisprudence. As has been recognised by jurisdictions across the globe, a product-by-process claim is permitted where it is found that it would be difficult to define the product with reference to its structural features. Such claims are allowed where it is not possible to satisfactorily or with sufficient clarity explain the characteristics of a novel invention on the basis of its composition or structural parameters. Patent Registries globally acknowledge and accept the possibility of structurally indefinable products. In fact, it is the acceptance of this facet of such claims which constitutes the point of origin of product-by-process claims. Such claims are permitted in situations where although the product is patentable, it defies definition and explanation in terms ordinarily accepted."*

> *"127… a product-by-process claim would be accepted and accorded statutory protection, only if the product itself be novel. Irrespective of the language in which such a claim may be couched, it is necessary that such a patent application speak of a novel product. It is this foundational precept on which product-by-process claims are tested. This is evident when the guidelines urge us to bear in mind that novelty of a process does not necessarily mean that the product itself represents an invention…". "…a product is not rendered novel merely by virtue of the fact that it*

[2] Vifor (International) Limited & Anr. vs Msn Laboratories Pvt Ltd & Anr., [FAO(OS) (COMM) 159/2023 & CM APPL. 39177/2023]

is produced by a new process. This since if novelty is claimed only in respect of a process, it would be treated and granted as a process patent…"

"128… It is thus manifest that for a patent application founded on a product-by-process claim being granted; it is imperative that it relate to an inventive and novel product notwithstanding the invention having been explained in process terms. The aforesaid discussion leads us to the irresistible conclusion that even in the case of product-by-process claims, it is the novelty of the product which must be established shorn of the process terms that may accompany such a claim…"

"143 *as long as the product-by-process claim pertains to a product which is novel and inventive and unknown in the prior art it would remain a product which would fall within the ambit of Section of 48(a)".*

Pharma-IE-4 for determination of novelty for Product-by-process claims:

Example 1:

Claim: Compound C obtained by a process X

Analysis:

Prior art (D1) teaches the same compound C with same characteristics. However, in D1 the compound C was prepared by process Y.

As the compound C is already identified in D1, it lacks novelty despite the fact that it has been prepared by a different method.

8. Assessment of inventive step

8.1 An invention should possess an inventive step in order to be eligible for patent protection. As per the section 2(1)(ja) of Patents Act, an invention will have inventive step if the invention is (a) technically advanced as compared to existing knowledge or (b) having economic significance or (c) both, and that makes the invention not obvious to a person skilled in the art. Further, the Manual of Patent Office Practice & Procedure has set out the guidelines for assessment of Inventive Step of inventions Chapter 09.03.03 of Manual).

8.2 The invention that creates the product must have a feature that involves technical advancement as compared to the existing knowledge or having economic significance or both and this feature should be such as to make the invention not obvious to a person skilled in the art.

8.3 Prior art for determining inventive step constitutes any "state of knowledge existing before the priority date of the claim under consideration." In other words, inventive step is determined vis-à-vis any matter published in any document anywhere in the world or any use before the priority date of the claim. Unlike the novelty, mosaicking of prior art documents is permissible in the context of inventive step.

8.4 In the case of **Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd**[3], Hon'ble Supreme Court observed on inventive step as:

> page no. 7:*"The expression "does not involve any inventive step" used in Section 2(1)(ja) of the Act and its equivalent word "obvious", have acquired special significance in the terminology of Patent Law. The 'obviousness' has to be strictly and objectively judged. For this determination several forms of the question have been suggested."*
>
> Further, in the **F. Hoffman la Roche Ltd. Vs Cipla Ltd**[4] case, at para 45 and 46 the Hon'ble Delhi High Court has endorsed that the obviousness test is what has been laid down in Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd.

[3] Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd [AIR 1982 SC 1444]
[4] F. Hoffmann-La Roche Ltd vs Cipla Ltd., Mumbai Central [CS (OS) No.89/2008 and C.C. 52/2008]

Further, "it is important to bear in mind that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an 'inventive step'. To be patentable the improvement or the combination must produce a new result, or a new article or a better or cheaper article than before. The combination of old known integers may be so combined that by their working inter relation they produce a new process or improved result. Mere collocation of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent. 'It is not enough', said Lord Davey in ***Rickmann v. Thierry (1896) 14 Pat. Ca. 105*** *Page No. 6 'that the purpose is new or that there is novelty in the application, so that the article produced is in that sense new, but there must be novelty in the mode of application. By that, I understand that in adopting the old contrivance to the new purpose, there must be difficulties to be overcome, requiring what is called invention, or there must be some ingenuity in the mode of making the adoption"* [Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries (AIR 1982 SC 1444)

Page 7 & 8 of the said Supreme Court Order states that

"...Another test of whether a document is a publication which would negative existence of novelty or an "inventive step" is suggested, as under: "Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, "this gives me what I want?" (Encyclopaedia Britannica; ibid) ...".

Paragraph 16 of Bombay High Court Order dated 11th July, 1968 states that

…To put it in another form: *"Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned ?..."* [Halsbury, 3rd Edn, Vol. 29, p. 42 referred to by Vimadalal J. of Bombay High Court in **Farbwerke Hoechst & B. Corporation v. Unichem Laboratories] (AIR 1969 BOM 255)**[5].

[5] Farbwerke Hoechst & B. Corporation v. Unichem Laboratories[AIR 1969 BOM 255]

8.5 **Skilled person:** The meaning of a person skilled in the art is extremely important in the context of inventive step analysis. This hypothetical person is presumed to know all the prior arts as on that date, even for non-patent prior art available to public. He should have knowledge of the technical advancement as on that date, and the skill to perform experiments with the knowledge of state of the art. He is not a dullard and has certain modicum of creativity.

In the matter of **General Tire & Rubber company v. The Firestone Tyre and Rubber Company Limited and others**[6] in the Supreme Court of Judicature-Court of Appeal on 7th September 1972, where it was held as:

"The proper test for obviousness is whether you think there is a reasonable chance of getting a useful result from what you learn from the prior art"; [Page 464] "The addressee for purposes of obviousness is an unimaginative skilled technician; he must be assumed to have read the whole of the prior art. The court should not take into account the subjective reactions (such as surprise) of persons who had not read the whole of the relevant prior art". [Page 464] "The only question to be considered in relation to each prior document is; is the step which differentiates the document in question from the claims of the patent-in-suit an obvious thing to do? Having considered this question in relation to each document separately you consider them all together and consider whether the skilled man would dovetail them together and if so what would he take out of which?[Page 465]"

Ex-post Facto analysis: To judge obviousness objectively, the skilled person needs to eliminate the hindsight analysis. The prior art needs to be judged on the date of priority of the application and not at a later date i.e. Para 32 of the Delhi High Court Order in the matter of **Avery Dennison Corporation Vs. Controller of Patents & Designs**[7] on 4th November 2022 assessed that

"it is not permissible to do a hindsight analysis or an ex-post facto analysis".

Further, it is also emphasized on para 19 of the said Order that

"The decision of the UK Supreme Court in Actavis (supra) identified the ten relevant considerations to be made while assessing obviousness. The Court mentioned that the factors identified in the list are not exhaustive. The relevant considerations are…. (8) Eighthly, the courts have repeatedly emphasised that one

[6] General Tire & Rubber company v. The Firestone Tyre and Rubber Company Limited and others, [[No. 17], 1972 [R.P.C.]]

[7] Avery Dennison Corporation vs Controller of Patents and Designs [C.A. (COMM.IPD-PAT) 29/2021]

must not use hindsight, which includes knowledge of the invention, in addressing the statutory question of obviousness. That is expressly stated in the fourth of the Windsurfing/Pozzoli questions ... (9) Ninthly, it is necessary to consider whether a feature of a claimed invention is an added benefit in a context in which the claimed innovation is obvious for another purpose ..."

In the matter of SAINT GOBAIN GLASS FRANCE vs ASSISTANT CONTROLLER OF PATENTS AND DESIGNS & ANR[8]. the Hon'ble Delhi High Court on 11th September 2025, analyzed the hindsight analysis of the term "obviousness" at para 48-50*, the Hon'ble Court stated:*

"48. The mosaicing of prior arts is also an internationally acceptable principle. A reference may also be made to Terrell on the Law of Patents, 20th Edition, Chapter 12 titled 'Invalidity Due to Obviousness (Lack of Inventive Step)', at paragraph 12-160, wherein it has been observed as follows:

"In Pfizer Ltd's Patent Laddie J referred to the passage in the 15th edn of this work dealing with mosaicing in the context of novelty (see para.11- 61), and continued: "This passage is directed particularly at the issue of mosaicing when applied to the law of novelty. The same approach applies to obviousness. There may well be invention in patching together disclosures from unrelated sources (see Von Heyden v Neustadt (1880) 50 L.J.Ch. 126). But, at least in relation to obviousness, the second part of this statement [that reliance on express cross referencing is permissible] does not represent a rigid but limited exception. When any piece of prior art is considered for the purposes of an obviousness attack, the question asked is 'what would the skilled addressee think and do on the basis of this disclosure?" He will consider the disclosure in the light of the common general knowledge and it may be that in some cases he will also think it obvious to supplement the disclosure by consulting other readily accessible publicly available information. This will be particularly likely where the pleaded prior art encourages him to do so because it expressly crossrefers to other material. However, I do not think it is limited to cases where there is an express cross-reference. For example if a piece of prior art directs the skilled worker to use a member of a class of ingredients for a particular purpose and it would be

[8] SAINT GOBAIN GLASS FRANCE vs ASSISTANT CONTROLLER OF PATENTS AND DESIGNS & ANR [C.A.(COMM.IPD-PAT) 13/2024 with I.A. 8216/2024]

obvious to him where and how to find details of members of that class, then he will do so and that act of pulling in other information is itself an obvious consequence of the disclosure in the prior art."

In the matter of pharmaceutical inventions, structural and functional similarity of the product provides this motivation to combine the teachings of the prior arts. A surprising effect, synergistic outcome of the combinations, prior art prejudice etc. usually demonstrates the non-obvious nature of the invention. However, it is reiterated that choosing a better alternative/substitute from the known alternative from the prior art to obtain the known results would not go beyond what may be normally expected from a person skilled in the art. Thus, when the solution is from a limited number of identified predictable solutions, which is obvious to try, even the demonstration of surprising effects etc. do not provide any answer to the obviousness.

While determining inventive step, it is important to look at the invention as a whole. Accordingly, the following points need to be objectively judged to ascertain whether, looking at it as a whole, the invention does have inventive step or not:

A structured four-step approach to determine the inventive step as stated in the **Lava International Limited Vs Telefonaktiebolaget LM Ericsson**[1]:

"The said steps are as under:

"1. Identifying the inventive concept embodied in the patent;

2. Imputing to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;

3. Identifying the differences if any between the matter cited and the alleged invention; and

4. Deciding whether those differences, viewed without any knowledge of the alleged invention, constituted steps that would have been obvious to the skilled man or whether they required any degree of invention."

A structured five-step approach to determine the inventive step as stated in the of Para 151 of F. Hoffmann-La Roche Ltd. and Ors. Vs. Cipla Ltd RFA (OS) 92/2012 and 103/2012 decided

on 27.11.2015[9] has laid down for determining inventive step and lack of obviousness. The steps involved in the said test are as follows:

> *"Step No.1 To identify an ordinary person skilled in the art,*
>
> *Step No.2 To identify the inventive concept embodied in the patent*
>
> *Step No.3 To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date*
>
> *Step No.4 To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications,*
>
> *Step No.5 To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hindside approach"*

However, various judicial pronouncements have referred to different analytical frameworks for the determination of inventive step, including the three-step, four-step and five-step approaches. In matter of SULZER MIXPAC AG vs ASSISTANT CONTROLLER OF PATENTS AND DESIGNS[10]. The divisional bench of Hon'ble Delhi High Court on 01st July 2026, that the courts have also clarified that such tests are not to be treated as rigid or mandatory formulas applicable in every case at para 24:

"24. Adjudication, under the Patents Act, has to be guided by the statute. To our mind, the five steps enumerated in para 120 of Roche merely provide guidance as to how, in a particular case, the court has to proceed while examining the aspect of inventiveness or obviousness of an invention, which is sought to be patented, vis-à-vis prior art. They cannot be regarded as commandments cast in stone, implicit compliance with which is essential in every case. Where the case is capable of being decided without strictly following the rigour of the said five steps, it cannot be said that the decision is vitiated solely on that ground".

Pharma –IE-5 examples for assessment of inventive step:

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[9] F. Hoffmann-La Roche Ltd. and Ors. Vs. Cipla Ltd [RFA (OS) 92/2012 and 103/2012]

[10] SULZER MIXPAC AG vs ASSISTANT CONTROLLER OF PATENTS AND DESIGNS, [LPA 545/2024]

Example 1:

Invention: Compound represented by the formula Py-B3, in which Py stands for a specific pyrazolone skeleton and B stands for ethyl. The compounds of the invention possess analgesic properties.

Prior Art: Closest prior art describes Py-B3, wherein B stands for methyl. The compound of the prior art was not known to possess any therapeutic activity.

Analysis:

Step 1: identifying the inventive concept embodied in the patent: the inventive concept is Py-B3, B stands for ethyl; where the compounds of invention possess analgesic properties.

Step 2: Imputing to a person skilled in the art having ordinary creativity what was common general knowledge in the art at the priority date:

This test requires two activities, namely, identifying the skilled person and the common general knowledge.

Common general knowledge: The skilled person has a thorough knowledge of the state of the art related to the organic chemistry of pyrazolones and also a thorough knowledge of the state of the art of the compounds or classes of compounds having analgesic activity. The knowledge must be of the date of the priority of the patent application in question, and not later than that. That is, the person must not consider any document published subsequent to the date of priority.

Step 3: Identifying the differences if any between the matter cited and the alleged invention; the difference between the prior art and the invention is the replacement of three methyl substituents at the annular positions and the pharmaceutical activity of the resultant compound.

Step 4: Deciding whether those differences, viewed without any knowledge of the alleged invention constituted steps which would have been obvious to the skilled man or whether they required any degree of invention: or whether there was reasonable expectation of success or coherent thread leading from the prior art.

The prior art compound, although structurally very close, does not provide any clue to the skilled person that the resultant compounds with a very nominal change would be successful as a pharmaceutical product. Changing from methyl to ethyl would have been obvious to the skilled person but the said change would not suggest achieving any

pharmacological property of the modified compound. Alternatively, it may be said that there was no prior art motivation.

Pharma-IE-6

Invention: Besylate salt of a compound A (A-B) with blood pressure lowering properties.

Background: Conversion of A-M (Maleate salt of compound A) to A-B significantly improves the processability in the manufacturing of the drug, and improves its stability, while the pharmacological property of A-B remains same as that of A-M.

Prior Art:

D1: The closest prior art D1 teaches Maleate (A-M) salt of compound A having same physiological properties.

D2: D2 shows a list of 53 pharmacologically acceptable anions as salt forming candidates from the list of drug approval authorities. However, the most commonly used anion is hydrochloride, whereas besylate is used for 0.25% of the approved drugs. Other than hydrochloride, which was used in approximately 43% of approved drugs, almost all other salts could be categorized as "seldom used." 40 out of 53 anions were used in less than 1% of drugs and 23 out of 53 were used in 0.25% or less of drugs.

D3: Prior art D3 shows that besylate salts impart excellent stability and other properties.

Analysis:

Step 1: Identifying the inventive concept embodied in the patent: besylate salt of a compound A with better processability.

Step 2: Imputing to a person skilled in the art having ordinary creativity what was common general knowledge in the art at the priority date:

The skilled person has a common general knowledge, has a thorough understanding of processability of drugs. He is capable of undertaking experiments within a limited area and is capable of choosing a better alternative/substitute from the known alternative from the prior art to obtain the known results. He is aware of D1, D2 and D3.

Step 3: Identifying the differences if any between the matter cited and the alleged invention; the difference is the replacement of maleate anion with besylate anion as salt forming agent.

Step 4: Deciding whether those differences, would have been obvious to the person skilled in the art. In the present case, the person skilled in the art had to try from a list of 53 anions. He would not have been dissuaded by the fact that besylate is used for 0.25% of the approved drugs as he had knowledge that other anions were also used rarely. Rather D3 would have motivated him to undertake the trials from within this set of 53 anions particularly keeping in view the better properties of the besylate salts. Considering that the besylate salts would have been obvious to try and having reasonable expectation of success he would go for such alterations. **The invention is therefore obvious.**

The inventive step in the subsequent examples has been analysed by following the steps as prescribed above.

Pharma –IE-7:

The claimed invention relates to a process for the preparation of Compound C by treating Compound A and Compound B in the presence of platinum catalyst. All the features of the invention are disclosed in the prior art except the platinum as a catalyst explicitly, but it was mentioned as noble metal catalysts.

Analysis: Prior art generically disclosed platinum as noble element which is also an equivalent element used in the art for similar purposes and obvious to the skilled person. Therefore, it is application of known feature in the prior art into claimed invention in an obvious way.

Pharma –IE-8:

The claimed invention relates to monoester of a known diol compound for treating cancer diseases using amino acids selected from lysine, valine, leucine and the like, as an esterifying agent. Due to poor oral bioavailability, the diol was unable to be used as oral delivery system. To improve the oral bioavailability, one of the hydroxyl group in the diol was converted into a monoester using said amino acids.

Prior art disclosed monoalcohol with similar structure having poor oral bioavailability was converted into an ester using amino acids selected from lysine, valine, leucine and the like, as an esterifying agent, which exhibit improved oral bioavailability in the treatment of cancer diseases. Amino acid used in the prior art as well as in the claimed invention is lysine.

Prior Art	Claimed Invention
R-CH2-OH ↓ R-CH2-OR’ R’ is lysine, valine, leucine and the like	HO –CH2-R-CH2-OH ↓ HO –CH2-R-CH2-OR’ R’ is lysine, valine, leucine and the like

Analysis: Object of the claimed invention was to provide a solution to overcome the poor oral bioavailability of diol, when administered as oral delivery system. One of the alcohol groups in the diol was converted into ester using lysine for improving the oral bioavailability of the diol.

Prior art addressed poor oral bioavailability for substantially similar structure of monoalcohol. The problem was solved by converting the monoalcohol into ester using lysine as an esterifying agent. Therefore, a person skilled in the art can be motivated with teachings of the prior art to use the amino acid for improving the oral bioavailability by converting diol into monoester of diol to solve similar kind of problem. Therefore, there is no technical advancement involved in the claimed invention.

Pharma-IE-9:

A pharmaceutical composition comprising first active agent in an amount from about 2 mg to about 4 mg corresponding to a daily dosage and second active agent in an amount from about 0.01 mg to about 0.05 mg corresponding to a daily dosage together with one or more pharmaceutically acceptable carriers or excipients. The composition consists of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days.

The first active agent present in the composition is in micronized form or sprayed from a solution onto particles of an inert carrier.

D1: The first and second active agents together with combination of those agents are known in the art.

D2: Micronisation for poorly soluble similar drugs is also known in the art for improved drug delivery.

Analysis: Micronized form of first active agent is novel aspect in the present composition. Dose and dosage regimen of first and second active agents in combination and micronisation for poorly soluble similar type of drugs are known in the art. Therefore, it is obvious to a person skilled in the art to convert poorly soluble active ingredient into micronized form for improved drug delivery. Further, changing the particle size is mere modification in the physical form of the active agent for improved and anticipated effect and therefore the claimed invention is obvious.

9. Industrial applicability

9.1 As per Section 2(1)(ac) of the Act, the expression “capable of industrial application”, in relation to an invention, means that the invention is capable of being made or used in an industry”. Further, Section 64(1)(g) of the Act provides that a patent is liable to be revoked if the invention is not useful. To be patentable an invention must be useful and capable of industrial application. The specification should disclose the usefulness and industrial applicability of an invention in a distinct and credible manner unless the usefulness and industrial applicability of the invention is already established, either in explicit or in implicit manner. The patent specification must disclose a practical application and industrial use for the claimed invention wherein a concrete benefit must be derivable directly from the description coupled with common general knowledge. Mere speculative use or vague and speculative indication of possible objective will not suffice.

An invention, in order to be patentable, must be capable of being made or used in some kind of industry. In this context, "industry" should be understood in its broadest sense as including any useful, practical activity as distinct from purely intellectual or aesthetic activity, and does not necessarily imply the use of a machine or the manufacture of an article.

The study material on ‘Intellectual Property Rights-Laws and Practice’ published by the Institute of Company Secretaries of India (ICSI) provided the following three conditions to satisfy the criteria of "industrial application”:[11]

- Can be made;(TANGIBLE)
- Can be used in at least one field of activity;(USEFUL)
- Can be reproduced with the same characteristics as many times as necessary.(CONCRETE)

Not industrial applicable:

- Personal/confidential use of any product
- Theoretical interesting compounds
- Mode of administration (Resilience)
- Any kind of artisan-made product or techniques

[11] https://www.icsi.edu/media/webmodules/FINAL_IPR&LP_BOOK_10022020.pdf

Examples:

- methods for the treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body
- commercially inapplicable inventions (e.g., inventions applied only for personal use, or inventions applied only for academic or experimental purposes); and
- practically inapplicable inventions or Frivolous inventions or inventions that are against laws of nature also do not have industrial application (e.g., "a method for preventing the increase in ultraviolet rays associated with the destruction of the ozone layer by covering the whole surface of the earth with an ultraviolet ray absorbing plastic film", the perpetual motion machine, a ghost-catcher).

Analysis of Industrial applicability:

The Examiner shall assess if the claimed invention is capable of use in any industry or made using an industrial process. Typically, the specification explains the industrial applicability of the disclosed invention in a self-evident manner. Usually industrial applicability is self-evident. If it is not, a mere suggestion that the matter would be industrially applicable is not sufficient.

For example, indicating that a compound may be useful in treating *unspecified disorders*, or that the compound has —*useful biological properties*, would not be sufficient for the compound. The specific usefulness has to be indicated.

In the matter of **Cipla Ltd. v. F.Hoffmann-La Roche Ltd. & Anr. (2015)**[12], the Division Bench of the Hon'ble Delhi High Court on 27th Nov, 2015, analyzed the term "Industrial Application" in the Section 2(1)(ac) of the Act. At paragraph 42, the Hon'ble Court stated:

> 42. Section 2(1)(ac) stipulates that an invention [as defined in Section 2(1)(j)] is _capable of being made or used in an industry'- thereby necessitating that an invention must have commercial use or manifestation. Further, even though an alleged invention may not be a final product, the same will be patentable only if it has some commercial viability. Thus, it is not the product which is the focus of attention but the actual physical substance created which has the potential of a commercial manifestation. Section 2(1)(ac) is clearly connected with Section 48 as it deals with "made" or "used" as also "new product" [through Section 2(1)(j) by using the term "invention"] which are all used in Section 48.

[12] Cipla Ltd. v. F.Hoffmann-La Roche Ltd. & Anr. [RFA(OS) 92/2012 and RFA(OS) 103/2012]

Pharma-IE-10 for industrial applicability:

Invention: Synthetic analogues of a steroid. The steroids possess certain medicinal properties. However, the compounds of the invention, as asserted, are subjects of serious investigation, being the analogue of compounds known for medicinal properties.

Analysis: The claimed compounds are not patentable as they lack any credible and specific utility. A mere scientific interest does not make something eligible for patentability.

Example 1

Invention: The application comprises three sets of claims:

(1) A compound of formula A

(2) A compound of formula B

(3) A process of making A and B, wherein, C and D are reacted at m to n degree centigrade, in an aprotic solvent Y, the said aprotic solvent being selected from a, b, c, d, e and subsequently distilled and purified to isolate A from B.

The specification describes the use of compound of formula A as having certain pharmaceutical applications. However, the specification does not disclose any use of the compound of formula B.

Analysis: Claim 2 is not allowable so far that the compound is not shown to possess any utility. Just because it is a by-product of a reaction for the preparation of the compound of formula A, does not make it a patentable subject matter.

10. Inventions not patentable:

Section 3 **(b):** Inventions contrary to morality or which cause serious prejudice to human, animal or plant life or health or environment are not patentable. Any invention, the primary or intended use or commercial exploitation of which is against the public order or morality or is capable of causing serious damage to the human, animal or plant life or causes damage to the environment or public health is not allowable under this section.

Pharma –IE 11

Example 1 Claim: A pharmaceutical composition comprising human totipotent embryonic cells or

a method of preparing a pharmaceutical product using human totipotent embryonic cells obtained from a human embryo wherein the preparation of the composition requires isolation and cultivation of the totipotent cells resulting in the destruction of the human embryo.

Analysis: The subject matter is not patentable under Section 3(b) of the Act, as the claimed method involves the destruction of human embryos. Human embryos represent the earliest stage of human life, and their destruction raises serious ethical and moral concerns. The primary use or commercial exploitation of such a method would be contrary to morality and the commercial exploitation of human embryos could cause serious harm to human life and health. Therefore, the claim is not patentable.

Example 2: Claim: A genetically modified peptide based herbicide spray designed for pest control purposes that kills insect pests including pollinating insects.

Analysis: The subject matter is not patentable under Section 3(b) of the Act, as the claimed invention poses a significant risk to ecosystems by harming pollinators critical for maintaining biodiversity and food production. The commercial exploitation of such technology could result in long-term environmental damage and threaten global food security. Therefore, the claim is not patentable.

Section 3(c): Scientific principles or abstract theory or discovery of living things or non-living substances are not patentable inventions. Section 3 (c) of the Patents Act, 1970 (as amended), excludes 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 from the scope of patentability. Compounds which are isolated from nature are not patentable

subject-matter. However, processes of isolation of these compounds shall be considered subject to requirements of Section 2 (1) (j) of the Patents Act, 1970 (as amended).

Accordingly, products such as microorganisms, nucleic acid sequences, proteins, enzymes, compounds, etc., which are directly isolated from nature, are not patentable subject-matter. However, processes of isolation of these products can be considered patentable subject to fulfilling the requirements of Section 2 (1)(j) of the Patents Act, 1970 (as amended).

In the matter of **Immunas Pharma, Inc. vs. Assistant Controller of Patents**, the Hon'ble Madras High Court on 6th March, 2024 analyzed the scope of the term "discovery" in the Section 3(c) of the Act. At paragraph 13, the Hon'ble Court stated[13]:

> *"...the noun "discovery" in the third limb is intended to apply both to living things and non-living substances occurring in nature. This is a pointer, albeit not conclusive, that the adjective "mere" does not extend to this limb as otherwise even a "living thing" could fall outside the scope of patent exclusion if there is something more than mere discovery..."*
>
> *"...that the qualifier "mere" is confined to the nearest reasonable referent "discovery of a scientific principle" and does not extend to "the discovery of any living thing or non-living substance occurring in nature..."*

Pharma –IE-12 for section 3(c):

Example 1:

Claim: A compound for cardiac disorder related activity, wherein the compound is obtained from the cerebrospinal fluid of horseshoe crab, Tachypleusgigas.

Analysis: The subject-matter is not patentable under Section 3 (c) of the Patents Act, 1970 (as amended) , because the application attempts to claim a compound, which is isolated from cerebrospinal fluid of embryos of horseshoe crab, Tachypleusgigas (i.e. a compound which is non- living substance occurring in nature). As per Section 3 (c) of the Patents Act, 1970 (as amended), a non-living substance occurring in nature is statutorily non-patentable subject- matter.

Section 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

[13] **Immunas Pharma, Inc. vs. Assistant Controller of Patents [(T) CMA (PT) No.118 of 2023]**

apparatus is not a patentable invention 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.

In the context of the pharmaceutical inventions, Section 3(d) deserves special attention. Section 3(d) stipulates that an incremental invention, based upon an already known substance, having established medicinal activity shall be deemed to be treated as a same substance, and shall fall foul of patentability, if the invention in question fails to demonstrate significantly improved therapeutic efficacy with respect to that known compound. After analysing the legislative history of Section 3(d), the Hon'ble Supreme Court commented;

> *"…We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds…".* [SC in **Novartis AG Vs. Union of India (UOI) and Ors**[14], 1st April 2013, Paragraph 103]

While interpreting what is "efficacy", the Hon'ble Supreme Court in the Novartis case[10] held that in the context of the pharmaceutical patenting the "efficacy" should be understood as "therapeutic efficacy". In Para 180 of the order, it was held:

> *"What is "efficacy"? Efficacy means "the ability to produce a desired or intended result". Hence, the test of efficacy in the context of Section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy" ..... It may be noted that the text added to Section 3(d) by the 2005 amendment lays down the condition of "enhancement of the known efficacy". Further, the explanation requires the derivative of "differ significantly in properties with regard to efficacy". What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that*

[14] Novartis AG Vs. Union of India (UOI) and Ors [CIVIL APPEAL Nos. 2706-2716 OF 2013]

directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy. While dealing with the explanation as provided in Section 3(d) it must also be kept in mind that each of the different forms mentioned in the explanation have some properties inherent to that form, e.g., solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to "therapeutic efficacy", are expressly excluded from patentability. Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy".

Also, the Supreme Court explained what would mean a "new product" in the context of Section 3(d) as stated in para 192:

"the new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind". However, in case of chemicals and especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation".

According to the Supreme Court, whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data.

Para 189 stated that;

"The position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. In this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel. No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base in vivo animal model."

Para 190 stated that;

"Thus, in whichever way section 3(d) may be viewed, whether as setting up the standards of "patentability" or as an extension of the definition of "invention", it must be held that on the basis of the materials brought before this Court, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of section 3(d), too, of the Act".

However, it is important to note that the Supreme Court has clarified further that the test of Section 3(d) of the Act does not bar patent protection for all incremental inventions of chemical and pharmaceutical substances.

Para 191 of the Judgment mentions;

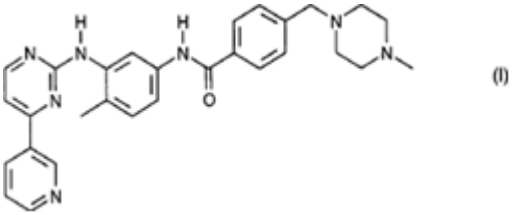
"We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment".

Pharma-IE-13 for section 3(d):

The invention relates to a β-crystalline form of methanesulfonic acid addition salt of imatinib and processes for the preparation thereof. The application was filed with the title: Crystal Modification of A N-phenyl-2-pyrimidineamine Derivative, Processes for Its Manufacture And Its Use. The substance claimed was a medicine for the treatment of chronic myeloid leukemia (CML).

The specification asserts that the claimed β-form has (i) more beneficial flow properties: (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate. No experimental data related to efficacy is provided in the specification for β-crystalline form of imatinib mesylate or imatinib mesylate.

Claims: A form of the methanesulfonic acid addition salt of a compound of formula comprising crystals of the β-modification.



(I)

A number of pre-grant oppositions were filed. The application for patent was refused under Section 25(1) on the ground that the invention was

- anticipated by US Patent no: 5521184 (Zimmerman Patent, disclosing Imatinib and salts), "Nature Medicine' of May 1996, and the Patent term extension certificate for the 1993 patent issued by the USPTO which specifically mentions imatinib mesylate as the product;
- obvious vis-à-vis US 5521184
- not allowable u/s 3(d): Applicant fails to prove enhanced efficacy (thirty percent bioavailability was held not meeting the requirement of "therapeutic efficacy").

Decision of Supreme Court: After several rounds of litigations in different forums, the matter reached before the Supreme Court.

It was argued on behalf of the appellant that

There is certainly no mention of polymorphism or crystalline structure in the Zimmermann patent. The relevant crystalline form of the salt that was synthesized needed to be invented. There was no way of predicting that the beta crystalline form of Imatinib Mesylate would possess the characteristics that would make it orally administrable to humans without going through the inventive steps.

It was further argued that the Zimmermann patent only described, at most, how to prepare Imatinib free base, and that this free base would have anti-tumour properties with respect to the BCR ABLkinase.

Thus, arriving at the beta-crystalline form of Imatinib Mesylate for a viable treatment of Chronic Myeloid Leukemia required further invention – not one but two, starting from Imatinib in free base form, (formation of mesylate and then beta crystalline thereof).

The Court mainly focussed its analysis on

1) whether imatinib mesylate was already known, and then
2) if it is a known substance, it must meet the criteria of enhanced efficacy as in Section 3(d).

The Court after analysing the documents in para 131 and 161of the Case Law held that,

> "Imatinib Mesylate is all there in the Zimmermann patent. It is a known substance from the Zimmermann patent". After finding that Imatinib Mesylate is a known substance from the Zimmermann patent itself……its pharmacological properties

are also known in the Zimmermann patent and in the article published in the Cancer Research journal (Cancer Research, January 1996). *"The subject product, that is beta crystalline form of Imatinib Mesylate, is thus clearly a new form of a known substance, i.e., Imatinib Mesylate, of which the efficacy was well known. It, therefore, fully attracts section 3(d) and must be shown to satisfy the substantive provision and the explanation appended to it". "It is noted, in the earlier part of judgment, that the patent application submitted by the appellant contains a clear and unambiguous averment that all the therapeutic qualities of beta crystalline form of Imatinib Mesylate are also possessed by Imatinib in free base…." [Paragraph 162]*

Further para 171 states that;

"…the appellant was obliged to show the enhanced efficacy of the beta crystalline form of Imatinib Mesylate over Imatinib Mesylate (non-crystalline). There is, however, no material in the subject application or in the supporting affidavits to make any comparison of efficacy, or even solubility, between the beta crystalline form of Imatinib Mesylate and Imatinib Mesylate" (non-crystalline). [Paragraph 171]

On the question of bio-availability the Court opines in the para 189 of the said case Law which is stated above (para no. 10.8 of this guideline) and hence the Court rejected the appeal

".... the position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. In this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel. No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base in vivo animal model".

The Court, therefore rejected the appeal.

In the matter of DS Biopharma Limited vs. The Controller of Patents and Designs[15]**,** the Hon'ble Delhi High Court on 30th August, 2022, at paragraph 14 stated that:

> *"14…For the purposes of a Section 3(d) objection, the one specific* ***known substance is to be identified*** *and the manner in which the claimed compounds are 'new forms' ought to be mentioned by the Patent Office, even if not in detail but at least in a brief manner…"* ***[Emphasis added]***

Section 3 (e): Mere Admixture Resulting only in Aggregation of The Properties or A Method of Making Such Mere Admixture

Claims related to compositions obtained by mere admixture resulting in aggregation of the properties of the individual components are not patentable under section 3(e) of Act. However, in a composition if the functional interaction between the features achieves a combined technical effect which is greater than the sum of the technical effects of the individual features, it indicates that such a composition is more than a mere aggregation of the features.

Section 3(e) of the Patents Act, 1970 (as amended) reflects the legislative intent on the law of patenting of combination/composition inventions in the field of chemical as well as biotechnological sciences.

Pharma-IE-14 for section 3(e):

Claim: A composition of Paracetamol (Antipyretic) and Ibubrufen (analgesic) to control pain and inflammation.

Analysis: The compounds used in the alleged invention are known for their activity. The application is silent on a combinative effect of these two compounds over the sum of their individual effects. Thus, the claimed subject-matter is non-patentable under Section 3 (e) of the Act.

Pharma-IE-15:

Invention: A pharmaceutical composition exhibiting anti-phlogistic, antipyretic and analgesic activity and high gastro-enteric tolerance in unit doses form which contained imidazole salicylate as the active ingredient in the amount of 100-600 mg and an inert carrier was claimed.

[15] DS Biopharma Limited vs. The Controller of Patents and Designs [C.A. (COMM.IPD-PAT) 6/2021 & I.A. 12828/2021]

The active compound imidazole salicylate and carriers are known in the art. Thus, the claimed composition is merely an aggregation of the ingredients involved, wherein the carrier is not playing any role in enhancing the activity of imidazole salicylate.

In the case of **Novozymes vs. Assistant Controller of Patents & Designs**[16], (T) CMA (PT) No. 33 of 2023, Madras High Court, dated 20/09/2023, the issue of patentability of enzyme variants was examined. The Hon'ble Court observed in Para 27

> *"...On examining the text of Section 3(e) and, indeed even by placing such text in context, I find that there is nothing therein that limits its application to a composition claim formed by the aggregation of known ingredients…".*

It was further stated in Para 28;

> *"...Equally, Section 3(e) does not appear to be limited in its application to independent claims. Instead, the object and purpose, as gleaned from text and context, appears to be to exclude from patent-eligibility any composition claim for a substance that merely exhibits the aggregate properties of its constituents..."*

Section 3 (i): Method of Treatment

According to Section 3 (i) of the Patents Act, 1970 (as amended), 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 is not an invention. Under this section, the Manual of Patent Office Practice & Procedure in (Chapter 09.03.05.08) states that the followings are excluded from patentability:

(a) Medicinal methods: As for example, a process of administering medicines orally, or through injectables, or topically or through a dermal patch;
(b) Surgical methods: As for example, a stitch-free incision for cataract removal;
(c) Curative methods: As for example, a method of cleaning plaque from teeth;
(d) Prophylactic methods: As for example, a method of vaccination;
(e) Diagnostic methods: Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic;

[16] Novozymes vs. Assistant Controller of Patents & Designs, (T) CMA (PT) No. 33 of 2023, Madras High Court, dated 20/09/2023

(f) Therapeutic methods: The term "therapy" includes prevention as well as treatment or cure of disease. Therefore, the process relating to therapy may be considered as a method of treatment and as such not patentable;

(g) Any method of treatment of animal to render them free of disease or to increase their economic value or that of their products. As for example, a method of treating sheep for increasing wool yield or a method of artificially inducing the body mass of poultry;

(h) Further examples of subject matters excluded under this provision are: any operation, treatments such as cosmetic treatment, sterilization, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor, any therapy or diagnosis practiced on the human or animal body.

(i) Application of substances to the body for purely cosmetic purposes is not therapy;

(j) Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus. Also, the manufacture of prostheses or artificial limbs and taking measurements thereof on the human body are patentable.

The Hon'ble Madras High Court, in the matter of **The Chinese University of Hong Kong v. Assistant Controller of Patents**, CMA (PT) No.1 of 2023, C.M.P. No.13206 of 2023 & W.P. No.7666 of 2023 & W.M.P. Nos.7828 & 7832 of 2023[17], dated 12/10/2023, examined the scope of Section 3(i) of the Patents Act, 1970.

The Hon'ble Court analyzed various provisions of Section 3(i) and stated that:

> *"23...A human being may be treated for a disease or disorder or condition by administering medicines, performing surgery or by administering therapy involving medicines or other forms of treatment such as radiation or a combination thereof. If such treatment is administered in order to cure the human being of a disease, it is curative. On the other hand, if medicine or vaccination is administered to prevent a human being from developing a disease or to prevent a more severe manifestation of such disease, it is prophylactic. The common thread running through the following categories - medicinal, surgical, curative, prophylactic and therapeutic - is that they are clearly methods of treatment of human beings."*

[17] The Chinese University of Hong Kong v. Assistant Controller of Patents [CMA (PT) No.1 of 2023, C.M.P. No.13206 of 2023 & W.P. No.7666 of 2023 & W.M.P. Nos.7828 & 7832 of 2023]

Regarding the interpretation of the Term 'Diagnostic', the Hon'ble Court has observed that:

> *"25…When viewed in context, i.e. in association with "forms of treatment", I conclude that the word "diagnostic" should be limited to diagnostic processes that disclose pathology for the treatment of human beings…"*

Scope of *In vivo* and *In vitro* Diagnosis: Regarding the scope of *in vivo* and *in vitro* diagnostic methods, at paragraph 26, the Hon'ble Court stated:

> *"26…As is evident from the language of Section 3(i), there is no indication therein that the word "diagnostic" should be confined to in vivo diagnosis…"*

Examination and Analysis of Claims: In relation to the analysis of claims for determining the patentability of the subject matter, the Hon'ble Court, at paragraphs 41, 42, 46, and 50, observed that:

> *"41…the standard I propose is to examine the claims, in the context of the complete specification, to determine whether it specifies a process for making a diagnosis for treatment. Such determination should be made by assuming that a person(s) skilled in the art, including a medical doctor, examines the claims and complete specification. If it is concluded that a diagnosis for treatment may be made, even if such diagnosis is not definitive, it would be patent ineligible, whereas, if diagnosis for treatment cannot be made, it would be patent eligible.…"*
>
> *"42…I am of the view that the embodiments of a claimed invention are relevant only for the purpose of ascertaining whether the process of the claimed invention per se points to a diagnosis for treatment. If such process does not uncover pathology for any reason, it would not be diagnostic for purposes of Section 3(i)…"*
>
> *"46… What is determinative, therefore, of whether a process is diagnostic is to ask the question whether the process is inherently and per se capable of identifying the disease, disorder or condition for treatment of the person…"*
>
> *"46…If the person(s) skilled in the art would not be in a position to diagnose the disease, disorder or condition, as the case may be, on the basis of the process because the process is not designed to diagnose diseases, disorders*

or conditions, such process, whether labelled as screening or anything else, would not qualify as diagnostic for purposes of Section 3(i)…"

"50…Although the claims delimit the scope and ambit of the monopoly claim, the embodiments set out in the complete specification can and should be examined to assess whether the process is per se diagnostic…"

Screening of Asymptomatic Persons under Section 3(i):

"44… In my view, if a screening test is capable of identifying the existence or non-existence of a disease, disorder or condition and/or the site, extent, severity or other aspects thereof for treatment of human beings, irrespective of whether the person concerned is symptomatic or asymptomatic, such screening test would qualify as a diagnostic test…"

Further, in the matter of ***Sequenom Inc. & Anr. v. The Controller of Patents***[18] (paragraph 79)**,** ***EMD Millipore Corporation v. Assistant Controller of Patents and Designs***[19] (paragraph 65), and ***Natera Inc. & Anr. vs. Assistant Controller of Patents & Designs***[20](Paragraph 79***)*** decided on 9th October 2025, the Hon'ble Delhi High Court interpreted the key features of **Section 3(i)** of the Patents Act as follows:

"the salient points for interpretation of Section 3(i) of the Act may be summarised as under:

(i) ***Products*** *used for diagnosis or therapeutic purposes, including* ***kits, equipment, machines, and physical products,*** *which satisfy the conditions of patentability* ***do not fall within the scope of exclusions under Section 3(i) of the Act*** *and would hence be patentable.*

(ii) A perusal of the various terminologies used in Section 3(i) of the Act shows that the exclusions are meant ***for processes which are employed by medical practitioners, para-medical personnel, nurses, etc****. The interpretation of key terms in Section 3(i) of the Act in the context of other provisions of the Act would be as under:*

[18] Sequenom Inc. & Anr. v. The Controller of Patents [C.A.(COMM.IPD-PAT) 13/2022 & 448/2022]

[19] EMD Millipore Corporation v. Assistant Controller of Patents and Designs, [C.A.(COMM.IPD-PAT) 7/2021]

[20] Natera Inc. & Anr. vs. Assistant Controller of Patents & Designs [C.A.(COMM.IPD-PAT) 16/2023]

(a) ***'Medicinal process'*** *would mean processes which are used for administration of medicines such as a* ***process for oral administration, a process for administration through intravenous therapy, a process for administration of medicine through topical, transdermal or subcutaneous routes or a process through insertion of the medicine****, etc. but* ***would not include medicinal products, medicines, medical devices, or even patentable product by process inventions.***

(b) 'Surgical process' means a process of performing surgery. However, surgical tools, surgical implements including surgical methods using novel tools and implements would all be patentable. For example, ***the manner of conducting a colonoscopy or heart transplant surgeries, including the method for sutures or the manner of creating an incision****, etc., which are commonly used by surgeons* ***would not be patentable****. However, a* ***novel product*** *such as an innovative scalpel used in conducting the surgery* ***would be patentable.***

*(c) 'Curative process' - this terminology is quite ambiguous and vague, considering the various other terms and expressions used in Section 3(i) of the Act. Curative means "****treatments and therapies aimed at eliminating a disease, injury, or illness to restore a person's health to its prior state"****. Thus, a process adopted by a medical practitioner for curing or healing a disease would not be patentable, but tools and products or novel patentable methods used for the same would not be excluded.*

(d) 'Prophylactic process' means a process for prevention of disease, for example, a ***process of administering a vaccine or a process of conducting cancer screening, blood test etc****.,* ***would not*** *be patentable. However,* ***preventive tools, preventive products or preventive mechanisms*** *which qualify the test of patentability* ***would not be excluded.***

(e) 'Diagnostic process' - The ***manner in which diagnosis is performed would not be patentable****, for example, the manner of checking blood pressure using different tools, the manner of doing a swab test, the process of checking glucose levels, etc., would not be patentable. However,* ***diagnostic products, diagnostic tools, diagnostic devices are patentable*** *so long as they satisfy the test of patentability and they do not unfairly monopolize processes*

of diagnosis which are to be generally used by medical practitioners, nurses etc. ***It is also clear that Section 3(i) does not make any distinction between in vivo or in vitro processes.***

(iii) ***Tools*** *which could be used for the purpose of diagnosis would also not be covered by the exclusion and* ***would be patentable****. However,* ***if tools only consist of software-based tools, which utilize data for the purpose of diagnosis, they would have to be examined under Section 3(k) of the Act for further technical effect and for satisfying the conditions for patentability.*** *In addition, it would have to be checked if these tools or processes by themselves give results which are capable of clear interpretation as to the existence or non-existence of a medical condition.*

(iv)The phrase ***"to render them free of disease or to increase their economic value"*** *qualifies* ***only treatment of animals*** *and not of human beings;*

(v) Mere identification of the ***regimen for the use of certain medicines*** *in a particular manner or frequency or form* ***would be excluded from patentability.***

(vi) ***Methods of treatment of plants*** *are* ***not covered by Section 3(i) of the Act*** *and would be patentable so long as the test of Section 3(j) of the Act is satisfied."[emphasis added]*

Furthermore, in the matter of *Sequenom Inc. & Anr. v. The Controller of Patents*[21], the Hon'ble Court stated that:

"102. In the opinion of this Court, when the language of the Section 3(i) of the Act uses the word diagnostic, the same would include positive and negative diagnosis. The persons who are eliminated from undergoing further confirmation tests in respect of any medical condition, genetic abnormality etc., shows that there is a tangible result achieved by the method/ test which is being performed. It would defeat the purpose of Section 3(i) of the Act, if a test is held to be patentable merely because the test does not confirm the

[21] Sequenom Inc. & Anr. v. The Controller of Patents [C.A.(COMM.IPD-PAT) 13/2022 & 448/2022]

presence of a particular medical condition, although it does eliminate the need for further examination in respect of that medical condition."

Additionally in *Natera Inc. & Anr. v. Assistant Controller of Patents & Designs*[22], the Hon'ble Delhi High Court defined the term **"diagnosis"** and observed that:

*"93…The term 'diagnosis' itself would mean the process of obtaining a result as to whether any particular medical condition exists or not as also the stage thereof, if any. It cannot be accepted that only those methods which **finally confirm** the presence of a particular illness, disease or medical condition would be a diagnostic method. In view of the discussion hereinabove on interpretation of diagnostic methods, where the result of performing a method would **initially confirm** the absence of a particular illness, disease, genetic defect, medical condition etc., or negation of the same in an individual, the said method would also fall within the scope of diagnosis - irrespective of the said method being performed as an in vivo or invitro test…"*

Applicability of Section 3(i) to Combination/Composition Claims

Sometimes the claims are so drafted that a combination/composition of drugs in certain dosage forms is claimed, but the claimed subject-matter relates to application or administration of individual drugs in simultaneous, sequential or concomitant manner. In such cases, although the claims are directed to a combination/composition of drugs, but the claimed invention resides in the method of administration of individual drugs in the said manner and thus, it falls within the scope of Section 3(i) of the Act.

Pharma-IE-16:

Claim 1: A method of treating cancer in a subject, the said method comprising administering simultaneously or sequentially a combination of Gemcitabine and P276-00 or the combination of Gemcitabine and P1446A, wherein the said cancer is selected from a group comprising of pancreatic cancer, lung cancer, colorectal carcinoma and head and neck cancer.

Analysis: The claimed subject-matter falls within the scope of statutorily non-patentable inventions under Section 3 (i) of the Act, as being directed to a method of treatment of human beings or animals.

[22] Natera Inc. & Anr. vs. Assistant Controller of Patents & Designs [C.A.(COMM.IPD-PAT) 16/2023]

Section 3(j) and 3(p): To avoid unnecessary repetition, serial no. 16 for 3(j), serial no. 18 for 3(p) relevant sections of the "GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS" and "GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL" are hereby incorporated by reference.

According to Section 3(j), plants or animals including its parts like seeds are not patentable subject matter. The only exception to this rule is micro-organisms. From the conjoint reading of Section 3(c) and 3(j), the micro-organisms, which occur in nature are not patentable subject matter. Accordingly, only genetically modified micro-organisms qualify for patentability. In the GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT (Chapter 16), Section 3(j) has been discussed with specific examples. According to Section 3(p) of the Act, an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components is not a patentable subject matter. "GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL" already issued by the Office discusses in details, the manner in which cases related to traditional knowledge may be handled [The Zero Brand Zone Pvt. Ltd. vs The Controller of Patents & Designs and ORS. on 5 July, 2024 [23]]

Pharma-IE-17 for Section 3(j):

Claim 1: A pharmaceutical composition comprising an antigen-presenting cell that expresses a polypeptide comprising at least an immunogenic portion of a breast tumour protein, or a variant thereof in combination with a pharmaceutically acceptable carrier or excipient, wherein the antigen presenting cell is a dendritic cell or a macrophage.

Analysis: Although claim 1 is directed to a pharmaceutical composition, it should be objected under Section 3(j) of the Act, since the composition essentially contains an antigen-presenting cell as an active ingredient and carriers or excipients are obvious features with the cell while in the composition.

Pharma-IE-18 for Section 3(p):

Claim: A method of treating an inflammatory bowel disease (IBD) in a subject in need thereof, comprising administering to the subject an effective amount of an extract of Andrographis paniculata, wherein said extract contains andrographolide, 14-deoxy-andrographolide, 14-deoxy-11, 12-dehydrogen-andrographolide and neoandrographolide.

[23] The Zero Brand Zone Pvt. Ltd. vs The Controller of Patents & Designs and ORS [(T) CMA (PT) No.146 of 2023]

Analysis: The claimed subject-matter falls within the scope of statutorily non- patentable inventions under Section 3 (p) of the Act, as being directed to a traditional knowledge in effect. This is clearly evident from an article published in the Journal of Natural Medicine (**Kakrani et al., "Traditional treatment of gastro-intestinal tract disorders in Kutch District, Gujarat State, India", Journal of Natural Medicine, Vol. 2/1(2002), pages 71-75**[24]). The cited article describes traditionally known treatments of gastro-intestinal tract disorders in Kutch district of Gujarat. In this article, 41 species of 37 genera belonging to 22 families are reported along with plant parts used for the medicinal treatments, including Andrographis paniculata and its medical indication. Thus, the claimed subject-matter, in effect, is traditional knowledge and non- patentable under Section 3 (p) of the Patents Act, 1970 (as amended).

[24] Traditional treatment of gastro-intestinal tract disorders in Kutch District, Gujarat State, India", Journal of Natural Medicine, Vol. 2/1(2002), pages 71-75

11. Sufficiency of Disclosure, clarity and support of the claims:

11.1 According to Section 10(4)(a) and (b) of the Patents Act, the Complete Specification shall fully and particularly describe the invention and its operation or use and the method by which it is to be performed and it should also disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection. As per Section 10(4)(c), every Complete Specification should end with a claim or a set of claims defining the scope of invention. Section 10(5) prescribes that the claims should be clear, succinct and fairly based on the description. Also, the claims must relate to a group of inventions linked so as to form a single inventive concept. For convenience, unity of invention has been discussed below, under separate head.

Sufficiency of disclosure with respect to biological material and deposits: If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty. The deposit of the material shall be made not later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. [As per amended Rule 138 of the Patents Rules, the time limit prescribed may be extendable for a maximum period of six months.] All the available characteristics of the material required for it to be correctly identified or indicated are to be included in the specification including the name, address of the depository institute and the date and number of the deposit.

In Para 17 of "GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL", it is directed that "*if the source and geographical origin of the biological material used in the invention is not disclosed in the specification, an objection shall be raised thereof in conformity with section 10(4)(a) & (b) of the Patents Act*." Therefore, the same is incorporated herein by reference and also, applicable in the present guidelines. Thus, while assessing the sufficiency of disclosure, non-disclosure of the source and geographical origin of the biological materials used in the invention would be treated as insufficiency of disclosure as per the requirement of Section 10(4)(ii)(d) of the Act. Nevertheless, in Para 20

of above said guidelines, it also directed that "*On the other hand, if the declaration in Form-1 regarding the use of biological material from India is cancelled out by the applicant and the specification also states that the source and geographical origin of the biological material is not from India, the specification should be amended by way of incorporation of a separate heading/paragraph at the beginning of the description that the biological material used in the invention is not from India and should clearly specify the country of source and geographical origin of the same.*" Therefore, while processing the patent application in which the above declaration is cancelled out by the Applicant, as directed, necessary amendments shall be sought for. If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty. The deposit of the material shall be made not later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. All the available characteristics of the material required for it to be correctly identified or indicated are to be included in the specification including the name, address of the depository institute and the date and number of the deposit.

The Complete Specification must describe "an embodiment" of the invention claimed in each of the claims and the description must be sufficient to enable those in the industry concerned to carry it into effect without their making further inventions and the description must be fair, i.e. it must not be unnecessarily difficult to follow.

Sufficient disclosure of the invention in the patent specification is the consideration for which a patent is granted. While assessing the sufficiency of disclosure, it must be ensured that the best method for performing the invention known to the applicant is described so that the whole subject-matter that is claimed in the claims, and not only a part of it, must be capable of being carried out by a skilled person in the relevant art without the burden of an undue amount of experimentation or application of inventive ingenuity.

The description in the specification should contain at least one example or more than one example, covering the full breadth of the invention as claimed, which enable(s) the person skilled in the art to carry out the invention. If the invention is related to product per se, description shall be supported with examples for all the compounds claimed or at least all the genus of the compounds claimed. Method for preparation and experimental data relating to properties of representatives of each embodiment claimed shall be incorporated in the description, which enable a person having ordinary skilled in the art can make use of the invention without undue burden.

Non-technical terms, like trademarks etc. should be discouraged and the applicant should be asked to replace them with equivalent technical terms.

The relevant date for complying with the requirement for sufficiency is the date of complete specification. In other words, a Complete Specification should provide enough information to allow a person skilled in the art to carry out substantially all that which falls within the ambit of what is claimed. Specific and substantial use of the invention along with any test conducted and results obtained for such an effect shall be disclosed at that time of filing. In case, application claimed substance, composition or combination, detailed report pertaining to the test, such as in vitro or in vivo, conducted and experimental results with inference of such a test shall be provided in the description. Test parameters, choice of testing method, mode of drug delivery, results obtained with explanation and inference shall be provided. If more than one genus or pharmacological use claimed in an application, relevant test for the best representatives of such genus and their pharmacological use shall be incorporated in the description.

It is not necessary to describe in the claims to a specification, processes by which a new chemical compound is discovered, when they are part of the common knowledge available to those skilled in the art who can, after reading them, refer to the technical literature on the subject for the purpose of carrying them into effect.

In the matter of SAINT GOBAIN GLASS FRANCE vs ASSISTANT CONTROLLER OF PATENTS AND DESIGNS & ANR[25]. the Hon'ble Delhi High Court on 11th September 2025, analyzed that

> "[Para 43] *as compliance with Section 10 of the Act, which requires that the invention be sufficiently disclosed, does not in itself establish that the claimed subject matter involves an inventive step. The two provisions operate in distinct spheres, and satisfaction of one does not dispense with the requirement of the other".*

In the matter of **The Regents of The University Of California Vs Controller General Of Patents, Designs &Trademarks & Anr. [C.A.(COMM.IPD-PAT) 143/2022**[26]] on 05.02.2024, Hon'ble Delhi High Court at para 10 and 22 observed that

> *"10… It is, therefore, evident that amendments to the original application can be made only by way of the following: -*
>
> i) *Disclaimer; or*

[25] SAINT GOBAIN GLASS FRANCE vs ASSISTANT CONTROLLER OF PATENTS AND DESIGNS & ANR [C.A.(COMM.IPD-PAT) 13/2024 with I.A. 8216/2024]

[26] The Regents of The University of California Vs Controller General of Patents, Designs &Trademarks & Anr. [C.A. (Comm.Ipd-Pat) 143/2022]

ii) *Correction; or*

iii) *Explanation.*

Additionally, the proposed amendments are tested against the following parameters:

iv) *Amendment should serve the purpose of incorporation of actual facts;*

v) *Effect of the amendment should not allow matter not in substance, disclosed originally or shown in the specification;*

vi) *Amended claim of the specification should fall within the scope of the original claim of the specification…"*

"22…Thus, in the opinion of this Court, the amendments serve only as an explanation to the original claims, amount to incorporation of actual facts, and do not disclose any matter which was not originally disclosed in the claims of specification filed before the amendment…"

Further, in the matter of **Opentv Inc Vs The Controller Of Patents And Designs [(C.A.(COMM.IPD-PAT) 14/2021**[27]] on 11.05.2023, Hon'ble Delhi High Court at para 50, 53 and 56 observed that

"50…The fundamental principle governing amendment of Claims is therefore, that amendments are permissible in the Claims so long as the said amendments are within the scope of the originally filed Claims as filed and do not expand the said Claims. Thus, reduction or narrowing down a Claim is permissible, but broadening, widening or expansion of Claims is not permissible…"

"53…Thus, amendments having been held to be permissible at the appellate stage, this Court is of the opinion that irrespective of whether the amendment is directed by the Court or is at the instance of Patent Applicant, so long as the requirements as laid down under Section 59 of the Act are fulfilled such that the amended claims are within the scope of original claims, is not breached, the amendment is permissible…"

"56…Conversion of method claims into system claims in the manner sought to be done, would be broadening of the Claims which is impermissible as per section 59 of the Act. There may be some exceptional cases where such a conversion may be permissible depending on the nature of the invention and the scope of Claims…"

[27] Opentv Inc Vs the Controller of Patents and Designs [(C.A. (COMM.IPD.PAT 14/2021]

Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruninga Corporation etc. Vs. Unichem Laboratories and Ors.[28], the Hon'ble Court stated that:

> *"16…the complete specification must describe "an embodiment" of the invention claimed in each of the claims and the description must be sufficient to enable those in the industry concerned to carry it into effect without their making further inventions "and the description must be fair, i.e. it must not be unnecessarily difficult to follow…".*

While examining the claims with respect to clarity and support as required under section 10(5) of the Patents Act, due consideration should be given to the provisions of section 10(4)(a) and (b) of the Patents Act, 1970 (as amended) as these requirements are complementary to each other.

Clarity and support of claims: As mentioned in connection with the type of claims, it was mentioned that in the pharmaceutical applications, claims are often filed as "Use of…". Such wordings in the claims are not permissible in that a claim should relate either to a product or to a process.

A claim may be lacking in support, if it is not fairly based on the description. Claims may be drafted in non-definitive terms and the scope of claim is often unreasonably broader than the description and enablement of the specification. Claims may embrace non-definitive terms like "comprising", "including", etc. to indicate certain components of the invention. Similarly, terms like "near to", "approximately", "thin" ', "strong" ', "a major part" ', "such as" ', "more", "less", "greater than", "less than", "at least", "When required" or "any", "can", "can be", "may", "may be" are used in the claims may lead to confusion and a subject to interpretation and case specific. Such terms or any other terms, should be closely examined vis-à-vis the support in the description and the scope of protection sought for ensuring the definitiveness of the claims.

Functional claims, i.e. claims where the substances are defined in terms of their physiological properties/results to be achieved, should be discouraged, as such claims not only lead to confusion regarding the scope of the invention, almost all the time, they are much wider in scope and are inconsistent with descriptions.

In pharmaceutical patenting, the claims are often drafted in terms of Markush formula. Special care should be given to search and examine such claims. Claims with Markush formulas may cover innumerable compounds and may be overbroad, thus leading to conclusion of inconsistency between description and claims. Also, such formulas can lead to

[28] Farbewerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruninga Corporation etc. Vs. Unichem Laboratories and Ors. [AIR 1969 Bom 255]

the question of plurality of distinct inventions. Compounds represented by different alternatives should have a technical interrelation ship.

Where a single claim defines alternatives of a Markush group, the requirement of a technical interrelationship is considered met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:

A) all alternatives have a common property or activity; AND

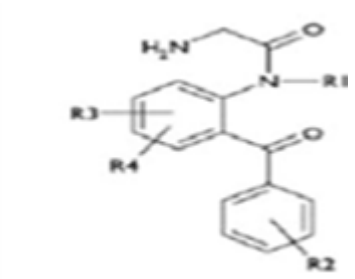
B) (1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR

B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

The claims of a specification may be said to be linked with a single inventive concept, if they are co-related to each other by a common thread. For example, the specification may contain a claim for (1) a drug (2) intermediates (3) process of making the compound of claim (1) and (2). However, the intermediates shall be allowed provided they are new and non-obvious and industrially applicable and further, the specification does not disclose any other use of the said intermediates.

Pharma-IE-19 for sufficiency of disclosure and support:

The alleged invention claims a compound of the following formula



Wherein, R1 is selected from phenyl, pyridyl, thiazolyl, thioalkyl, alkoxyl and methyl; R2- R4 are methyl, tolyl or phenyl, pyridyl… the compounds are used for increasing the oxygen intaking capability of blood.

Description: the specification embraces innumerable compounds covering formula as above. The examples however are restricted to the limitation that R1 is always phenyl, e.g.:

R1	R2	R3	R4
phenyl	tolyl	phenyl	methyl
phenyl	tolyl	pyridyl	tolyl
phenyl	pyridyl	methyl	tolyl

Analysis: The claimed subject-matter defines R1 as being selected from a broad group comprising phenyl, pyridyl, thiazolyl, thioalkyl, alkoxyl and methyl. However, the embodiments and working examples disclosed in the specification are limited exclusively to compounds in which R1 is phenyl. No experimental data, synthetic examples, comparative results, or technical guidance are provided for compounds wherein R1 is any of the other claimed substituents, namely pyridyl, thiazolyl, thioalkyl, alkoxyl or methyl. Consequently, the specification does not demonstrate that the technical contribution of the alleged invention extends across the full breadth of the claimed genus.

In the absence of adequate disclosure enabling the skilled person to prepare and use compounds throughout the entire claimed scope without undue experimentation, the claims extend beyond what has been actually described and supported in the specification. The broad definition of R1 is therefore not commensurate with the disclosure and lacks adequate support.

Further, it is pertinent to distinguish between the requirements of support and sufficiency of disclosure. While support requires that the scope of the claims be justified by and correspond to the technical contribution disclosed in the specification, sufficiency of disclosure requires that the invention be described in a manner sufficiently clear and complete for a person skilled in the art to perform it over the whole scope of the claims. Although these are distinct legal requirements, they are closely related. In the present case, since the specification only enables compounds having R1 = phenyl, the absence of disclosure for the remaining claimed alternatives also gives rise to a prima facie objection regarding sufficiency of disclosure, in addition to the objection that the claims lack adequate support.

DEPOSITION OF BIOLOGICAL MATERIAL

If the invention mentions a biological material in the specification, which is not available to the public and is not described in such a way as to satisfy the requirements of

clauses (a) and (b) of the Section 10(4) of the Act such material shall be deposited with an International Depository Authority (IDA) recognized under the Budapest Treaty.

The deposit of the material shall be made not later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. All the available characteristics of the material required for it to be correctly identified or indicated in the specification including the name, address of the depository institute and the date and number of the deposit.

Depository Authorities:

The International Depository Authorities in India under the Budapest Treaty are:

1. Microbial Type Culture Collection and Gene Bank (MTCC)
   Institute of Microbial Technology (IMTECH), CSIR-Institute of Microbial Technology, Sector 39-A, Chandigarh - 160036, India.
   Website- https://mtccindia.res.in/

2. Microbial Culture Collection (MCC)
   National Centre for Cell Science (NCCS), Savitribai Phule Pune University Campus, Ganeshkhind, Pune - 411007, Maharashtra, India.
   Website: http://www.nccs.res.in

3. National Agriculturally Important Microbial Culture Collection (NAIMCC)
   ICAR-National Bureau of Agriculturally Important Microorganisms Kushmaur, Mau Nath Bhanjan - 275103, Uttar Pradesh, India.
   Website: https://nbaim.icar.gov.in

   Reference to IDA under the Budapest Treaty under Section 10(4)(d)(ii) should be read with Section 2(1)(aba) of the Patents Act, 1970 (as amended).

12. Unity of invention

The requirement of unity of invention is provided by the following provision in the Patents Act and Manual of Patent Office Practice and Procedure as referred in Chapter 05.03.14. As per the provisions of section 10(5) of Patents Act the claim or claims of a Complete Specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept.

Determination of Unity of Invention

(1) The Claims of a Specification shall relate to a single inventive concept. In case, an application comprises a plurality of inventive concepts the Examiner refers to the same in his report. The application may be divided in order to meet the objection of plurality of distinct inventions.

(2) The determination whether a group of inventions is so linked as to form a single inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

(3) Unity of invention between process and apparatus or means requires that the apparatus or means have been specifically designed for carrying out the process.

(4) Independent claims of different categories may relate to a single inventive concept and may be allowed in one application, when they are linked to form a single inventive concept and are supported by the description.

In other words when there is a group of inventions in a specification they should be linked by a single inventive concept or there should be a technical relationship among the claimed inventions, which makes the inventive contribution over the prior art. This determination should be done on the content of the claims supported by the description in the light of the prior art. In case of a drug or pharmaceutical product, claims may be directed to a drug or pharmaceutical product, a process of making the product, a composition containing the drug.

In the field of pharmaceuticals patent applications may have the claim containing huge number of chemical compounds by Markush structures, chemical compounds as intermediate and final products, compositions comprising different chemical components, processes for their manufacture, their uses or applications, even devices or apparatus used for carrying out specific processes are usually claimed in a single application. Sometimes it becomes complicated to handle search and examination of such combinations of different categories of

claims and variable dependency of claims. Interpreting such claims as claimed in the application relate to a single invention or a group of inventions linked so as to form a single inventive concept or lack of unity.

Lack of unity may be evident in an application in the following ways:

A priori', i.e., before consideration of prior art, if the claims falling in different groups do not share the same or corresponding technical feature.

`A posteriori', i.e., after a search of the prior art, if the shared technical feature fails to make a contribution over the prior art.

Pharma-IE-20 of unity of invention:

Claims

(1) An antibiotic of formula I for treatment of staphylococcal infection.

(2) A steroid of formula A for treatment of staphylococcal infection.

(3) A bioactive compound of formula X for treatment of staphylococcal infection.

Analysis: The subject matter of claims 1-3 does not comply with the requirement of unity of invention, as the claims do not relate to a single invention or to a group of inventions so linked as to form a single inventive concept. Although all three claims are directed to the treatment of staphylococcal infection, the common therapeutic indication alone does not constitute a special technical feature capable of establishing unity.

Specifically, claim 1 relates to an antibiotic of Formula I, claim 2 relates to a steroid of Formula A, and claim 3 relates to a bioactive compound of Formula X. These compounds are structurally distinct and belong to different classes of chemical entities. They do not share any common structural element, common chemical scaffold, or common special technical feature that defines a contribution over the prior art. The mere fact that the compounds are intended for the same therapeutic use does not establish a technical relationship among the claimed inventions.

Since each claimed product represents an independent chemical entity with its own structural characteristics and technical contribution, each claim constitutes a separate invention. Accordingly, claims 1-3 are not linked by a single general inventive concept and, therefore, lack unity of invention.

Combinations of Different Categories of Claims

Illustrative examples showing combinations of different categories of claims

Pharma-IE-21

Claim 1: A compound of formula I.

Claim 2: A method of preparing the compound of formula I.

Claim 3: The composition containing compound of formula I as a fungicide.

Analysis: Claim 1 is directed to the compound per se, claim 2 is directed to the process for preparing the same compound, and claim 3 is directed to a composition comprising the compound of Formula I as the active fungicidal ingredient. The process and the composition are technically and functionally dependent upon the novel compound defined in claim 1 and derive their inventive significance from it. Thus, the claimed product, the process for its preparation, and its composition are so linked as to form a single inventive concept through the common special technical feature, i.e., the compound of Formula I. Accordingly, claims 1-3 meet the requirement of unity of invention.

Unity of invention in Markush claims

In Markush claims the unity of invention shall be considered to be met when the alternatives claimed are of a similar nature. The Markush group of alternative chemical compounds can be regarded as being of a similar nature is subjected to the fulfilment of the following conditions:

a) They have a common property or activity,
b) All of the Compounds derived from Markush Formula should have common structure.

Pharma-IE-22 showing unity of invention in Markush claims

A compound A of formula: R1-R2-R, wherein R1 is indolyl moiety and R2-R3 are methyl, benzyl, or phenyl. The compounds are useful as pharmaceutical for treatment of asthma.

Analysis: The claimed subject matter satisfies the requirement of unity of invention, as the claimed compounds constitute a Markush group linked by a single general inventive concept. All the claimed compounds share a common significant structural element, namely the indolyl moiety at R1, while the variations are limited to the substituents R2 and R3, which are selected from methyl, benzyl, or phenyl. The common structural feature is essential to the identity of the claimed compounds and is associated with the same disclosed technical property, namely their utility as pharmaceutical agents for the treatment of asthma. Since the alternatives encompassed within the Markush formula are structurally related and possess a common technical

effect attributable to the shared structural element, they are linked by a single inventive concept. Accordingly, the claimed Markush group complies with the requirement of unity of invention.

Pharma-IE-23:

The claim relates compound R1-R2-R3, Wherein R1 is a heterocyclic moiety comprising diverse molecular species and R2-R3 are methyl, benzyl, or phenyl.

Analysis: The claimed compound of formula R1-R2-R3 does not satisfy the requirement of unity of invention. While R2 and R3 are limited to methyl, benzyl, or phenyl, R1 is broadly defined as a heterocyclic moiety encompassing a wide variety of structurally diverse molecular species. The breadth of the definition of R1 includes numerous unrelated heterocyclic frameworks that do not share a common significant structural feature capable of establishing a technical relationship among the claimed compounds. Consequently, the alternatives encompassed by R1 cannot be regarded as forming a single Markush group linked by a common special technical feature. In the absence of a common structural element associated with a common technical effect, the claimed compounds cannot be considered to form a single general inventive concept. Therefore, the claim lacks unity of invention.

Unity of invention in Intermediate and Final Product

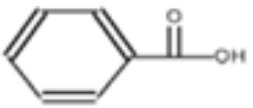
The intermediate is the starting product that is chemically or physically converted to create an end product. The fulfilment of the requirement of unity of invention between intermediate and final product, is subjected to the fulfilment of the following conditions:

(a) At times intermediate(s) are also allowable provided they pass the patentability criteria and it is totally specific to the particular patent application., and

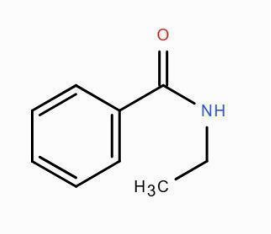
(b) Technically interrelated, also meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all sharing the same essential structural element.

Illustrative example for Unity of invention in Intermediate and Final

Pharma –IE-24:

Claim 1: (intermediate) 

Claim 2: (final product)

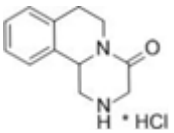


Analysis: Claims 1 and 2 satisfy the requirement of unity of invention, as they are linked by a single general inventive concept. Claim 1 is directed to an intermediate compound, while claim 2 is directed to the final product prepared using the intermediate. The chemical structures of the intermediate and the final product are technically closely interrelated, in that the essential structural element present in the intermediate is retained and incorporated into the final product. Thus, the intermediate makes a direct technical contribution to the preparation and identity of the final product.

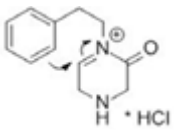
The intermediate is specifically designed and suitable for the synthesis of the claimed final product, and the structural relationship between the two establishes a clear technical link. The common essential structural element constitutes the special technical feature that defines the contribution of the claimed inventions over the prior art. Accordingly, the intermediate and the final product are so linked as to form a single general inventive concept, and therefore unity of invention exists between claims 1 and 2.

Pharma-IE-25:

Claim 1: I (final product)



Claim 2: II (intermediate)



Analysis: Claims 1 and 2 satisfy the requirement of unity of invention, as they are linked by a single general inventive concept. Claim 1 is directed to compound (I), the

final product, while claim 2 is directed to compound (II), an intermediate specifically disclosed for the preparation of compound (I). Although the overall chemical structures of the intermediate and the final product differ considerably, compound (II) functions as an open-ring precursor that is directly converted into compound (I) during the synthesis. Consequently, the intermediate and the final product are technically closely interrelated.

Furthermore, both compounds share a common essential structural element, which is retained during the conversion of the intermediate into the final product and represents the technical feature linking the claimed subject matter. The intermediate is not an unrelated chemical entity but is specifically adapted for the preparation of the claimed final product, thereby establishing a direct technical relationship between the claims. The shared essential structural element constitutes the special technical feature that defines the contribution of the claimed inventions over the prior art. Accordingly, claims 1 and 2 are linked so as to form a single general inventive concept, and therefore comply with the requirement of unity of invention.

Divisional Application in context to plurality of Invention

Moreover, patent applicant may file one or more further application if the application does not satisfy the requirements of unity of invention under the provision of Section 16 of Patent Act. Please refer the chapter 06.01 of Manual for Patent Office Practice and Procedures.

Para 18 of the Divisional bench of Delhi High Court Order noted that;

> *"Section 16(1) in unambiguous terms enables the filing of a further application in respect of an invention, provided it is disclosed in the provisional or complete specification already filed. As the learned Judge rightly observes there appears to be no justification to restrict the filing of a Divisional Application only to a situation where the plurality of inventions is found in the claims. The significance of the provision using the expression "disclosed in the provisional or complete specification" can neither be ignored nor discarded."*

Further, Para 32 of the said Court Order hold that;

> *"a Divisional Application moved in terms of Section 16 of the Act would be maintainable provided the plurality of inventions is disclosed in the provisional or complete specification that may have been filed. We are further of the considered opinion that Section 16 does not suggest or conceive of a distinction between the contingency of a Divisional Application when moved by the applicant of its own motion or where it comes to be made to remedy an objection raised by the Controller. In either of those situations, the plurality of inventions would have to*

be tested based upon the disclosures made in either the provisional or complete specification."

[reference made in the matter of Syngenta Limited Vs Controller of Patents C.A.(COMM.IPD-PAT) 471/2022, dated 13/10/2023[29]]

Rule 13(2A): As per this new Rule filing of divisional application out of divisional is possible. However, such further filed divisional application should be filed before the grant of divisional application from which it was divided out. Nevertheless, priority date, term of patent will be counted from the main application.

- As this new Rule divisional application out of provisional specification can also be possible.

Disclaimer:

1) The guidelines set out above contain, where feasible, certain illustrations. These illustrations are not intended to exhaust the manner in which the relevant guidelines are to be applied in practice. Examiners are requested to examine applications on a case-to-case basis, without being prejudiced by the specific illustrations being provided herein. In case of any conflict between these Guidelines and the Patents Act, 1970 and the Rules made thereunder, the provisions of the Act and Rules shall prevail. The Guidelines are dynamic and the Patent Office will update the same as and when required.

2) The Case Laws as mentioned in the guidelines are for interpretation pertaining to relevant Sections of The Patent Act, 1970 and purely dynamic in nature.

[29] Syngenta Limited Vs Controller of Patents [C.A.(COMM.IPD-PAT) 471/2022]

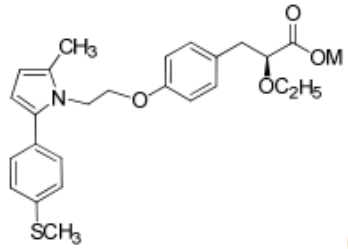
ANNEXURE – I: A Non-Exhaustive Indicative List of Examples

Novelty u/s 2(1)(j)

Pharma-IE-26:

Claim:

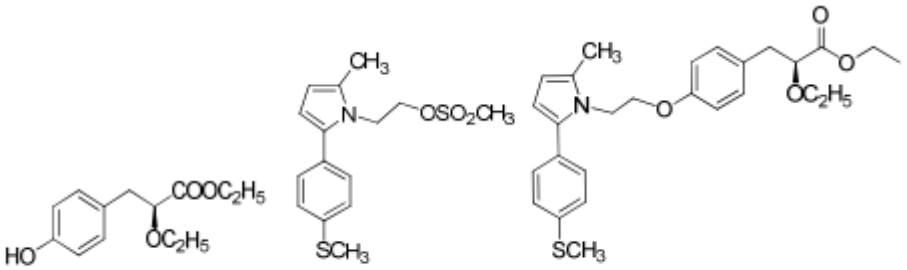
1. A process for the preparation of saroglitazar or its pharmaceutically acceptable salts of Formula (IB),



(IB)

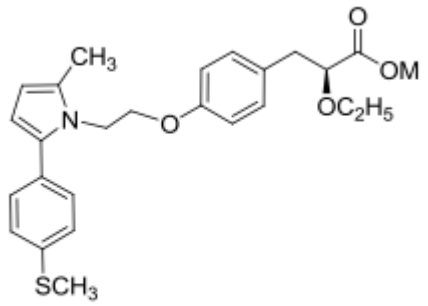
wherein M is a pharmaceutically acceptable cation, the process comprising:

(a) reacting a hydroxy compound (A) with a mesylate compound (A1) in a mixture of solvents at a temperature between 35 ^{0} C to 85 ^{0} C to obtain an alkoxy ester compound of Formula (II);



(A) **(A1)** **(II)**

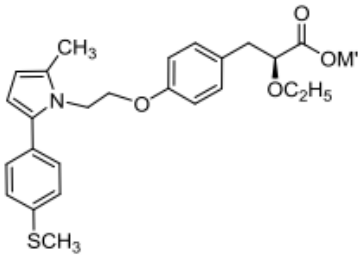
(b) hydrolyzing the alkoxy ester compound of Formula (II) using a base to obtain a compound of Formula (IB-1);



(IB-1)

wherein M is a pharmaceutically acceptable cation selected from sodium (Na), potassium (K), lithium (Li), calcium (Ca), barium (Ba), magnesium (Mg), strontium (Sr) and zinc (Zn);

(c) optionally, neutralizing the compound of Formula (IB-1), with an acid to obtain a compound of Formula (IB-2)



(IB-2)

wherein M' is hydrogen; and

(d) converting the compound of Formula (IB-2) to the compound of Formula (IB).

Analysis:

The present application relates to an improved process for the preparation of pyrrole derivatives having hypolipidemic and hypocholesteremia activities. In particular, the invention relates to an improved process for the preparation of 2-,5-ethoxy-3-(4-(2-(2-methyl-5-(4-(methylthio) phenyl)-1H-pyrrol-1-yl) ethoxy) phenyl) propanoate i.e. Saroglitazar and its pharmaceutically acceptable salts, hydrates, solvates, polymorphs or intermediates thereof.

Prior art document discloses the same or substantially same subject matter as claimed in the present application wherein converting the saroglitazar to its pharmaceutically acceptable salt. However, it does not disclose neutralizing the compound of Formula (IB-1), with an acid to obtain a compound of Formula (IB-2) and also it is evident from

the statement of claim 1 that the process for the preparation of Compound of Formula IB wherein the substituents "M" is a cation. Therefore, the step C is an optional step and not a part of the claimed invention. Thereby, in view of the above disclosure the claimed subject matter lacks novelty u/s 2(1)(j) of the Patents Act, 1970 (as amended).

Pharma-IE-27:

Claim:

A compound of formula:

R^1–Ar–X–R^2,

wherein: Ar is a 5- or 6-membered heteroaryl ring selected from pyridine, pyrimidine, pyrazole, triazole; X is selected from the group consisting of NH, O, S;R^1 is selected from the group consisting of methyl, ethyl, benzyl; R^2 is selected from the group consisting of morpholine, piperidine, piperazine, azetidine;

and pharmaceutically acceptable salts thereof**.**

Analysis:

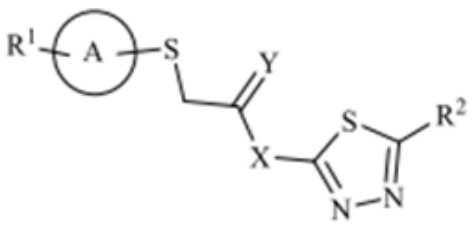
Prior art document discloses a compound ethyl–pyrimidine–NH–piperidine, useful for treatment of ALK positive non-small cell lung cancer. Thereby, in view of the above disclosure this exact compound can be generated from the present invention of the compound of Formula R^1–Ar–X–R^2. Therefore, it is clear that the specific compound can anticipate the generic formula as claimed in the present disclosure..

Therefore, it anticipates the novelty of the claimed subject matter u/s 2(1)(j) of the Patents Act, 1970 (as amended).

Pharma-IE-28:

Claim:

A heterocyclic thioacetamide derivative having chemical formula (I):



Formula **(I)** ;

wherein

X is selected from NH, NR, S, O, CHR, SO_2 or bond and said bond is a

single bond, double bond or a triple bond;

Y is selected from O, S or a heteroatom;

ring A is selected from a substituted aryl, a heteroaryl or a bicyclic ring

system including a monocyclic ring system or a bicyclic ring system, and the

Heterocyclic ring contains atleast one ring heteroatom selected from Nitrogen, Sulphur or Oxygen;

R^1 is H or C_{1-12} hydrocarbyl; and

R^2 is selected from a substituted aryl, heteroaryl or bicyclic ring system

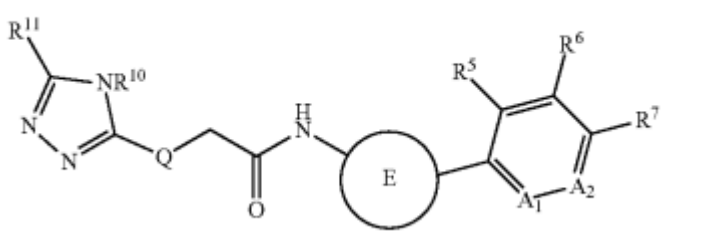
similar or different from ring A.

Analysis:

The present claim relates to a heterocyclic thioacetamide derivative. Moreover, the present claims provide a series of heterocyclic thioacetamide derivatives having chemical formula (I) that acts as orthosteric or allosteric inhibitors of SHP2 for the effective management of SHP2-mediated diseases by binding to either allosteric site or orthosteric site.

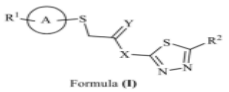
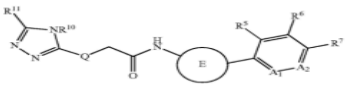
Prior art document discloses compounds of formula (I), pharmaceutical compositions thereof and methods for modulating aquaporin 9. It also relates to pharmaceutical compositions comprising the compounds of formula I and a method of modulating AQP9, such as e.g. with the aim of treating diabetes, in a subject comprising administration of the compounds or pharmaceutical compositions thereof.

Formula (I)



In view of the above disclosure of the prior art document, it is noted that the prior art document discloses about compounds for modulating aquaporin that are having significantly different chemical formula as compared to the claimed compound of the present invention wherein Thioacetamide linked heterocyclic hybrids comprising of 5'-substituted-1',3',4'-triazole and 5'-substituted-1,3,4-thiadiazole rings is present in the prior art document and in the present application Thioacetamide linked heterocyclic hybrids comprising of either 5'-substituted-1',3',4'- thiadiazole or benzothiazole and 5-substituted-1,3,4- thiadiazole rings is reported.

Differences between the Prior art and the Present Invention:

Parameters	Present Invention	D1
Objective	A thioacetamide derivative and a method of synthesis thereof	Compounds for modulating aquaporins
Chemical formula	 Formula (I)	
Substituent groups	X is selected from NH, NR, S, O, CHR, SO_2 or a bond (single, double or triple); Y is selected from O, S or a heteroatom; ring A is selected from a substituted aryl, a heteroaryl or a bicyclic ring system including a monocyclic ring or a bicyclic ring system, and the heterocyclic ring contains at least one ring heteroatom (nitrogen, sulphur or oxygen); R^1 is H or C_{1-12} hydrocarbyl; and R^2 is selected from a substituted aryl, heteroaryl or bicyclic ring system similar or different from ring A.	Q is S , CH_2 or O; E is a 5-membered heteroaryl or a 6-membered heteroaryl having 1, 2, 3 or 4 heteroatoms selected from N, O or S; A_1 and A_2 selected from the group consisting of CH, CR^2 and N.

Thus, the technical features of the prior art document is different from the claimed invention and hence the subject matter of the claim is novel u/s 2(1)(j) of the Patents Act, 1970 (as amended).

Pharma-IE-29:

Claim:

An improved process for preparation of 1H-imidazole-4-carbaldehyde of Formula-I, comprising,

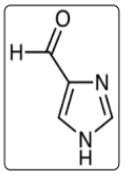
a) reaction of fructose with basic cupric carbonate, ammonia and formaldehyde in presence of a protic solvent to obtain copper complex of corresponding imidazole derivative,

b) cleavage of copper-imidazole complex by adding sodium dithionite to obtain crude (1H-imidazol-4-yl)methanol,

c) optionally, purification of crude (1H-imidazol-4-yl)methanol obtained in step b) with an alcoholic solvent to obtain (1H-imidazol-4-yl)methanol,

d) adding manganese dioxide (MnO_2) to a solvent containing (1H-imidazol-4-yl)methanol obtained in step c) to obtain crude 1H-imidazole-4-carbaldehyde,

e) purification of crude 1H-imidazole-4-carbaldehyde obtained in step d) with an alcoholic solvent to obtain 1H-imidazole-4-carbaldehyde.



(Formula I)

Analysis:

Prior art Document discloses a process for preparation of (1H-imidazol-4-yl) methanol, which uses 95% fructose as a raw material and includes reaction with basic cupric carbonate, ammonia and formaldehyde. The process involves cleavage of copper imidazole complex by passing hydrogen sulfide into reaction mass and it also includes additional steps for purification of product by preparation of corresponding picrate and hydrochloride salts.

In view of the above disclosures in the prior art document, the present invention discloses the use of sodium dithionite for cleaving copper-imidazole complexes whereas the prior art document relies on additional salt like picrate and hydrochloride salts formation and aeration steps, which are avoided in the present application for patent. Thereby, the claimed subject matter in relation to a process for preparation of 1H-imidazole-4-carbaldehyde of Formula-I is novel with respect to the prior art document u/s 2(1)(j) of the Patents Act, 1970 (as amended).

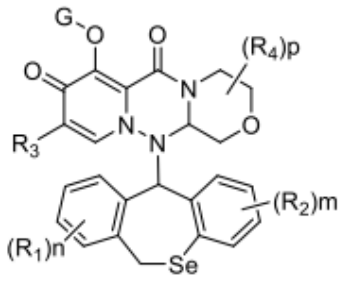
Examples: Obviousness/Inventive step u/s 2(1)(ja)

For the sake of clarity, common general knowledge may be assessed based on the relevant prior art.

Pharma-IE-30:

Claim:

A Compound of Formula (I):



(I),

or a pharmaceutically acceptable salt, stereoisomer or solvate thereof, wherein:

each R_1 is independently selected from the group consisting of H and halo;

each R_2 is independently selected from the group consisting of H and halo;

R_3 is selected from the group consisting of H, halo, Me, CN, and P (O) Me_2;

each R_4 is independently selected from the group consisting of C_1-C_6 alkyl and C_3-C_6 cycloalkyl, wherein any two of R_4 are optionally taken, together with the atoms to which they are attached, to form a C_3-C_6 cycloalkyl;

n and m are each independently 0, 1, 2, 3, or 4;

p is 0, 1, 2, or 3; and

G is H or is selected from the group consisting of C(O)R, C(O)OR, C(O)NR'R, $C(R')_2$-OC(O)R, $C(R')_2$-O-C(O)OR, and $C(R')_2$-O-C(O)NR'R, wherein

each R is selected from the group consisting of C_1-C_6 alkyl, phenyl, pyridyl, C_3-C_6 cycloalkyl, and a 4-6 membered heterocyclic ring containing one or two heteroatoms selected from the group consisting of N, O and S as ring members, wherein the C_1-C_6 alkyl, phenyl, pyridyl, C_3-C_6 cycloalkyl, and 4-6 membered heterocyclic ring of R are independently optionally substituted with one or two substituents selected from the group consisting of H, halo, CN, OH, NH_2, C_1-C_3 alkyl, phenyl, C_1-C_4 alkoxy, C_1-C_3 haloalkyl, and C_1-C_3 haloalkoxy; and each R' is independently selected from the group consisting of H and C_1-C_3 alkyl.

Analysis:

The present application relates to a compound of formula I that may inhibit influenza virus replication, and are accordingly useful for treatment of viral infections caused by influenza virus composition.

Prior art D1 discloses substituted polycyclic pyridone derivatives having cap-dependent endonuclease inhibitory activity, and pharmaceutical compositions including thereof. Furthermore, it relates to a compound having anti-viral activity and compositions and method for treating and/or preventing disease caused by a virus. D1 differs with respect to the present application in regard to the substitution of selenium atom by sulphur.

Prior art D2 discloses that similar structure PZ25 (structure to be incorporated), a Sulphur analog of PZ51 (structure to be incorporated) had little anti-MRSA activity, it was suggested that selenium is essential for the antibacterial activity of PZ51. PZ25 also lost its Glutathione Stimulating Hormone (GSH) peroxidase-like activity.

Step 1: **Identify the person skilled in the art:** A medicinal or pharmaceutical chemist with specialized knowledge in antiviral drug discovery and development

Step 2: **Identify the relevant common general knowledge in the art at the priority date**: The skilled person has a common general knowledge pertaining to Structure–Activity Relationship (SAR) in Medicinal Chemistry, a thorough understanding of processability of drugs and is capable of choosing a better alternative/substitute from the known alternative from the prior art to obtain the known results.

Step 3: **Identifying the inventive concept embodied in the patent:** The inventive concept lies in the compound of formula I that may inhibit influenza virus replication, and are accordingly useful for treatment of viral infections caused by influenza virus composition.

Step 4: **Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claims as construed:** The difference is the replacement of Selenium atom with Sulphur atom in the compound of Formula I that inhibits influenza virus replication.

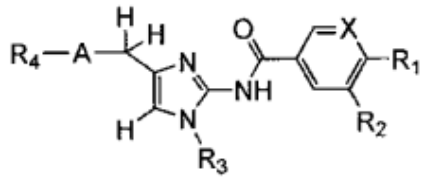
Step 5: **Deciding whether those differences, viewed without any knowledge of the alleged invention constituted steps which would have been obvious to the skilled man or whether they required any degree of inventive ingenuity:** In the present case, the person skilled in the art had to try from various chalcogen group elements to incorporate into the similar structure of Formula I .Moreover, the use of same group

chalcogen is obvious to person skilled in the art and he would arrive at the present claimed subject matter with routine experimentation without exercising any inventive skills. Thereby the replacement of Selenium atom with Sulphur atom in the compound of Formula I inhibiting influenza virus replication appears obvious to a person skilled in the art in view of the documents D1-D2. By combining the inventive features as disclosed in the documents D1-D2 and common general knowledge, the alleged invention is obvious to a person skilled in the art. Therefore, the claimed invention lacks inventive step & fails to meet the requirement of section 2(1)(ja) of the Patents Act, 1970 (as amended).

Pharma-IE-31:

Claim:

A compound of formula (I), or a pharmaceutically acceptable salt, a prodrug, a solvate, or a stereoisomer thereof:



(I)

wherein

X is =CH- or =N-;

R_1 and R_2 are each independently H or 5-10 membered heteroaryl; or R_1 and R_2, together with the carbon atoms to which they are attached, form a 5-7 membered heterocyclic ring;

R_3 is C 6-10 aryl, 5-10 membered heteroaryl, C_{6-10} aryl-C_{1-3} alkyl, C_{3-10} cycloalkyl, or C_{3-10} cycloalkyl-C_{1-3} alkyl;

A is a single bond, C_{1-6} alkylene, -C(=O)-$(CH_2)_n$-, -O-C(=O)-$(CH_2)_n$-, -N(-Rx)- $(CH_2)_n$-, -N(-Rx)-C(=O)-$(CH_2)_n$-, -C(=O)-N(-R_x)-$(CH_2)_n$-, or -(CH_2) m-N(-R_x)-C(=O)- $(CH_2)_n$-, wherein n is an integer of 0 to 6, m is an integer of 0 to 6, and R_x is H or C 1-6 alkyl;

R_4 is hydroxyl, C_{1-6} alkyl, hydroxyl C_{1-6} alkyl, C_{1-10} alkoxy, amino, C_{1-6} alkylamino, diC_{1-6} alkylamino, C_{6-10} aryl, C_{3-10} cycloalkyl, 5-10 membered heteroaryl, 4-10 membered

heterocycloalkyl, or C_{6-10} aryl-(CH 2)$_p$-4-10 membered heterocycloalkyl, wherein p is an integer of 0 to 3;

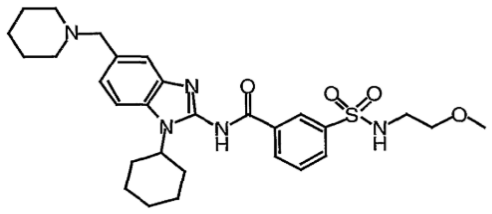
the aryl, the cycloalkyl, the heteroaryl and the heterocycloalkyl each optionally have at least one substituent selected from the group consisting of halogen, C_{1-6} alkyl, C_{1-6} alkoxy, C_{1-6} alkoxy,-C_{1-6} alkyl, haloC_{1-3} alkoxy, hydroxycarbonyl, haloC_{1-3} alkyl, oxido, amino, C_{1-6} alkylamino, diC_{1-6} alkylamino, C_{3-6} cycloalkyl, 4-7 membered heterocycloalkyl, hydroxyC_{1-6} alkyl, cyano, C_{1-6} alkylcarbonyl, C_{1-6} alkylsulfonyl, Oxo, nitro, C_{1-6} alkoxycarbonyloxy-C_{1-6} alkyl, and trimethylsilylethoxymethyl; and

The heterocyclic ring, the heteroaryl and the heterocycloalkyl each contain at least one heteroatom selected from the group consisting of N, O and S.

Analysis:

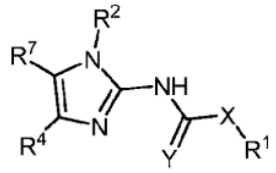
The present claim relates to N-(1H-imidazol-2-yl) benzamide compound, or a pharmaceutically acceptable salt,a solvate, or a stereoisomer thereof, and a pharmaceutical composition comprising the same as an active ingredient which inhibit IRAK4 (interleukin-1 receptor-associated kinase 4) activity.

Prior art Document D1 discloses pharmaceutical compositions comprising a pharmaceutically acceptable carrier or excipient and compound 35 which is used for the prevention or treatment of conditions or diseases mediated by IRAK wherein the compound 35 corresponds to the compound of formula (I) of the present application when X is CH; R_3 is C6 aryl (phenyl).



Compound 35

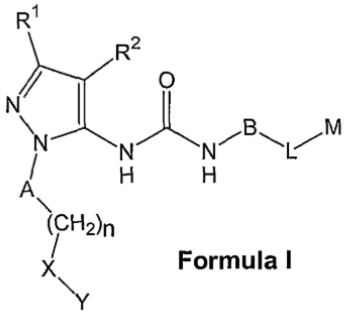
The difference between document D1 and the present application lies in (i) the scope of R1 and R2; (ii) imidazole substituted with CH_2-A-R4. D2 discloses 2-(acylamino)imidazole with therapeutic activity, including selective activity against cancer cells, and compositions comprising them.



I

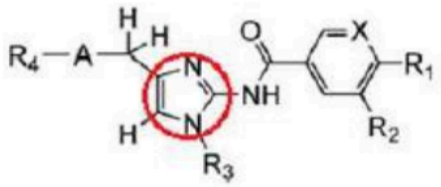
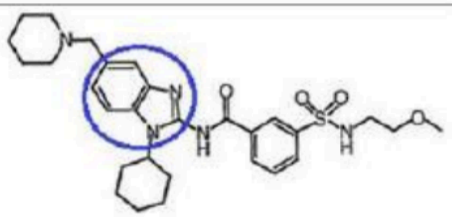
or a salt thereof;

D3 also discloses substituted pyrazolyl urea derivatives (compound of formula I), pharmaceutical compositions which contain them, and methods for treating cancer.



Formula I

Although D1 discloses a compound of a general structure with an imidazole ring, none of the compounds synthesized in the disclosure of D1 contain an imidazole ring. Instead, all of the compounds described in the complete specification of D1 contain a bicyclic benzimidazole ring, as indicated with a blue circle in the table below.

Compound of formula (I) of subject application	Compound 35 of D1
	

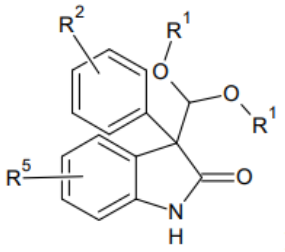
D1 substantially fails to disclose the basic structure of the compound of formula (I) of present application; it would require undue effort for a person skilled in the art to arrive at the compound claimed in the present invention. Similarly, D2 and D3 also fail to disclose the compound of formula (I). Even after combining the disclosures of Document D1-D3, a person skilled in the art would not be motivated to further make any changes to arrive at the compound of the present invention. Thereby, the claim of the present application is non-obvious. Further, it is also observed that the inhibition of

IRAK4 (interleukin-1 receptor-associated kinase 4) activity is better in comparison to the closest prior art document D1. Therefore, the present claimed subject matter is inventive over the cited prior art documents u/s 2(1) (ja) of The Patents Act, 1970 (as amended).

Pharma-IE-32:

Claims:

1. A Process for the preparation of Compound of Formula I:



Formula I

wherein

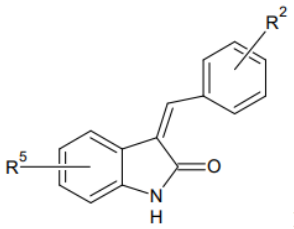
R^1 is -C1-C6 alkyl; and

R^2 is one or more substituent selected from H, halogen, $-R^1$, $-OR^1$, $-NR^3R^4$, $-CONR^3R^4$, $-COOR^3$, $-N(R^3)COR^4$, $-COOR^3$ or $-NO_2$;

R^3 is selected from H, $-R^1$;

R^4 is selected from H, $-R^1$;

R^5 is one or more substituent selected from H, halogen, $-R^1$, $-OR^1$, $-NR^3R^4$, $-CONR^3R^4$, $-COOR^3$, $-N(R^3)COR^4$, $-COOR^3$ or $-NO_2$, comprising reacting compound of formula II.



Formula II

Wherein

R^2 is as defined above,

With a compound of formula III

R^1 -OH

Wherein

R^1 is as defined above, in presence of at least one molar equivalent of (diacetoxyiodo) benzene.

2. The process as claimed in claim 1 wherein R^5 is H.

3. The process as claimed in claim 1 wherein R^1 is methyl, ethyl, propyl or isopropyl.

4. The process as claimed in claim 3 wherein R^1 is methyl.

5. The process as claimed in claim 1 wherein the process uses 2 to 5 molar equivalents of (diacetoxyiodo)benzene.

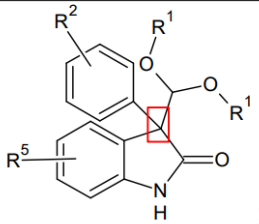
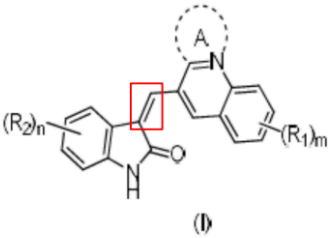
6. The process as claimed in claim 1 wherein the process is carried out at a temperature from about 5 °C to about 100 °C.

7. The process as claimed in claim 1 wherein the process is carried out under stirring for 1 to 24 hours.

Analysis:

The claims relate to a process for the preparation of 3-heteroaryl indolin-2-one derivatives. The present claims further relate to a process for the preparation of compound of formula I comprise reacting compound of formula II with R1-OH in presence of at least one molar equivalent of (diacetoxyiodo)benzene.

Prior art document D1 discloses a process for the synthesis of arylidene-oxindole compounds.

Present invention	**D1**
 **Formula I**	 (I) substituted arylideneoxindoles of formula (I):

In view of the above disclosures, D1 discloses a process for the synthesis of arylidene-oxindole compounds while compounds prepared in the present invention are not arylidene-oxindole compounds. The substituted 2-indolinone compounds prepared in D1 are different than substituted 2-indolinone compounds prepared in the present

invention. Moreover, the claimed process results in new 2-indolinone derivatives (compound of formula I) which are not disclosed in prior art document D1. Also, none of the documents describe the process of the present invention. Further, there is no motivation to use at least one molar equivalent of (diacetoxyiodo)benzene for the preparation of novel 2-indolone derivatives of formula I. Therefore, the process of the present claim is non-obvious and inventive over the combined teaching of D1 u/s 2(1)(ja) of The Patents Act,1970 (as amended).

Pharma-IE-33:

Claim:

A method for manufacturing a face-wash composition; wherein said method comprises:
−(i)blending in pre-determined amounts sodium lauryl sulphate, sodium cocoyl isethionate, tapioca starch and polymethylsilsesquioxane for 15 to 25 minutes at a temperature in the range of 60 to 90 °F, to obtain a first blend;
(ii) blending in pre-determined amounts silica, glycerin, Azadirachta indica seed powder, Glycyrrhiza glabra rhizome powder, methylisothiazolinone phenoxyethanol, talc and fragrance for 15 to 25 minutes at a temperature in the range of 60 to 90 °F to obtain a second blend;
(iii)blending together the first blend and the second blend for 15 to 25 minutes and at a temperature in the range of 60 to 90 °F to obtain a blended mixture; and − sieving the blended mixture through sieves having mesh size in the range of 2000 to 841 micron, to obtain the face-wash composition.

Analysis:

The present application relates to a face-wash composition and a method for manufacturing the same via blending and sieving to obtain the face wash composition.
Prior Art Document D1 discloses a herbal cleanser composition and a method of preparing said composition. A herbal cleanser composition comprising extracts of organically certified herbs and polyglucosides, which is naturally derived. The said extract of herbs is obtained from a blend of herbs selected from Aloe barbadensis, Glycyrrhiza glabra (rhizome), Oryza sativa, Cinnamomum zeylanicum, Azhadirachta indica (seed), Curcuma longa, in various combination thereof. D1 further discloses a preparation method of a herbal cleanser composition comprises blending the organically certified herbs and extracting the resultant herbal blend employing Super Critical Fluid Extraction (SCFE), mixing the resultant extract of blend with naturally derived polyglucoside, mixing naturally derived excipients and essential oils.

Document D2 teaches a herbal anti-acne face wash containing aqueous extract of neem leaves (Azadirachta indica), turmeric (Curcuma longa), liquorice root (Glycyrrhiza glabra), shahi jeera, orange peel & hydro alcoholic extract of fruit of nutmeg (Myristica fragrance). Document D3 discloses a skin whitening cosmetic preparation which comprises in combination an extract of Glycyrrhiza glabra root and glycolic acid, lactic acid, malic acid, citric acid, Pyruvic acid, Tartaric acid, Salicylic acid.

Step 1: **Identify the person skilled in the art:** A cosmetic chemist skilled in developing skin-care or personal hygiene products

Step 2: **Identify the relevant common general knowledge in the art at the priority date:** The skilled person has a common general knowledge pertaining to use of surfactants and other blending agents in preparing face wash composition and standard formulation processes.

Step 3: **Identifying the inventive concept embodied in the patent:** The inventive concept of the present invention lies in the specific method of manufacturing a face-wash composition that combines traditional herbal powders with cosmetic excipients and a structured, low-temperature, multi-step blending and sieving process.

Step 4: **Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claims as construed:** The difference between the prior art and the claimed invention is temperature controlled blending and sieving.

Step 5: **Deciding whether those differences, viewed without any knowledge of the alleged invention constituted steps which would have been obvious to the skilled man or whether they required any degree of inventive ingenuity:** D1-D3 teaches a similar cleansing composition comprising extracts of neem (*Azadirachta indica*) and liquorice root (*Glycyrrhiza glabra*) and the process for preparation of the composition comprises blending and sieving analogous to the claimed subject matter. The rest of ingredients in claimed composition are known excipients and doesn't have any technical features of the claimed process. Hence, the subject matter of claims lacks inventive step u/s 2(1)(ja) of the Patents Act, 1970 (as amended).

Examples : Section 3(d):

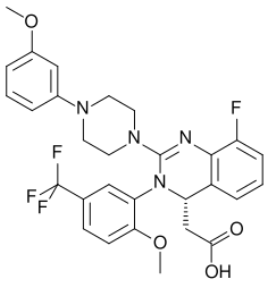
Where enhanced therapeutic efficacy is relied upon for the purpose of Section 3(d) of the Patents Act 1970 (as amended), the Complete Specification may contain experimental data,

including comparative data with the closest prior art or known substance, demonstrating enhancement in therapeutic efficacy. Such data, where available, shall be taken into consideration while assessing compliance with the requirements of Section 3(d) of the Patents Act, 1970 (as amended).

Pharma-IE-34: Salt of a known substance

Claim: Potassium Salt of 2-[(4s)-8-Fluoro-2-[4-(3-Methoxyphenyl)Piperazin-1-Yl]-3-[2-Methoxy-5-(Trifluoromethyl)Phenyl]-4h-Quinazolin-4-Yl]Acetic Acid for the treatment of cytomegalovirus (CMV) infections.

Analysis: Prior art discloses a compound 2-[(4s)-8-Fluoro-2-[4-(3-Methoxyphenyl)Piperazin-1-Yl]-3-[2-Methoxy-5-(Trifluoromethyl)Phenyl]-4h-Quinazolin-4-Yl] Acetic Acid, commonly known as Letermovir, is an antiviral drug for the treatment of cytomegalovirus (CMV) infections.



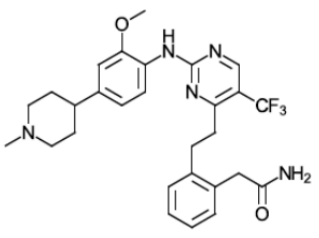
Letermovir

The present application relates to the potassium salt of Letemovir which does not show enhancement in the efficacy over known efficacy of Letermovir as disclosed in prior art. Thus the claim attracts under section 3(d) of The Patents Act, 1970 (as amended).

<u>Prior art teachings & study needs to be elaborated for comparison</u>

Pharma-IE-35: Salt of a known substance

Claim: L-tartrate Salt of Formula-I



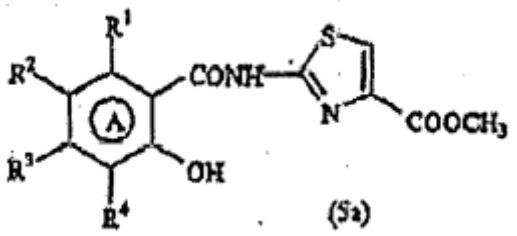
Formula I

Wherein the compound of Formula I used as an antagonist for Focal Adhesion Kinase (FAK).

Analysis: Prior art discloses a compound of Formula-I which shows activity against Focal Adhesion Kinase (FAK). The present application demonstrates L-tartrate salt of Formula-I which shows enhanced therapeutic efficacy over the compound of Formula-I. As tartrate salt of known substance (Formula-I) shows enhancement of known therapeutic efficacy, thus the claim passes the bar of 3(d) of The Patents Act, 1970 (as amended).

Pharma-IE-36: Ester of a known substance

Claim: A Compound of formula-5a wherein ring A represents a benzene ring R' is a hydrogen atom; R^2 and R^3 are each a methoxy group; and R^4 is a hydrogen atom which is used for treatment of gastrointestinal dysmotility.



(5a)

Analysis: Prior Art document discloses an acid form of claimed compound (5a) i.e., 2-[N-(4,5-dimethoxy-2-hydroxybenzoyl)amino]-4-carboxy-1,3-thiazole which has an effect for the improvement of gastrointestinal dysmotility. The claimed compound (5a) is considered to be a mere discovery of new form of known substance i.e. ester derivative of known compound as the claimed compound does not disclose the improved therapeutic efficacy with respect to gastrointestinal dysmotility in comparison to the prior document. Thus the claim attracts section 3(d) of The Patents Act, 1970 (as amended).

Pharma-IE-37: Ester of a known substance

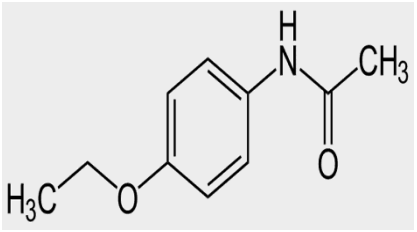
Claim: Etoposide malic acid esters used as an anti-cancer agent.

Analysis: Prior art document discloses etoposide as a chemotherapeutic agent used for the treatment of different forms of cancer. Etoposide malic acid esters are modified forms of the anticancer drug etoposide, where the etoposide molecule is linked to malic

acid through ester bonds. Etoposide malic acid esters show enhanced cytotoxicity i.e. better therapeutic efficacy against KB and MCF-7 cancer cells over prior art documents. Thus, the claim satisfies the requirements of Section 3(d) of the Patents Act, 1970 (as amended).

Pharma-IE-38: Ether of a known substance

Claim: A compound of Formula-I (Paracetamol ethyl ether) which is used for treating fever and mild to moderate pain.

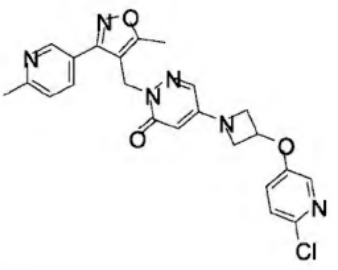


Formula-I

Analysis: Prior art discloses paracetamol or N-acetyl-para-aminophenol as a non-opioid analgesic and antipyretic agent used to treat fever and mild to moderate pain. The present application discloses the compound of Formula-I (Paracetamol ethyl ether) i.e. ether derivative of Paracetamol, which does not show enhanced therapeutic efficacy over Paracetamol as disclosed in prior art. Thus, the claimed subject matter does not satisfy section 3(d) of the Patents Act, 1970 (as amended).

Pharma-IE-39: Ether of a known substance

Claim: A compound having IUPAC name 5-[3-[(6-chloro-3-pyridyl)oxy]azetidin-1-yl)-2-[[5-methyl-3-(6-methyl-3-pyridyl)isoxazol-4-yl) methyl) pyridazin-3-one, used as positive allosteric modulators ("PAMs").

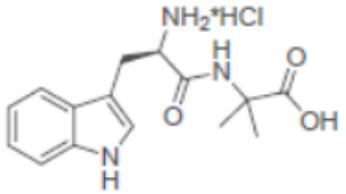


Formula-I

Analysis: A compound having IUPAC name 5-[3-[(6-chloro-3-pyridyl)oxy]azetidin-1-yl)-2-[[5-methyl-3-(6-methyl-3-pyridyl)isoxazol-4-yl) methyl) pyridazin-3-one is a Isoxazolyl ether derivative compound. Compound of Formula-I is useful for therapy or prophylaxis in a mammal, and in particular to GABA alpha-5 receptor positive allosteric modulators (PAMs) as claimed by applicant. Prior document discloses the compound 5-(3-hydroxyazetidin-1-yl)-2-[[5-methyl-3-(6-methyl-3-pyridyl)isoxazol-4-yl)methyl) pyridazin-3-one. The compound disclosed in prior art are negative allosteric modulators ("NAMs") of GABAA α5, while the compounds of the present invention are positive allosteric modulators ("PAMs"). Therefore the claimed ether derivative compound shows enhanced therapeutic efficacy over the prior document. Hence, the claim satisfies the requirements of Section 3(d) of the Patents Act, 1970 (as amended).

Pharma-IE-40: Polymorphic form of a known substance

Claim: Form II of (R)-2-[2-amino-3-(indol-3-yl)propionylamino]-2-methylpropionic acid, characterized by an X-ray powder diffraction pattern displaying peaks at 2θ (d value Å) angles of 5.87 (15.067), 11.91(7.432), 17.99 (4.931), 30.35 (2.945) used for the topical treatment of glaucoma and dry age-related macular degeneration.



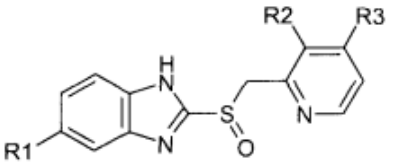
Analysis: Prior art document discloses the compound (R)-2-[2-Amino3-(indol-3-yl)propionylamino]-2-methylpropionic acid, used for the topical treatment of glaucoma and dry age-related macular degeneration. Present application relates to polymorph (form-II) of the compound which does not show better therapeutic efficacy towards the topical treatment of glaucoma and dry age-related macular degeneration over the known compound as disclosed in prior art document. Thus the claim is not patentable under section 3(d) of The Patents Act, 1970 (as amended).

Pharma-IE-41: Polymorphic Form of a known substance

Claim: A crystalline polymorphic form A of 1,5 beta-hydroxy-osaterone acetate, which is a crystalline polymorphic form having diffraction peaks at the following diffraction angles 2θ in a powder X-ray diffraction spectrum:9.6° ± 0.2°, 17.1° ± 0.2°, 20.2° ± 0.2°; which has a melting point of 280 to 283 degree Celsius ; which is a prism crystal structure, which is used for treatment of androgen-dependent diseases.

Analysis: The present application relates to the crystalline polymorphic form A of 1,5 beta-hydroxy-osaterone acetate which shows better therapeutic efficacy over 1,5 beta-hydroxy-osaterone acetate in treating diseases that require a gradual and continuous effect such as androgen-dependent diseases as disclosed in prior art. Thus, the claim satisfies the requirements of Section 3(d) of the Patents Act, 1970 (as amended)

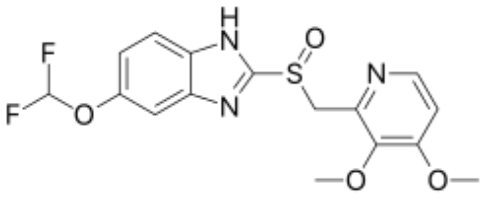
Pharma-IE-42: Claims: Compounds of the general formula 1



(1)

in which R1 is difluoromethoxy; R2, R3 aremethoxy; ; wherein at least one of the hydrogen atoms of R1, R2, R3 or any combination of R1, R2 and R3 is replaced by a deuterium atom which is used for treatment of gastroesophageal reflux disease (GERD).

Analysis: In the prior art Pantoprazole of formula-II is already known.



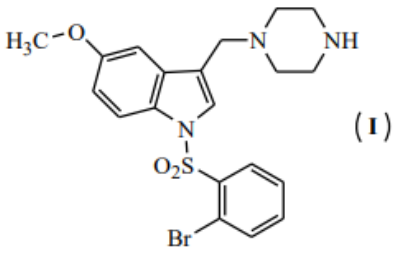
Formula-II

The claimed compound is Deuterated Pantoprazole. In the experimental details, the data provided by the applicant(s) are those related to the metabolic stability and intrinsic clearance value. Improved metabolic stability and intrinsic clearance value show how the system acts on the drug. However, the claimed deuterated molecule does

not show any enhancement in the therapeutic efficacy towards gastroesophageal reflux disease (GERD) over pantoprazole molecule of formula-II as disclosed in the prior art document. Thus the claimed subject matter is not patentable under section 3(d) of The Patents Act, 1970 (as amended).

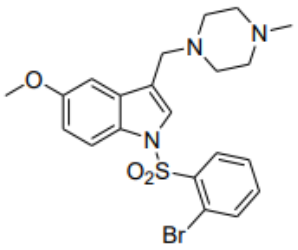
Pharma-IE-43: Metabolite of a known substance

Claim: An active metabolite of 1-[(2-bromophenyl)sulfonyl]-5-methoxy-3-[(4-methyl-1-piperazinyl)methyl]-1H-indole di-mesylate monohydrate is 1-[(2-Bromophenyl)sulfonyl]-5-methoxy3-[(1-piperazinyl)methyl]-1H-indole having formula (I) which is used as a selective serotonin 6 (5-HT6) receptor antagonist.



(I)

Analysis: The compound of Formula-II is known in the prior art.



Formula-II

Applicant provided comparative therapeutic efficacy data of metabolite of compound of formula I vs formula II, from where it is evident that metabolite of compound of formula I which is claimed in the present application, shows significant enhancement in the therapeutic efficacy over the metabolite of compound of formula-II as disclosed in the prior art document. Thus, the claim satisfies the requirements of Section 3(d) of the Patents Act, 1970 (as amended).

Pharma-IE-44: Pure form of a known substance

Claims: A crystalline form of Naproxen characterized by PXRD peaks at 6.58, 12.64, 13.34, 16.77, 18.71, 18.91, 20.1, 20.31, 22.21, 22.47, 23.58, 23.85, 27.37, 27.81, and 28.39 degrees with purity more than 99.9%, used as a non-steroidal anti-inflammatory drug (NSAID).

Analysis: From the prior art, it is known that Naproxen with 95% purity, a widely used non-steroidal anti-inflammatory drug (NSAID) effective for rheumatoid arthritis. In the present application, Naproxen with purity >99.9% shows improved flowability and compressibility, higher melting point, greater shelf-life stability but failed to show any enhancement of the therapeutic efficacy towards rheumatoid arthritis compared to the Naproxen with 95% purity as disclosed in prior art. Thus the claim is not patentable under section 3(d) of The Patents Act, 1970 (as amended).

Pharma-IE-45: Pure form of a known substance

Claim: A stable crystalline polymorph of the hydrochloride salt of N-(3-ethynylphenyl)6,7-bis(2-methoxy ethoxy)-4-quinazolinamine designated as Form-P with purity more than 99.8%, characterized by an x-ray powder diffraction pattern having characteristic peaks expressed in degrees 2-theta at approximately 2.97, 5.80, 6.36, 9.97, 10.54, 11.48, 15.00, 15.80, 16.64, 17.11, 17.62, 18.15, 18.58, 19.06, 19.78, 20.74, 22.14, 22.96, 23.72, 24.45, 25.67, 26.40, 27.30, 28.14, 28.76, 29.44, 30.15, 30.82, 32.21, 32.95, 33.99, 34.59, 40.49, 40.64, 42.02, 43.87 used for treatment of solid tumours.

Analysis: From prior art it is known that hydrochloride salt of N-(3-ethynylphenyl)6,7-bis(2-methoxy ethoxy)-4-quinazolinamine (Form A) with 94% purity is an established anticancer compound, used in treatment of solid tumours**.** In the present application, it is disclosed that the Form P of N-(3-ethynylphenyl)6,7-bis(2-methoxy ethoxy)-4-quinazolinamine with purity more than 99.8% shows 44% better therapeutic efficacy in tumour volume reduction with respect to N-(3-ethynylphenyl)6,7-bis(2-methoxy ethoxy)-4-quinazolinamine Form A. Thus, the claim satisfies the requirements of Section 3(d) of the Patents Act, 1970 (as amended).

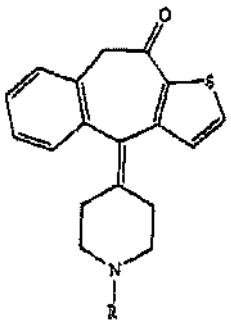
Pharma-IE-46: Isomer of a known substance

Claim: The pure S-enantiomer of ibuprofen characterized by XRD peaks in degrees 2-theta at approximately 7.04, 14.21, 14.79, 16.2, 17.05, 19.25, 20.51, 21.75, 22.11, 22.41, 23.4, 25.9 which is used as a nonsteroidal anti-inflammatory drug.

Analysis: From the prior art it is known that ibuprofen, a racemic mixture (50:50 R- and S-isomers), widely used as a nonsteroidal anti-inflammatory drug. Racemic mixture of R and S enantiomers is used due to ease of synthesis. In the application, applicant fails to show any enhancement in the therapeutic efficacy value of S-enantiomer towards inflation in human body over racemic mixture, except slight improvements in bioavailability. Thus the claim is not patentable under section 3(d) of The Patents Act, 1970 (as amended).

Pharma-IE-47: Isomer of a known substance

Claim: A pharmaceutical composition comprising the S-isomer of norketotifen having the structure:



Where R is H, having an optical purity of at least 95% enantiomeric excess and pharmaceutically acceptable salts and solvates thereof, together with a pharmaceutically acceptable carrier, said composition being substantially free of the corresponding R-isomer, used as an antagonist to histamine H-1 receptor.

Analysis: From prior art, it is known that nor-ketotifen, used as a racemic mixture is a histamine H-1 antagonist with-varying degree of histamine H-2 antagonism. In the present application, applicant shows that S-isomer of norketotifen shows better therapeutic efficacy than the racemic mixture of norketotifen with less side effects.

Thus, the claim satisfies the requirements of Section 3(d) of the Patents Act, 1970 (as amended).

Pharma-IE-48: Complex of a known substance

Claim: Zinc–Ibuprofen Complex where ibuprofen is coordinated with a divalent zinc ion (Zn^{2+}), forming a non-covalent ionic complex which is used as an anti-inflammatory and analgesic agent.

Analysis: From the prior arts it is known that Ibuprofen is a widely used NSAID with known anti-inflammatory and analgesic effects. In the present application, applicant shows that Zinc-Ibuprofen complex shows improved solubility and stability. However, there is no significant improvement in the therapeutic efficacy of the claimed complex over Ibuprofen. Thus the claim is not allowable under section 3(d) of The Patents Act, 1970 (as amended).

Pharma-IE-49: Complex of a known substance

Claim: A zinc-curcumin complex with better antioxidant property.

Analysis: From the prior art it is known that curcumin is a natural polyphenol with antioxidant properties. In the present application, applicant claims that zinc-curcumin complex which shows better therapeutic efficacy towards antioxidant property over curcumin. Thus, the claimed subject matter satisfies the requirements of Section 3(d) of the Patents Act, 1970 (as amended).

Pharma-IE-50: The mere discovery of any new property/new use of a known substance

Claim: 2-Acetoxybenzoic acid (Aspirin) which exhibits free radical scavenging activity and therefore acts as a natural antioxidant in vitro.

Analysis: In prior art, it is known that 2-Acetoxybenzoic acid (Aspirin) is a well-known and widely used antipyretic, analgesic, and anti-inflammatory drug. The applicant's claim is directed toward a mere discovery of a previously unknown property of a known substance (aspirin). The claimed subject matter is therefore not allowable under Sections 3(d) of The Patents Act, 1970 (as amended).

Pharma-IE-51: The mere use of a known process

Claims: A process for coating paracetamol tablets with a film of HPMC (hydroxypropyl methylcellulose) using Pan Coating Machine.

Analysis: Prior art document discloses film coating of tablets using hydroxypropyl methylcellulose (HPMC) using a standard pan coating machine. Further, HPMC coated paracetamol is also known in the prior art. Therefore, the present application relates to the mere use of a known coating process which does not result in a new product or employ at least one new reactant. Hence, the claimed process is not patentable under section 3(d) of The Patents Act, 1970 (as amended).

Pharma-IE-52: The mere use of an unknown process

Claim: A process of preparing a micronized form of ranitidine mesylate, comprising subjecting ranitidine mesylate to jet milling under nitrogen atmosphere at 50 psi.

Analysis: Prior art discloses Jet milling (micronization) is a standard process in air atmosphere to reduce particle size of APIs and improve dissolution. Whereas, the present process is carried out under nitrogen atmosphere at 50 psi which results in a new crystalline form of ranitidine mesylate. Thus, the claimed subject matter satisfies the requirements of Section 3(d) of the Patents Act, 1970 (as amended).

Section 3(e)

Pharma-IE-53: Formulation of a Pharmaceutical Dosage

Claim: A pharmaceutical formulation consists of obinutuzumab and Bruton's tyrosine kinase (BTK) inhibitor, wherein the said BTK inhibitor is 6-amino-9-[(3R)-1-(2-butynoyl)-3-pyrrolidinyl]-7-(4-phenoxyphenyl)-7,9-dihydro-8H-purin-8-one or a salt thereof, formulated as a tablet, for the treatment of a lymphoma or lymphocytic leukemia.

Analysis: Prior art document discloses obinutuzumab, which shows anti CD20 activity and is useful for treatment of lymphoma or lymphocytic leukemia. Whereas, the

combination of obinutuzumab with the BTK inhibitor as claimed does not exhibit any synergistic effect. Further, no improvement in therapeutic efficacy of an anti-CD20 activity for the treatment of a lymphoma or lymphocytic leukemia could be found with obinutuzumab and BTK inhibitor formulation. Therefore, the subject matter of the claim is not allowable u/s 3(e) of the Patents Act, 1970 (as amended).

Pharma-IE-54: Formulation of Drug Delivery System

Claim : A drug delivery system of at least one pharmaceutically active substance that is a cationic amphiphile by itself being a cytotoxic or a cytostatic compound present in protonated form and selected from of doxorubicin, mitoxantrone, epirabıcın, daunorubıcın, idarubicin, topotecan, or a combination thereof, which pharmaceutically active substance is present in the drug delivery system in particles of a complex between said pharmaceutically active substance and a sodium salt of the methyl ester of N-all-trans-retinoyl cysteic acid, a sodium salt of methyl ester of N-13-cis-retinoyl cysteic acid, or a combination thereof, said particles of said complex having an effective average particle size of less than 50 nm, wherein the particles of said complex are essentially amorphous; the particles of said complex are entrapped in nanoparticles formed of a sodium salt of the methyl ester of N-all-trans-retinoyl cysteic acid, sodium salt of methyl ester of N-13-cis-retinoyl cysteic acid, or a combination thereof, and wherein the said drug delivery system comprises at least one other pharmaceutically active substance having a solubility per se in water of less than about 100 μg/ml being a cytotoxic or cytostatic compound selected from taxane, said other pharmaceutically active substance being in particulate form with an effective average particle size of less than about 100 nm, wherein, the particles of said other pharmaceutically active substance are essentially amorphous, the particles of said other pharmaceutically active substance are entrapped together with the particles of said complex in said nanoparticles, and the weight-to-weight ratio of said sodium salt of methyl ester of N-all-trans-retinoyl cysteic acid, sodium salt of methyl ester of N-13-cis-retinoyl cysteic acid, or combination thereof, to the combined weight of said other pharmaceutically active substance and said complex is in the range from about 05:1 to about 20:1.

Analysis: The drug delivery system claimed is comprised of one pharmaceutically active drug like doxorubicin, another pharmaceutically active substance selected from taxane family, e .g docetaxel and a cationic amphiphile of sodium salt of cis/trans retinoyl cysteic acid. The evidence showed an addition of doxorubicin and docetaxel

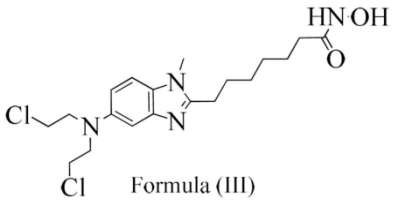
gives enhancement factor i.e. EF (day 3) and EF (day 4) values of 43 and 10 over doxorubicin and docetaxel alone. While, the combination of doxorubicin/ docetaxel/methyl ester of N-all-trans-retinoyl cysteic acid /N-13-cis-retinoyl cysteic acid gives EF (day 3) and EF (day 4) values of 185 and 267. As the instant application demonstrates the achievement of synergistic effect produced by the formulation doxorubicin, docetaxel and sodium salt of cis/trans retinoyl cysteic acid, and hence, the claimed subject matter is allowable u/s 3(e) of the Patents Act, 1970 (as amended).

Pharma-IE-55: A Pharmaceutical Composition

Claim: A pharmaceutical composition comprising:

(a) a cyclopolysaccharide, and

(b) a compound of Formula (III) , or a pharmaceutically acceptable salt thereof,



Formula (III)

wherein the minimum ratio of cyclopolysaccharide to compound of Formula (III) is from 16:1 weight/weight..

Analysis: Prior-art document discloses the compound of formula III is and its therapeutic effect. The addition of cyclopolysaccharide in the said compound of formula III does not provide any further effects on enhancement of the known therapeutic efficacy. Therefore, the instant application does not provide any synergistic effect produced by the combination of two individual drug components in the claimed ratio compared to the individual components. Hence, the claimed subject matter is failing to meet the criteria of section 3(e) of the Patents Act, 1970 (as amended).

Pharma-IE-56: A Pharmaceutical Composition

Claim. A pharmaceutical composition comprising:

i. a selective cyclooxygenase-2 inhibitor, wherein the selective cyclooxygenase-2 inhibitor is celecoxib,

ii. a guaifenesin-derived carbamate agent, wherein the guaifenesin-derived carbamate agent is methocarbamol,

wherein the active agent celecoxib is in a concentration of 1000 mg and the active agent methocarbamol is in a concentration of 50 mg.

Analysis: The therapeutic efficacy data in rats were provided for Clelcoxib and methocarbamol alone, both known in the prior art, and for claimed composition in claimed ratio. The evidence showed that the composition (celecoxib 1000 mg/kg + methocarbamol 50 mg/kg) showed synergistic anti-nociceptive effects over the aggregated effects produced by celecoxib (1000 mg/kg) and methocarbamol (50 mg/kg) alone. The claim is thus allowable u/s 3(e) of the Patents Act, 1970 (as amended).

Section 3(i)

Pharma-IE-57: Medicinal Treatment

Claim: A method of treatment of a humans suffering from type 2 diabetes, the method comprising: administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising metformin, wherein the administration is carried out orally, and wherein the treatment results in a reduction in blood glucose levels and improvement in insulin sensitivity.

Analysis: The application relates to treating patients suffering from type 2 diabetes by administering orally a pharmaceutical composition comprising metformin, Therefore, the claim relates to medicinal treatment of human beings to cure from type 2 diabetes, and hence, it is not allowable u/s 3(i) of the Patents Act, 1970 (as amended).

Pharma-IE-58: A Method of Surgical Treatment

Claim: A method of removal of one or more affected teeth from a human patient, comprising:

(i) administering local or general anesthesia to the patient to ensure pain control during the procedure;

(ii) making an incision in tissue surrounding the target tooth to expose the underlying bone and tooth structure;

(iii) performing osteotomy as necessary by removing bone adjacent to the tooth to facilitate extraction;

(iv) sectioning the tooth, if required, to enable easier removal of individual root fragments;

(v) elevating and removing the tooth or its fragments using dental elevators and forceps;

(vi) irrigating and debriding the surgical site to remove debris and reduce infection risk;

(vii) approximating and suturing the gingival tissue to promote healing; and

(viii) providing post-operative medications to the patient, including analgesics and antibiotics as needed.

Analysis: The subject matter of the claim discloses a procedure for extraction of one or more affected teeth of human. The stages of treatment like anaesthesia, incisions, osteotomy, tooth removal, and suturing are necessary to complete the surgical procedure. Therefore, the subject matter of claim is related to surgical treatment of human beings to render them free of disease and hence, is not allowable u/s 3(i) of the Patents Act, 1970 (as amended).

Pharma-IE-59: Curative Treatment-1

Claim: A method of healing a skin wound or cut, the method comprising:

administering topically to the wound a therapeutically effective amount of a composition comprising Nifedipine and Lidocaine daily,and wherein said administration promotes accelerated wound healing by stimulating tissue regeneration.

Analysis: The claimed subject matter relates to a method of healing a wound or cut by applying a drug combination of nifedipine and lidocaine in a therapeutically effective amount. The claim relates to curative treatment of human beings and hence, it is not allowable u/s 3(i) of the Patents Act 1970 (as amended).

Pharma-IE-60: Curative Treatment-2

Claim: A method of camouflaging a tonal imperfection comprising the steps of a. identifying a skin tone of a user having a tonal imperfection using a skin tone identification method; b. instructing the user to select a pigmented cosmetic composition adapted to camouflage the tonal imperfection based on the user's skin tone; c. selecting the pigmented cosmetic composition; and d. selectively targeting and depositing the selected pigmented cosmetic composition substantially only onto the tonal imperfection; wherein the pigmented cosmetic composition comprises an average composition L* value of 15 to 35 units greater than an average skin L* value of the user.

Analysis: The subject matter of the instant claim discloses a method of applying pigmented cosmetic composition onto the skin. The tonal imperfection, where the composition is applied, refers to an area of keratinous surface which is different in colour, typically darker, than the surrounding keratinous surface. The subject matter of the claim is merely directed towards application of substances to the body for purely cosmetic purposes and not to cure any diseases. Therefore, the subject matter of the claim is not related to any curative treatment of human beings and is allowable u/s 3(i) of the Patents Act, 1970 (as amended).

Pharma-IE-61: Curative Treatment-3

Claim: A method for blackening white or gray hair, comprising the steps of:

a) applying a composition to the white or gray hair, wherein the composition comprises one or more active agents selected from the group consisting of natural or synthetic hair colorants, antioxidants, and hair conditioning agents;

b) allowing the composition to remain on the hair for a predetermined period sufficient to effectuate coloration of the white or gray hair; and

c) rinsing the composition from the hair, thereby producing blackened hair with improved hair texture and appearance.

Analysis: The subject matter of the instant claim discloses a method of blackening of hair by applying a colorant composition to the white or grey hair. The subject matter is merely directed towards application of substances to the body for purely cosmetic purposes and not to cure any hair related diseases. Therefore, the subject matter of the

claim is not related to any curative treatment of human beings and is allowable u/s 3(i) of the Patents Act, 1970 (as amended).

Pharma-IE-62: Prophylactic Treatment

Claim: A method of treating a human subject at risk of human immunodeficiency virus (HIV) infection, comprising administering orally, a therapeutically effective amount of a pharmaceutical composition comprising tenofovir disoproxil fumarate and emtricitabine,wherein, the administration reduces the likelihood of HIV infection in the subject.

Analysis: The claimed subject matter relates to prevention of HIV before it occurs in humans at risk of HIV infection by administering orally a pharmaceutical composition of tenofovir disoproxil fumarate and emtricitabine. As the claim is related to prophylactic treatment of human beings, it is not allowable u/s 3(i) of the Patents Act.

Pharma-IE-63: Diagnostic Treatment-1

Claim: A method of demonstrating the impact of different treatments on a surface comprising the steps of: i. applying two toothpastes to two tooth enamel surface(s), such that the two surfaces are brushed with two toothpastes with differing abrasivity, ii. imaging the said surface(s) to create an image, iii. converting the imaging data into a format suitable to create a magnified topographical image for a 3D printer using 3D-CAD software, iv. producing a magnified 3D model of the imaged surface(s) using a 3D-printer, v. comparing the two 3D images of the two surfaces brushed with the toothpastes with different abrasivity**.**

Analysis:

The present claimed subject matter discloses two clearly distinct methods performed on the body disclosed as embodiments, i.e. a therapeutic method performed on the body comprising the step of removing only pathogenic bacteria from the tooth enamel by applying the two toothpastes. Thus, the presently claimed subject matter is considered as a method for the prophylactic (both diagnostic and therapeutic) treatment on teeth of the human body to render them free of disease. Therefore, the claimed subject matter is not allowable under section 3(i) of the Patents Act, 1970 (as amended).

Pharma-IE-64: Diagnostic Treatment-2

Claim: A Method for determining amount of nucleic acids in a blood sample comprising:

providing an untreated whole blood sample;

introducing the sample into a device adapted for accommodating a sample in a fluid state;

and determining a value indicative of the presence and/or amount of nucleic acids associated with a viral infection in the sample by performing a microarray based analysis in the microfluidic device wherein the viral infection is an infection with HIV.

Analysis: The subject matter of the claim is directed to a method of determining a value indicative of the presence and/or amount of nucleic acids associated with HIV, viral infection in an untreated whole blood sample. The method is performed in a single microfluidic device and the steps do not define any medical diagnostic technique for the medical treatment further. It is, therefore, evident that the method is not directed to any diagnostic treatment of the human beings or animals but to a diagnostic process run by a device on the basis of a blood sample. Hence, the claim is allowable u/s 3(i) of the Patents Act, 1970 (as amended).

Pharma-IE-65: Diagnostic Treatment-3

Claim: A method of diagnosis of cervical cancer by colorimetric quantification of acetic acid, wherein the quantification method comprises the steps of:

a. collection of sample fluid from subject;
b. adding tetrachloroauric (III) acid trihydrate to a sample fluid to prepare a reaction mixture;
c. obtaining a colored reaction mixture by adding ascorbic acid to the reaction mixture of step (a);
d. corelating the color of the reaction mixture of step (b) with a pre-determined color to colorimetrically quantifying the amount of acetic acid in the sample.

Analysis: The subject matter of the claim discloses a method of diagnosis of cervical cancer by colorimetric quantification of acetic acid. The subject matter indicates a chemical method for the quantification of acetic acid performed in-vitro as a screening

test in the diagnosis of cervical matter and is not related to a method of treatment. Therefore, the subject matter of the claim is allowable u/s 3(i) of the Patents Act, 1970 (as amended).

Pharma-IE-66: Therapeutic Treatment

Claim: A method of treating a neurological disease or disorder in a mammal, which method comprises administering to said mammal in need of such treatment a therapeutically effective amount of a proteosome based composition with glatiramer acetate where the disease is selected from the group consisting of early onset Alzheimer's disease, late onset Alzheimer's disease, presymptomatic Alzheimer's disease, Serum Amyloid A (SAA) amyloidosis, prion disease, hereditary Icelandic syndrome, senility and multiple myeloma.

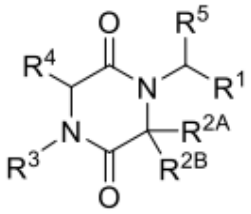
Analysis: The claim relates to a method of therapeutic treatment of neurological disease e.g. Alzheimer's disease in human by administering with effective amount of a proteasome based composition with glatiramer acetate. The claimed subject matter is linked to method of treatment and therefore, is not allowable u/s 3(i) of the Patents Act, 1970 (as amended).

Sufficiency of Disclosure u/s 10 of the Patents Act, 1970

Pharma-IE-67

Claim:

A compound of formula (I):



(I)

or a pharmaceutically acceptable salt thereof, wherein:

R^1 is selected from the group consisting of substituted or unsubstituted phenyl and substituted or unsubstituted pyridyl;

R^{2A}, $R^{2B,}$ and R^3 are defined by any one of (i) – (iii):

(i) R^{2A} is H or substituted or unsubstituted alkyl; R^{2B} is selected from the group consisting of H, substituted or unsubstituted alkyl, substituted or unsubstituted alkenyl, substituted or unsubstituted alkynyl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted cycloalkenyl, substituted or unsubstituted cycloalkynyl, substituted or unsubstituted heterocyclyl, substituted or unsubstituted aryl, and substituted or unsubstituted heteroaryl; and R^3 is substituted or unsubstituted phenyl or substituted or unsubstituted pyridyl;

or (ii) R^{2A} is H or substituted or unsubstituted alkyl; R^{2B} is substituted or unsubstituted phenyl or substituted or unsubstituted pyridyl; and R^3 is substituted or unsubstituted alkyl;

or (iii) R^{2A} and R^{2B} are taken together with the carbon atom to which they are attached to form G^1 , wherein G^1 is a substituted or unsubstituted cycloalkyl, substituted or unsubstituted cycloalkenyl, substituted or unsubstituted cycloalkynyl, or substituted or unsubstituted heterocyclyl ring, each of which is optionally fused to a phenyl ring; and R^3 is selected from the group consisting of substituted or unsubstituted alkyl, substituted or unsubstituted alkenyl, substituted or unsubstituted alkynyl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted cycloalkenyl, substituted or unsubstituted cycloalkynyl, substituted or unsubstituted heterocyclyl, substituted or unsubstituted aryl, and substituted or unsubstituted heteroaryl; R^4 is H or substituted or unsubstituted alkyl; and R^5 is H or substituted or unsubstituted alkyl; wherein, when one or more of provisions (a) – (c) apply, then R^1 is substituted or unsubstituted pyridyl or phenyl substituted with at least one substituent other than methyl or methoxy: (a) R^{2A} and R^{2B} are as defined by (i) and R^3 is substituted or unsubstituted phenyl; (b) R^{2A} and R^3 are as defined by (ii) and R^{2B} is 4-methoxyphenyl; (c) R^{2A} and R^{2B} are as defined by (iii) and R^3 is 4-methoxyphenylmethyl.

Analysis:

The present claim as described is too broad and unclear in scope w.r.t “substituted or unsubstituted alkyl”, “substituted or unsubstituted alkenyl”, “substituted or unsubstituted alkynyl”, “substituted or unsubstituted cycloalkyl”, “substituted or unsubstituted cycloalkenyl”, “substituted or unsubstituted cycloalkynyl”, “substituted or unsubstituted heterocyclyl”, “substituted or unsubstituted aryl”, and “substituted or unsubstituted heteroaryl” etc. Hence, the use of such terms and expressions “substituted

or unsubstituted" in the claims embrace an infinite number of possibilities not yet explored in the Complete Specification as numerous permutations and combinations are possible. Claims should be restricted to what is disclosed in the description in order to meet the requirement of Section 10(4)(c) of the Patents Act, 1970 (as amended).
Further, the expression "heteroaryl" used in the claim is very broad, vague and unclear as the applicant had failed to provide: (a) the name of heteroatom, (b) number of heteroatom involved in ring, (c) point of attachment of the heterocyclic ring, (d) substitution pattern of the ring whether monosubstituted, disubstituted, trisubstituted, etc, (e) How many membered heterocyclic ring, (f) nature of the heterocyclic ring whether aromatic or not, etc. These points should be clearly supported by the complete specification to comply with the requirements of section 10(4)(c) of the Patents Act, 1970(as amended).

Pharma-IE-68:

Claim:

A compound of Formula (I):

Formula (I):R^1-Ar^1-NHCO-R^2

Wherein,

Ar^1 is a substituted or unsubstituted aryl or heteroaryl ring selected from phenyl, pyridyl, quinolyl, thiazolyl, or pyrimidinyl, substituted with 1 to 3 substituents independently selected from halogen, C_1–C_4 alkyl, C_1–C_4 alkoxy, trifluoromethyl, nitro, or cyano;

R^1 is selected from hydrogen, methyl, ethyl, isopropyl, or hydroxymethyl;

R^2 is selected from:(i) Piperidinyl, morpholinyl, or azepanyl optionally substituted with hydroxyl or carboxylic acid;

(ii) A heterocyclic ring selected from pyrazolyl, imidazolyl, or thiazolyl;

and pharmaceutically acceptable salts, esters, or prodrugs thereof.

Analysis:

In the description of the present invention relates to a novel class of kinase inhibitor compounds, pharmaceutical compositions comprising them and use, particularly for the treatment of proliferative disorders such as cancer.

1. General Synthetic Scheme

i) Amide coupling between Ar^1-NH_2 and a carboxylic acid derivative of R^2 and

ii) Use of reagents like EDCI, DCC, or HATU for peptide bond formation.

2. **Specific Working Examples**

Include 5–10 individual compounds with:

i) Chemical name

ii) Structural formula

iii) Analytical data (e.g., NMR, MS, HPLC)

3. Biological Data

Include enzyme inhibition data (e.g., IC_{50} for EGFR, JAK2, or other kinases).

4. Example Compound Covered by Claim 1

Compound where Ar^1 = 4-chlorophenyl, R^1 = methyl, R^2 = piperidin-4-yl
IUPAC Name: N-methyl-N-(4-chlorophenyl)-2-(piperidin-4-yl) acetamide

The claimed Markush structure is well-supported by the disclosure, with clearly defined alternatives for each substituent, a general synthetic route, and multiple specific examples illustrating the scope of the invention. The description further provides pharmacological data and utility for the claimed compounds. Also, the claim is supported by the description, and each alternative is enabled. Therefore, the complete specification clearly and sufficiently describes the invention, including the best method of performing it, to enable a person skilled in the art to carry out the invention without undue experimentation. Thereby, in view of the disclosures no objections arise with respect to sufficiency of disclosure u/s 10(4) of The Patents Act, 1970 (as amended).

Pharma-IE-69:

Claims:

1) A process for preparing a pharmaceutical composition comprising mixing a therapeutically effective amount of an active agent with pharmaceutically acceptable excipients and forming a dosage form.

2) The process as claimed in claim 1, wherein the dosage form is a tablet or capsule.

Analysis:

The description of the complete specification providedthe Process Steps to prepare the composition that comprises:

1. The active ingredient is blended with excipients.
2. The mixture is processed into a suitable oral dosage form such as a tablet or capsule.
3. The formulation may optionally include flavoring agents, coloring agents, or preservatives.

The Complete Specification fails to adequately identify and characterize the active pharmaceutical ingredient used in the composition i.e. no structural formula, chemical name, has been disclosed. The composition is described in broad and generic terms, such as "a therapeutically effective amount" of an "active agent" and "pharmaceutically acceptable excipients," without providing specific quantities, proportions, or examples. Furthermore, the method of preparation is unclear with respect to "standard pharmaceutical techniques" without detailing the actual process steps, operational conditions (e.g., temperature, mixing time, equipment used), or formulation stages which is necessary for process steps requirement. The absence of at least one concrete working example and supporting experimental data renders the disclosure non-enabling. In view of the above, the invention as disclosed lacks sufficiency of disclosure Hence, the complete specification filed in the disclosure of the present claimed subject matter does not comply with the requirements of Section 10(4) of the Patents Act, 1970 (as amended).

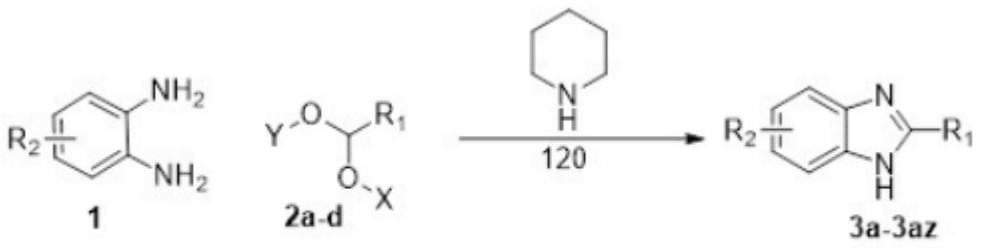
Pharma-IE-70:

Claims:

1. A one-pot process for preparation of 2-substituted-1H-benzo[d]imidazole derivatives (3a-3az), said process, comprising:

reacting 1 equivalent of o-phenylenediamines (0.924 mmol) (1) with 1 equivalent 0.924 mmol of methyl and/or phenyl acetals (2a and 2d), and trifluoro methyl and/or

difluoromethyl hemiacetals (2b and 2c) by heating at a temperature in a range of 100-120º C for 1-2 hours in presence of a catalyst;



2. The process as claimed in claim 1, wherein R1 is selected from CH_3, CF_2, CHF_2 and Ph.

3. The process as claimed in claim 1, wherein R2 is selected from 4-Fluoro, 4-Chloro, 4-Bromo, 4-Nitro, 3, 4-dimethyl, 4, 5-dimethyl, 4, 5-dicloro, 1-methyl, 2-methyl, pyridine, 5-bromo pyridine, naphthalene-1, 4-dione.

4. The process as claimed in claim 1, wherein X is selected from H, CH_3 and C_2H_5.

5. The process as claimed in claim 1, wherein Y is selected from CH_3 and C_2H_5.

6. The process as claimed in claim 1, wherein the catalyst is piperidine.

7. The process as claimed in claim 1, wherein the 2-substituted-1H-benzo[d]imidazole derivatives are used in pharmaceutical, agrochemical, and material science.

Analysis:

The present claimed subject matter relates to a new, one-pot synthetic methodology for preparation of versatile 2-substituted-1H-benzo[d]imidazole derivatives (3a-3az), with good to excellent results by reacting o-phenylenediamines with readily available methyl and/or phenyl acetals and trifluoro methyl and/or difluoro methyl hemiacetals on direct heating at 100-120º C without using any solvent, additives or metal catalysts.

The one-pot process for the preparation of 2-substituted-1H-benzo[d]imidazole derivatives is described in a clear and complete manner, enabling a person skilled in the art to perform the invention without undue experimentation. All essential elements, including the starting materials, molar equivalents, reaction conditions (temperature, time, catalyst), and scope of substituents (R_1, R_2, X, Y), are explicitly disclosed. Furthermore, the illustrative embodiments are supported through variations in the acetal

and diamine reactants, thereby ensuring that the scope and utility of the invention are clearly established. Hence, the present complete specification fully and particularly describes the invention and the manner in which it is to be performed, as required under Section 10(4) of the Patents Act,1970 (as amended).

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