

Patent: An Important Tool for Promoting Drug Discovery and Improving Public Health

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Abstract

A patent is an important intellectual property concerning pharmaceutical products. This review aims to provide a general overview of patent, patentable pharmaceutical products with examples and patent role in improving public health. The literature for this article was collected from PubMed, Orange Book database of the United States Food and Drug Administration, Espacenet, US Patent and Trademark Office, World Intellectual Property Organization, and other authentic websites. A patent is granted if an invention is novel, non-obvious, and useful. The major patentable pharmaceutical inventions include patent of a compound or drug molecule, the process for preparing a drug, active pharmaceutical ingredient (prodrug, salt, solvate, or specific enantiomer), polymorph (crystalline and amorphous), co-crystals, a second indication of the existing drug, different dosage forms of a drug (solid, semi-solid, liquid, and injectables), drug combinations, particle size based invention, vaccine, diagnostic kit, and medicinal plant-related inventions. Recent drug discovery processes employ artificial intelligence (AI) tools. The AI-based invention is also patentable if it satisfies the patentability criteria. A patent system promotes innovation and economic development and makes its benefits available for public health. In general, a marketed patented pharmaceutical product is expensive. However, the patent system has flexible tools, including research exclusions, compulsory licensing, parallel imports, and monopoly for a limited period to accommodate public interest and health needs. The participation of pharmaceutical researchers (Government sector and private sectors) in developing pharmaceutical innovation is crucial for public health and safety in the long term. Accordingly, a good patent system balances patentee rights and public interest.

Key words: Artificial intelligence, drug, intellectual property, patent, pharmaceuticals, public health

INTRODUCTION

Intellectual property (IP) reflects the creation of the human mind that can solve existing problems in a scientific field. Companies and scientists can protect their creation of mind or IP in the form of IP rights (IPR) for a specified period in a particular country. The IPR, or IP protection, is an important domain of a country's social, cultural, and economic development.^[1,2] Seven important IPs can be protected as IPR.^[2] These IPs comprise copyright (protects artistic/literary work or software including books, drawings, and music), trademarks (protects the brand name of product or service including the symbol of famous brands such as McDonald,

Apple, and Nike), industrial design (protects the look of an item/product including the design of famous cars such as Ferrari, Bugatti, and Lamborghini), layout design (protects the internal circuit of a product like I-phone's internal circuit), trade secret (protects commercially valuable secrets like

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preparation formula of Coca-Cola and Pepsi), geographical indications (protects goods specific to the defined territory like Indian basmati rice), and patent (protection of the invention of novel treatments, drugs, or medicine for a disease) [Figure 1].^[1-4]

Drug discovery and development are essential for improving public health and fighting diseases.^[5] For example, the scientific fraternity created many drug discovery and development-related inventions to combat COVID-19. Our search (Keyword: COVID-19 in the title, abstract, or claim) on the Espacenet patent database on February 14, 2025, revealed 7811 COVID-19-related patents/patent applications the scientists filed.^[6] Similarly, thousands of patents/patent applications can be searched in patent databases related to drug discovery and development related to a specific diseases such as diabetes, hypertension, tuberculosis, HIV infection, central nervous system diseases, and unmet medical needs.^[6-8] This review provides an overview of patents, various drug-related patents, and their importance in improving public health. This article will be useful to scientists (pharmaceutical industries and academia) and research scholars and may encourage them to design and work on patentable inventive research work. The data of this article were collected from freely available databases such as PubMed (Keyword: Patent in the title or abstract), Orange Book of the United States Food and Drug Administration (USFDA) (for searching patents on specific drugs),^[9] and different patent databases such as Espacenet, United States Patent and Trademark Office (USPTO), and World Intellectual Property Organization (WIPO) (for collecting the information about the claimed invention).^[6-8]

PATENT

A patent is a set of exclusive rights granted by a state (national government or country) to an inventor (or their assignee) for a limited period (20 years from the date of filing) in exchange for publicizing their invention. A patent has a territorial right, i.e., the exclusive rights granted by a country are specific to the country that granted the patent. For example, if a patent is granted in the United States of

America (USA), its rights are limited to the USA and cannot be exercised in other countries. Accordingly, a patent owner can only prevent others from making, using, offering for sale, selling, or importing infringing products in the country where the patent has been granted.^[5,10-12] The creation of the mind is patentable, provided it is novel, non-obvious (involves an inventive step), and has industrial applications (utility).

Novelty

This criterion means that the subject matter of the claimed research work (CRW) must be unknown to the person of ordinary skill (POS) in the relevant field of technology and is not part of the existing state-of-the-art (ESA) (publication in any form, public or commercial use, and any public disclosure) when filing the patent application.^[13-15]

Non-obvious (Inventive step)

The term “non-obvious” refers to the predictability of the CRW concerning the ESA and knowledge of the POS. The CRW must not be a predictable expansion or extension of the ESA or prior art/knowledge. To be patentable, the CRW must involve an inventive step (a technical advance compared to the ESA or knowledge of the POS or economic significance). For example, COX-2 inhibitors are well-known anti-inflammatory agents. Accordingly, the POS can predict the use of all COX-2 inhibitors in diseases caused by high levels of COX-2. Therefore, the use of COX-2 inhibitors in all diseases caused by high levels of COX-2 is obvious. This fact of the CRW will not fulfill the criteria of non-obviousness and may destroy the patentability of the CRW. This criterion aims to encourage true inventors and honor them for their inventiveness.^[5,14-19]

Industrial application

This patentability criterion ensures that the CRW is not a mere theoretical concept or idea that does not solve the problems of the ESA. This aspect of patentability also ensures that the CRW has practical utility (commercial use, technological advancement, or economic development) in its field. A novel,

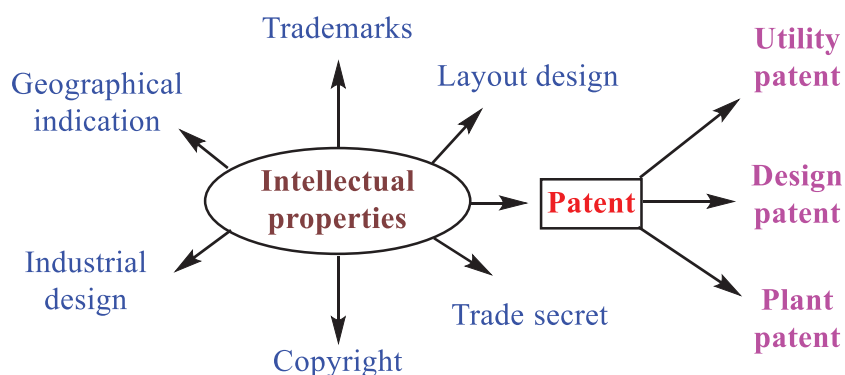


Figure 1: Important intellectual property

inventive, and useful subject matter is called an invention. When this invention is commercialized or marketed, it becomes an innovation.^[5,14-17,20]

Apart from the three main criteria of patentability, other points like disclosure of the best mode, wherein the applicant has to disclose the best way to carry out the invention; one patent is granted to one invention (unity of invention); the POS must be able to carry out the claimed invention without due experimentation (enablement); complete disclosure of the invention (written description and claims); and the patentable subject matter as defined in the patent law also play an important role in getting a patent [Figure 2].^[1,20]

GENERAL STEPS OF PATENT APPLICATION FILING

When scientists believe that they have created a patentable invention that fulfills the above-mentioned patentability criteria, they intend to file a patent application in the desired country, for example, the USA, or in regional offices such as European Patent Office (EPO), African Regional Intellectual Property Organization (ARIPO), Eurasian Patent Organization (EAPO), or Gulf Cooperation Council (GCC).^[5,21-25] The general steps of patent application filing are provided below.

Understanding the invention

The scientists discuss their invention in layman's language with the patent agent and provide relevant information to the patent agent or attorney. The scientists may also specify the shortcomings and differences of the disclosed closest prior art (patent and non-patent literature) relevant to their invention. These data help a patent agent understand the invention's key features and make an appropriate plan (identification of the appropriate keywords, combinations of keywords, and chemical structures for prior art searching) for the patentability evaluation of the invention.^[26]

Patentability evaluation

This step is one of the most important steps of patent application filing and ensures that the invention fulfills the patentability requirements mentioned above. An accurate patentability evaluation speeds up the grant of the patent in a cost-effective manner. The patent agent makes use of different paid software (SciFinder, STN, Reaxys, and Delphion) and non-paid databases (USPTO, Espacenet, PatentScope, patent office database of a specific country like Japan Patent Office, PubChem, PubMed, E-molecules, Google Scholars, etc.) for the patentability evaluation utilizing different keywords that patent agent understood during the discussion with the scientists. This process must be given sufficient time to understand the invention's technical features clearly, making it novel, non-obvious over prior art, and industrially useful. This understanding helps draft a good patent application for filing at the patent office.^[23,27]

Patent application drafting

A patent is a legal document. Accordingly, it must be drafted critically, keeping patent laws in mind. A well-written patent application discloses the claimed invention's details clearly in the best mode and comprehensively, enabling the POS to replicate the invention without undue experiments. It also discloses different patentable embodiments and aspects with experimental support. The patent application's claims must be clear, unambiguous, and supported by the detailed specification of the patent application. These disclosures help the patent examiner understand the technical feature that makes it patentable and make appropriate decisions promptly. Scientists can draft their patent applications without consulting a patent expert or agent. However, the patent is a legal document. Therefore, a patent expert or patent agents help is desirable.^[20,24,28,29]

Filing of the priority/complete patent application

A patent application can be drafted as a provisional or complete (non-provisional) patent application [Figure 3].

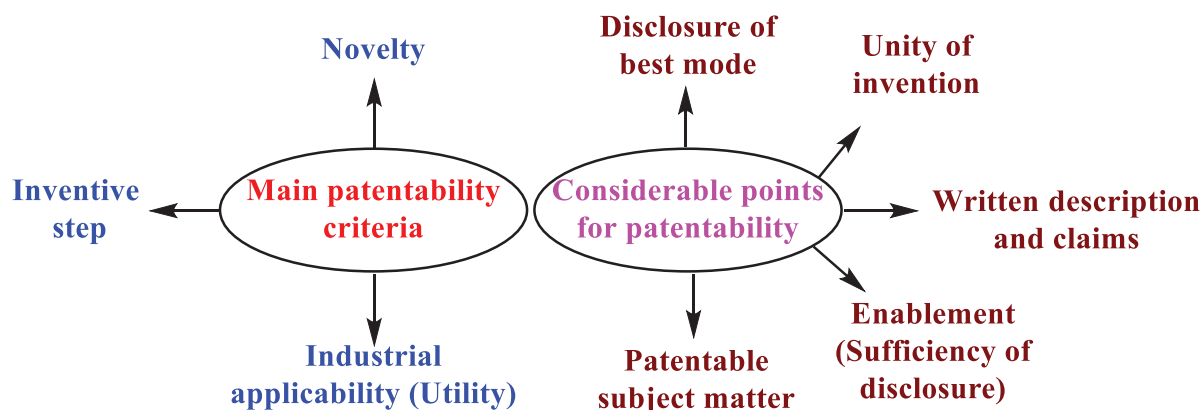


Figure 2: Patentability criteria

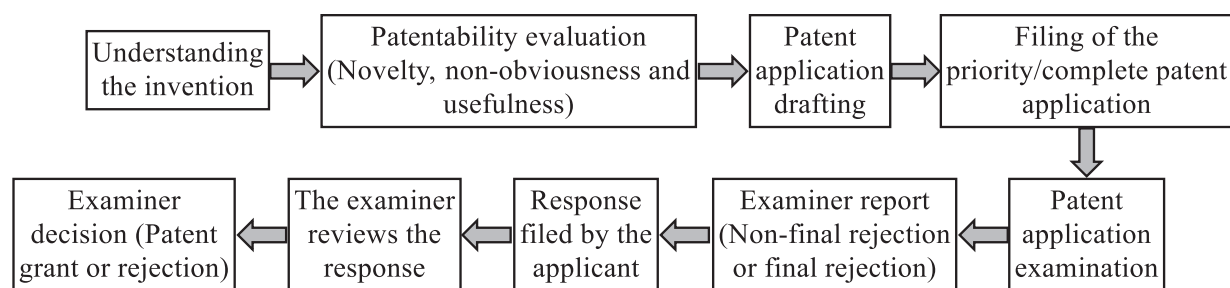


Figure 3: General steps of patent application filing

A provisional patent application is drafted when the invention is incomplete, and scientists are still working on the invention. The provisional patent application is filed to get a priority date. This is advantageous as the patent examiner will not consider public disclosures published after the priority date. The priority application may be submitted with or without the claims. The provisional patent application provides “patent pending status” to the inventor or its assignee, gives time to the inventors to complete their inventions, and plans the filing of their applications in different countries. A country’s patent office generally gives 1 year for the applicant to submit the complete patent application with the claims at the patent office. This is imperative to note that changes are possible in the provisional patent application before filing the complete specification. However, no changes are allowed once a complete patent application has been filed at the patent office.^[5,23,30]

Patent application examination

The applicant must submit an examination request after filing the complete patent application at the desired patent office by paying the required fees to initiate the patent application examination. The applicant can also request early application publication by paying the required fees. The examiner starts the examination process and can make different types of decisions. First, the examiner may allow the submitted claims. This decision is possible for a professionally well-written patent application. Second, the examiner may send a non-final rejection. In this case, the examiner may make certain objections related to novelty, inventive steps, lack of enablement, lack of support for the broad scope of the claims, and clarity of some aspects of the patent application. The examiner may also cite some relevant prior art asking the inventor to provide additional experimental data to prove the patentability of their inventions. The main idea of non-final rejection is to allow the applicant to amend the claims to overcome the examiner’s objection and to get a patent grant. Third, the examiner may reach a final rejection if they are not satisfied with the claim amendments made by the applicant. In such cases, the applicant may meet with the examiner to understand the examiner’s point of view and request the examiner to give sufficient time to make further amendments. The applicant can also take the help of legal experts and file a continuity patent application with new patentable claims.^[5,31,32]

Submitting a response to the examiner’s report

The applicant is bound to respond appropriately to the examiner’s report to get a patent grant. Accordingly, the applicant must read the examiner’s report carefully, critically analyze the prior art, amend the claims appropriately, and make a clear, concise, well-structured response with supporting evidence. Timely submission of the professionally well-drafted response helps to convince the examiner to grant the patent.^[5,23,32]

Examiner decision

The examiner reviews the response submitted by the applicant. The examiner can grant or reject the patent application depending on the merit of the response and patent application.^[5,23]

IMPORTANT PARTS OF A GRANTED PATENT

A patent contains three important parts [Figure 4].^[20]

Cover page

This page of the patent contains information regarding the patent country, patent number, patent date, title, abstract, patent application number, priority date, filing date, information on inventors, applicants, and assignee, patent classification, information about cited references by the applicant and the examiner, data of the examiner and patent attorney, and the number of claims and drawings [Figure 4].^[33]

Patent specification

This part of the patent provides essential and detailed information about the invention to meet the legal requirements of the patent law. This part must contain complete disclosure of the claimed invention enabling the POS to carry out the invention without undue experiments. Various critical parts of a patent specification comprise title, cross-references, the field of the invention, background of the invention mentioning the shortcomings and challenges of the prior art and the

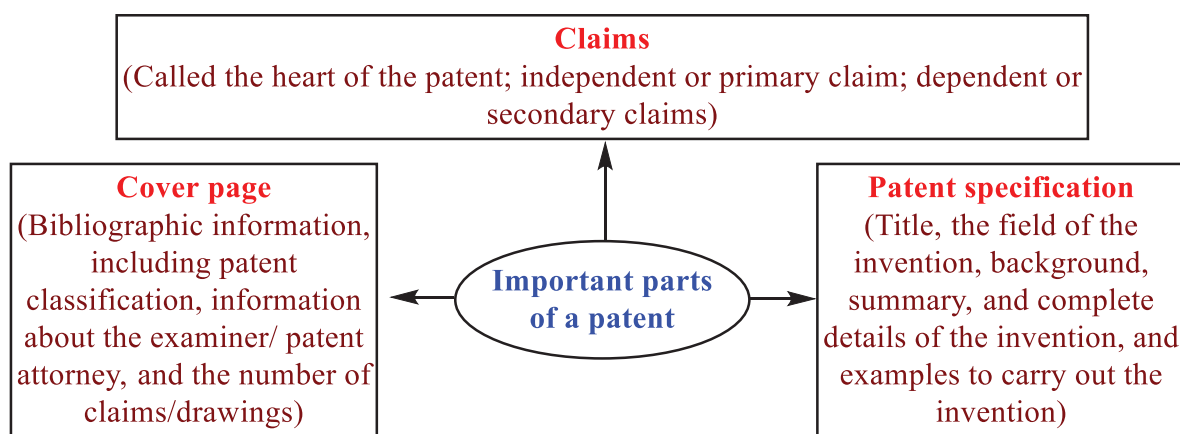


Figure 4: General anatomy of a patent document

existing technologies, summary of the invention providing advantages and benefits of the invention, clearly detailed and comprehensive description of the invention, examples of the invention in the best mode that POS can replicate without undue experimentations, claims and an abstract [Figure 4]. A well-written patent specification is essential to satisfy the patentability criteria [Figure 2], facilitates a smooth examination process, and offers strong protection to patent claims.^[20,33]

Claims

Claims (the heart of a patent) are the most crucial part of a patent and define the legal scope of the protected invention. A granted patent contains at least one clear, specific, well-structured claim supported by the patent specification. A granted patent may also contain more than one claim. There are two types of claims. An independent or primary claim defines the invention's main elements or technical features without any reference to any other claim. The independent claims provide broad legal protection to the invention. The dependent or secondary claims contain limitations of the independent claims and provide a narrower legal protection to the invention. The claim's scope reflects the patent's strength and enforceability [Figure 4].^[20,33] For example, an independent claim states "a compound A." This claim has only one technical feature, i.e., compound A. Suppose "compound A" is present in any product (even as an impurity) that the patentee does not authorize. In that case, the patentee can file an infringement suit against the owner or marketer of that marketed product. More are the limitations in the independent claims; it is easy to design around them. For example, an independent claim states "a composition comprising compound A and compound B." Suppose there are two products in the market. A product contains only compound A along with other compounds except for compound B. Similarly, a product contains only compound B along with other compounds except for compound A. These two products will not come under the scope of the claimed invention ("a composition comprising compound A and

compound B"). However, if a product contains compound A and compound B in any quantity or proportion along with other compounds, this product will come under the scope of the claimed invention.

ADVANTAGES AND DISADVANTAGES OF PATENTS

A patent protects inventive technology and provides a monopoly to the patentee for 20 years from the patent application's filing date. During the tenure of the patent, the patentee can market its patented product exclusively and prevent the second party from using, manufacturing, selling, or importing the patented product without the patentee's permission. If the second party does so, the patentee can legally sue the second party in court and demand compensation. However, a second party can take a license from the patent owner regarding these aspects. This exclusive monopoly and licensing of patents provide financial benefits, increase the market value, help expand the business, and offer a competitive advantage to the patentee (or an organization) over its competitors in the same field of technology. Patent sharing is also an advantage, wherein two patent holders can negotiate to use their technology to create new technologies without any financial interchange [Figure 5].^[34]

Big and small-scale organizations benefit from patents. However, the cost of filing a patent application may not be bearable for all small businesses, or the total cost of patent filing may be more than the worth of the product. The patent law mandates a patent applicant to disclose the claimed invention in the best possible way so that the POS can carry it out. This enablement requirement discloses the invention's secrecy publicly. Accordingly, some organizations prefer trade secrets over patents. The lengthy process of getting a patent (2–4 years) is also a disadvantage of the patent. During this period, the claimed product may become outdated due to changes in the demand for the product in the market [Figure 5].^[34]

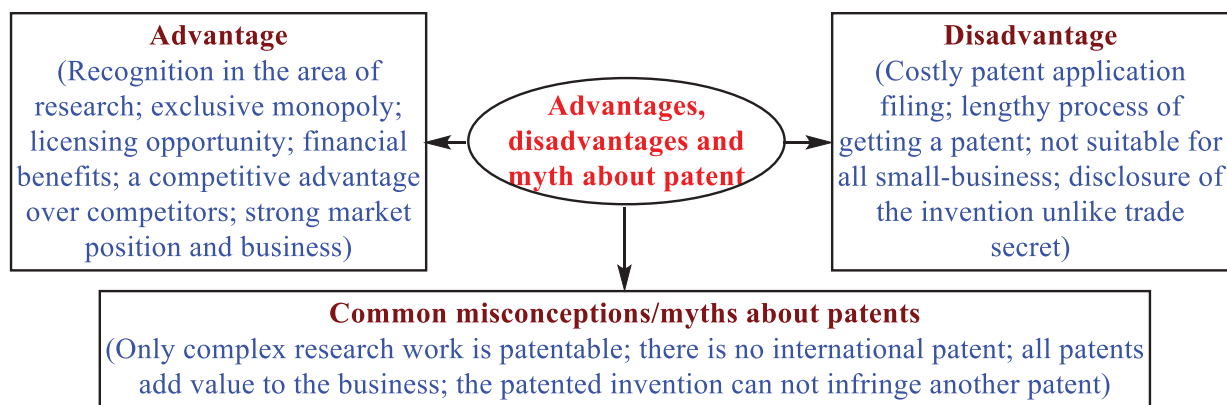


Figure 5: Advantages, disadvantages, and common myth about patent

COMMON MISCONCEPTIONS/MYTHS ABOUT PATENTS

Many scientists think that only complex research work is patentable. However, this is not true. A simple idea/technology is patentable if it fulfills the patentability criteria. Most granted patents do not add any value to the business or offer financial benefits to the patentee. It must be clear that only commercially exploitable patents can add value to your business and provide financial benefits to the patentee. There is no worldwide patent, but an international patent enforceable in different contracting countries of a regional office (EPO, ARIPO, EAPO, and GCC) is possible. Suppose the patentee files patent applications in regional offices like EPO, ARIPO, EAPO and GCC. In that case, the patentee can get a patent that may be enforceable in all EPO, ARIPO, EAPO, and GCC member countries. An applicant can get a patent, but the still patented product may infringe another's patent. For example, company X has a valid patent for "a compound of Formula A." The applicant can get a patent for a patentable composition of compound A. However, the applicant cannot market the patented composition without authorization from company X because the composition contains "a compound of Formula A" and infringes the patent granted to company X [Figure 5].^[35]

TYPES OF PHARMACEUTICAL PATENTS

The process of drug discovery and development has a direct impact on improving public health. New drugs or treatments are required continuously for various reasons, including combatting emerging diseases (COVID-19); treating existing unmet medical needs; developing precise medicines for gene-specific diseases; providing cost-effective and patient-compliant treatments; and tackling the increasing cases of drug resistance.^[36] A pharmaceutical company can get different types of patents based on the field of invention. Thousands of pharmaceutical patents are available on the patent database and cannot be covered in this article. Therefore, the authors provide one or two examples of

different pharmaceutical patents to limit the text of this article to an acceptable level.

Compound patent

As the name suggests, this patent claims an inventive chemical compound. A drug is also a chemical compound. Therefore, a compound patent claims a drug compound and other chemical compounds. A compound patent claims a drug generically (US4681893A claims atorvastatin calcium), specifically (US5273995A claims atorvastatin calcium) or generically and specifically (US7157456B2 claims rivaroxaban).^[33,37,38] It is important to understand that there is a difference between a compound patent and a product patent. A product patent may be any product containing a drug compound. For example, a tablet is a product containing a drug compound along with other pharmaceutically acceptable excipients.

Process patent

Bexagliflozin (Brenzavvy), an SGLT2 inhibitor, was approved by the USFDA on January 20, 2023, to control glycemia among type-2 diabetes patients.^[39] US7838499B2 claims bexagliflozin and also provides its preparation process.^[40] A compound patent may disclose a process for the preparation of the drug. However, the process disclosed in the compound patent may be difficult to carryout (multiple steps and long reaction cycle), non-economical (poor yield and use of expensive chemicals), or non-ecofriendly (use of hazardous materials).^[41] These facts trigger the development of a new process for preparing a drug compound. Accordingly, US11198703B2 claims an improved process (simple, cost-effective, eco-friendly, efficient, and commercially scalable) for preparing bexagliflozin that involves fewer unit operations and avoids tedious workup.^[41] An interesting process patent is related to atorvastatin calcium (hypolipidemic agent). Oxidation of drugs like atorvastatin is a common phenomenon and is related to the shelf life of its marketed drug products. This

fact motivated inventors to prepare stabilized atorvastatin calcium with having extended shelf life.^[42] Using a pure drug in the marketed product is essential for the patient's safety. Many drugs may pose difficulty in their purification process. This necessitates developing a process for improving the purity of a drug.^[43] The USFDA approved rezafungin on March 22, 2023, to treat invasive candidiasis.^[44] Recently, a patent application in China related to the industrially applicable purification process providing rezafungin in >99% purity and >70% yield.^[43]

Intermediate for preparing the drug

Sometimes, an intermediate becomes a bottleneck in the drug preparation process. The pharmaceutical company strategically files a patent claiming important intermediates in such cases. These patents may be considered “blocking patents” for other companies and force them to look for alternative ways to develop a new drug process.^[45] Ceftaroline fosamil (Teflaro) was approved by the USFDA in 2010 to treat bacterial infections.^[46] US6417175B1 claims an important intermediate for preparing Ceftaroline fosamil.^[47] Drug manufacturing companies may also file processes for preparing important intermediates of drugs. For example, CN114605438A claims a process for preparing critical intermediates for ceftaroline fosamil.^[48]

Active pharmaceutical ingredient (API)

API is the main form of the drug (prodrug, salt, solvate, specific enantiomer, or polymorph) that is utilized to prepare the final drug product (tablet, capsule, injection, etc.).^[49] A drug compound may not pose suitable physical and chemical properties to develop the intended drug product. Similarly, the specific enantiomer of a drug compound may be more potent than another enantiomer. These facts make it essential to develop a suitable API for the drug compound.^[50]

In 2014, the USFDA approved two dosage forms of tedizolid phosphate (oral tablet and powder for injection) to treat bacterial infections.^[51] In this case, tedizolid phosphate (a phosphate prodrug of tedizolid) has been utilized to manufacture the tablet and powder for injection due to its promising physicochemical properties.^[52] Tedizolid phosphate has been claimed in US8420676B2.^[53]

The citrate salt of tofacitinib (Xeljanz) was first approved by the USFDA as a tablet form in 2012.^[54] Tofacitinib citrate was better in developing this dosage form than other salts. Accordingly, tofacitinib citrate salt was claimed generically and specifically in two different patents.^[55,56]

The marketed API of intravenous Teflaro injection is ceftaroline fosamil monoacetate monohydrate. The monoacetate monohydrate solvate of ceftaroline fosamil is claimed to have higher solid stability, solubility, and purity

than other solvates. Accordingly, US6906055B2 specifically claims the marketed API of Teflaro.^[57]

Citalopram hydrobromide salt, marketed as Celexa (tablet and solution form), is an antidepressant drug.^[58] However, its S-isomer (Escitalopram) is more potent than citalopram.^[58] Accordingly, the oxalate salt of the S-isomer of citalopram (escitalopram; marketed as Lexapro in tablet and solution form) was claimed in USRE34712E.^[59] A similar case relates to omeprazole and esomeprazole.^[60]

Polymorph of drugs

A polymorph is a solid-state form of a chemical compound possessing a definite crystal structure or arrangement. A chemical compound can exist in polymorphic forms, including crystalline and amorphous. The polymorphs of a chemical compound have different solid-state properties (melting point, solubility, density, surface properties, etc.). The solubility of a drug's polymorph may affect its bioavailability and therapeutic effect. The other solid-state properties may affect the stability of a drug's polymorph. Selecting a suitable polymorph also plays an important role in developing a drug's optimal dosage form (tablet, capsule, etc.). Therefore, patenting of polymorph is an important aspect of pharmaceutical industries.^[61]

Fezolinetant (Veoza), an antagonist of the tachykinin NK3 receptor, was approved by the USFDA to treat vasomotor symptoms associated with menopause on May 12, 2023.^[62] Recently, Teva Pharmaceuticals filed a patent application claiming different crystalline forms of Fezolinetant, including crystalline form 2, form 3, form 4, form 5, and amorphous form of Fezolinetant.^[63] The claimed crystalline forms of Fezolinetant are stated to have acceptable stability (chemical and physical), solubility, low hygroscopicity, and improved characteristics (flowability, compressibility, and bulk density) to develop different dosage forms. Umbralisib tosylate (Ukoniq), an oral PI3K delta inhibitor, was approved by the USFDA on February 5, 2021, to treat follicular lymphoma.^[64] A patent application has been filed by Johnson Matthey claiming the amorphous umbralisib monotosylate, which is supposed to have better solubility and stability than other known forms of umbralisib tosylate.^[65] Similarly, a patent application claiming the crystalline form of trofinetide (Daybue; approved by the USFDA on March 10, 2023) has been filed by Acadia Pharmaceuticals.^[66] Nowadays, pharmaceutical industries are inclined to develop co-crystal, a relatively new strategy in drug development. A co-crystal combines an API with another compound (co-former) in a definite stoichiometric ratio to produce a different solid state with improved properties, including solubility, stability, hygroscopicity, and crystallinity.^[67] These benefits motivate researchers to patent co-crystals. For example, Nuformix Technologies Limited has filed a patent application claiming the olaparib: hydroxybenzoic acid cocrystal in 1:1 and 2:1 ratio.^[68]

Indication

In a few cases, a compound is known, but it has never been employed to treat any diseases. Scientists work on these compounds to determine their utility as a treatment for a disease. In such cases, the compound patent of the known compound cannot be granted. However, scientists can get a patent for using a known compound to treat an illness. During the COVID-19 pandemic, many patent applications were filed concerning using some natural compounds to treat COVID-19. For example, a Chinese patent application was filed in 2020 claiming the use of thymoquinone in the preparation of medicaments for preventing and treating coronavirus infection.^[69]

Second indication

Drug repurposing is a cost-effective strategy to identify a new or second indication of an existing drug. Different drug authorities have approved many drugs for more than one disease.^[70] The case of milnacipran is one of the examples of drug repurposing. Milnacipran was an approved antidepressant in many countries, except in the USA.^[71] In the late 90s, Cypress Bioscience identified the utilization of milnacipran as a potential treatment of fibromyalgia and filed a patent application that was granted as a patent in 2003.^[72] In 2009, the USFDA approved milnacipran hydrochloride (Savella) to manage fibromyalgia.^[71] The readers can also recall that during the COVID-19 pandemic, many scientists reported using many existing drugs to treat COVID-19.^[73]

Different dosage forms of a drug

Many types of dosage forms are known to pharmaceutical scientists. It is not possible to list patents related to all dosage forms. The patents related to some types of dosage forms are provided in Table 1.

Drug combinations

Using a drug combination is a common phenomenon for treating many diseases, including cancers, HIV infection, tuberculosis, hypertension, and diabetes, for various reasons (synergistic and additive effect, reduced drug resistance, dose reduction, and treatment tailoring).^[99] Some of the patented drug combinations are summarized in Table 2.

Particle size

A drug's particle size impacts the drug's stability, absorption rate, bioavailability, cellular uptake, distribution, and elimination of the drug, and designing a suitable dosage form with improved patient compliance.^[105] The Chinese patent number CN114652688B claims a tablet wherein montelukast has $D_{90} < 75$ microns, rapidly dissolving the tablet.^[78] A similar

case has been observed for escitalopram, wherein Lundbeck got an Australian patent (AU2005218713B2) claiming crystalline particles of escitalopram oxalate characterized in that the median particle size is at least 20 μm .^[106] The patent specification of AU2005218713B2 states that the claimed particle size escitalopram has a lesser propensity to develop a specific impurity of escitalopram.

Impurity

A drug's impurity is an unwanted compound in it or its product. A drug's impurity may be of various types, including process-related impurity and drug degradation-related impurity. In a few cases, it may be difficult to remove a process-related impurity or drug-degradation-related impurity completely. Accordingly, these impurities may always exist with the drug and its product.^[107] These impurities may play an important role in the business of an innovator. A Merck patent was filed on this basis. The patent claimed a commercial scale composition comprising 0.20 area % or less of dimeric impurity (dimer of simvastatin).^[108] The patent specification states that reducing this dimer impurity in the final product is difficult because the standard purification methods (re-crystallization with heat) promote the forming of these impurities.

Vaccine

Vaccines are biological products that stimulate the immune system against a particular pathogen like bacteria or virus. Vaccines play an important role in community health and are mainly employed for the prevention of many diseases, including monkeypox, COVID-19, polio, measles, and influenza.^[109-112] A recent article in Nature Biotechnology discusses international patent applications filed by CureVac, Moderna, and BioNTech for COVID-19 vaccines.^[109] WIPOs report provides a patent landscape on COVID-19 vaccines.^[113] Another interesting article also discusses the vaccine patents for COVID-19.^[114]

Monkeypox virus (a pox virus) recently affected the world in 2022. The smallpox vaccine (Jynneos) has been used to combat monkeypox disease (MPX).^[110] Recently, many patent applications have been filed for the monkeypox vaccine. For example, a Chinese patent application claims a monkeypox virus vaccine comprising a monkeypox virus antigen and a pattern recognition receptor agonist cyclic dinucleotide.^[115]

Diagnostic kit

Early disease diagnosis is important to identify the risk factors, provide better treatment, reduce disease progression and treatment costs, prevent and control the disease, and improve quality of life.^[116] The arrival of the COVID-19 pandemic and MPX encouraged the development of diagnostic diseases for these diseases. For example, Beijing

Table 1: Examples of patents/patent applications related to different dosage forms of a drug

S. No.	Patent/patent application number (Applicant)	Claimed invention
1	CN115844840B (Sinopharm Pharmaceutical)	A tablet containing (by mass percentage) paracetamol (86.88 parts), binder (4.52 parts), disintegrant (2.90 parts), filler (5.21 parts), and lubricant (0.49 parts). ^[74]
2	US11096896B2 (Fertin Pharma)	A buccal tablet comprising a population of particles (directly compressible sugar alcohol and non-directly compressible sugar alcohol particles) and an active ingredient (paracetamol, aspirin, caffeine, chlorpheniramine, fluticasone, propranolol, sumatriptan, ampicillin, oxytocin, and many more) to be released in the oral cavity for absorption through the oral mucosa. ^[75]
3	CN115531336A (Leadingpharm Medical Technology)	A sublingual tablet containing pantoprazole sodium (20 mg), at least one diluent, at least two flavoring agents, at least one taste-masking agent, at least one adhesive, at least one disintegrant, and at least one lubricant. ^[76]
4	CN114533693B (Shenyang Okina Pharmaceutical)	A stable effervescent tablet for children, the elderly, and patients who cannot swallow paracetamol, wherein the tablet contains paracetamol, anhydrous citric acid, monosodium citrate, sodium bicarbonate, anhydrous sodium carbonate, sodium benzoate, mannitol, glycine, polyethylene glycol, and simethicone in different proportions. ^[77]
5	CN114652688B (Lunan Pharmaceutical)	A stable, fast integrating, and highly bioavailable chewable tablet containing pulverized and sieved montelukast sodium, wherein the particle size of montelukast sodium raw material is controlled at D90<75 microns. ^[78]
6	CN115518053A (Qingdao Guohai Biopharmaceutical)	A capsule comprising a capsule shell containing quick-release granules components (vitamin E, ginseng, zinc sulfate, pollen, water-soluble carrier, and disintegrant) and sustained-release granules components (vitamin E, ginseng, zinc sulfate, pollen, polyvinyl alcohol, polylactic acid, and coating material). ^[79]
7	CN111195311A (Nanjing Gritpharma)	A patient-compliant and stable antimicrobial lozenge comprising cetylpyridinium chloride, clover extract, aloe extract, adhesive agent, and filler. ^[80]
8	CN115364059B (Beijing Leadingpharm)	A granule composition containing cefpodoxime axetil, diluent, disintegrant, binding agent, surfactant, glidant, lubricant, correctives, and essence. ^[81]
9	WO2023126531A1 (Fine House)	An oral pharmaceutical solution comprising lenalidomide, water, and a cosolvent (glycol or a polyol), wherein the pH of the solution is from 1.0 to 3.0. ^[82]
10	CN114983938A (Guangdong Jiabo Pharmaceutical)	An oral composite emulsion comprising 1–5% orlistat and 10–15% medium-chain triglyceride. ^[83]
11	WO2022185338A1 (Alkem Laboratories)	A stable oral suspension comprising celecoxib, suspending agents, and pharmaceutically acceptable excipients. ^[84]
12	US11617795B2 (Spielberg Max)	A palatable oral syrup comprising acetaminophen, agave syrup, and a diluent, wherein the syrup has a viscosity of <1500 centipoise at about 22°C. ^[85]
13	RU2334522C1 (OooNpoFitodent)	An elixir for oral care containing extract of herbs of nettle and plantain, flowers of chamomile and calendula, myrrh, vitamin A, sodium fluoride, anionic surfactant, antiseptic, glycerin, nipagin, and nipose perfume. ^[86]
14	CN115645359A (Xiamen Zixu Pharmaceutical)	Oral drops containing levocetirizine hydrochloride, glycerol, maltitol, glacial acetic acid, and sodium acetate. ^[87]
15	KR102500957B1 (Chulhan Kim)	A herbal gargle composition containing Goldamcho extract, Dokhwal extract, Hawthorn root extract, Maple japonica extract, Raven japonica root extract, Agub pear root extract, Wiryeongseon extract, and immersion wine. ^[88]
16	US9855209B1 (King Abdulaziz University)	An alcohol-free anti-bacterial mouthwash consisting of an aqueous extract of <i>Salvia libanotica</i> and <i>Malva sylvestris</i> , essential oil, and an emulsifier. ^[89]
17	US10272129B1 (Hayes Deborah)	An anti-inflammatory ointment consisting of coconut oil, sweet weed, green ginger, Indian pink, slippery root, velvet plant, American walnut husks, tanner's bark, magnesium flakes, gravel root, mad dog weed, and nigella seed. ^[90]

(Contd...)

Table 1: (Continued)

S. No.	Patent/patent application number (Applicant)	Claimed invention
18	US9801895B1 (Humax Pharmaceutical)	An anti-leishmaniasis topical cream containing Amphotericin B, sodium methylparaben, sodium propylparaben, monobasic sodium phosphate, cetyl alcohol, light mineral oil, a mixture (cetyl alcohol, glyceryl stearate, PEG-75 stearate, ceteth-20 and steareth-20), white petrolatum, glycerol monostearate, and water. ^[91]
19	US2023015062A1 (Yusuf Zaki)	A gel formulation comprising sodium chloride, sodium bicarbonate, sodium carbonate, sodium lactate, sodium acetate, trisodium citrate, a gelling agent, and water from a sterilized and deionized source. ^[92]
20	US10653623B2 (Cristcot)	A suppository comprising hydrocortisone acetate, colloidal silicon dioxide, and an oleaginous base (triglycerides). ^[93]
21	US9629861B2 (Forest Laboratories Holdings)	An injectable antibacterial pharmaceutical composition comprising ceftaroline fosamil and L-arginine. ^[94]
22	US5023257A (Bayer)	An intramuscular injection formulation comprising enrofloxacin with an acid or base in oily suspension. ^[95]
23	WO2022109052A1 (Bexson Biomedical)	A subcutaneous injection composition comprising flumazenil, and at least one pharmaceutically acceptable excipient, wherein the concentration of flumazenil in the pharmaceutical composition is >0.7 mg/mL. ^[96]
24	KR20230031457A (Hanmi Pharm)	An eye drop composition containing hyaluronic acid and water, wherein the eye drop has a dynamic viscosity of 1–10 cps measured at 20°C. ^[97]
25	CN102526056B (Livzon Pharmaceutical)	An ear drop preparation (gel or emulsion) containing voriconazole, ambroxol hydrochloride, and a dispersing agent. ^[98]

Table 2: Examples of some drug combination patents/patent applications

S. No.	Patent/patent application number (Applicant)	Summary
1	WO2022200982A1 (Pfizer)	A method of treating metastatic castration-sensitive prostate cancer with a combination of talazoparib and an anti-androgen (abiraterone acetate and enzalutamide). This combination therapy is claimed to possess better therapeutic benefits than monotherapy, improved dosing schedule, and reduced potential to develop drug resistance. ^[100]
2	WO2022051198A1 (ViiV Healthcare Company)	A method of preventing pregnancy and treating/preventing HIV infection with a safe and stable combination of cabotegravir and a contraceptive agent (Levonorgestrel). ^[101]
3	US11590154B2 (RedHill Biopharma)	A method for treating pulmonary <i>Mycobacterium avium</i> complex (MAC) disease using a patient-compliant combination (oral and once-a-day dosing) of clarithromycin (475 mg), clofazimine (mg), and rifabutin (120 mg). ^[102]
4	CN115501320A (Nanchang University)	A method of treating hypertension combined with carotid arteriosclerosis with a safe and effective composition of enalapril maleate-folic acid tablet combined with atorvastatin calcium tablet. ^[103]
5	US11103469B2 (Novartis)	A method of delaying loss of glycemic control for 5 years or more in a patient with type 2 diabetes mellitus with a combination of a DPP-IV inhibitor (vildagliptin) and metformin. ^[104]

Yixinbochuang Biotechnology filed a patent application claiming a polypeptide-based diagnostic kit for detecting new coronary pneumonia.^[117] Similarly, Jilin University (China) filed a patent application for a composition for detecting the MPX virus (West Africa and Central Africa clade).^[118]

Plant-related inventions

Various types of plant-related patents are possible, including the medicinal composition of plants, specific use of a

natural compound, an isolated natural compound with some limitations, and the process for isolating the natural compound from a plant. Some patent examples of plant-related inventions are provided in Table 3.

Miscellaneous

Apart from the above-discussed types of pharmaceutical patents, other types of patents are also possible, including patents related to pharmaceuticals (cosmetics, containers,

Table 3: Examples of plant-related patents/applications

S. No.	Patent number	Summary
1	WO2023021479A1 (Alakart Biopharma)	A synergistic polyherbal formulation containing <i>Swertia chirata</i> , <i>Zingiber officinale</i> , <i>Tinospora cordifolia</i> , <i>Justicia adhatoda</i> , <i>Terminalia chebula</i> , and <i>Trichosanthes cucumerina</i> for treating SARS-CoV-2 infection. ^[119]
2	CN114146072A (Wuhan University)	Use of thymoquinone in developing medicines to treat and prevent coronavirus infection. ^[69]
3	US4740521A (Purdue Research Foundation and King Saud University)	A compound (called Saudin) in substantially pure form. Saudin occurs naturally in <i>Cluytia richardiana</i> . In this case, Saudin has not been protected or patented <i>per se</i> . Instead, the claim on Saudin has an additional limitation “substantially pure form.” The definition of “substantially pure form” is missing in the patent specification. However, it may be present in the prosecution history of US4740521A. ^[120]
4	CN104672075A (Jiangnan University)	A process for extracting thymoquinone from seeds of <i>Nigella</i> . ^[121]

dispensers, spray, medicated masks, and monoclonal antibodies) which are discussed in our previous publications.^[122-127] Design patents are also granted for pharmaceutical products. USD977623S (Paediatis) claims the ornamental design for a pharmaceutical capsule.^[128] USD958649S (Gilead Sciences) claims an ornamental design for a pharmaceutical package.^[129]

A patent can be obtained if an invention is novel, non-obvious, and useful. Novelty is an important patentability criterion. However, it is imperative to understand the general meaning of discovery concerning patents. In general terms, discovery refers to something that already existed in nature (inherent existence) but is unknown to POS.^[130] For example, a plant contains millions of compounds. Many of these compounds may be inherently present in this plant but are still not isolated and are unknown to POS. Suppose a scientist identifies a new compound from the plant. This compound identification may be considered a discovery and not novel due to its inherent existence in the plant. However, if a scientist modifies any of the properties of the identified compound to make it useful using their mind, this step may make this research work novel and inventive. The same principle applies to identifying a drug's metabolite. A drug called “Drug A” is metabolized in the body and provides different metabolites. There is a possibility that a metabolite called “metabolite X” is produced, but it remains unknown to scientists. Later, another scientist files a patent claiming metabolite X *per se*. However, the examiner may reject the claim based on “inherent anticipation.” In such cases, the patent applicant has to prove that “metabolite X” is never produced during the metabolism of “Drug A.” Inherent anticipation can invalidate a granted patent.^[131]

The inventive step is another criterion for patentability. Herein, understanding the concept of significant “unexpected results” is important. For example, a scientist unexpectedly proves that a COX-2 inhibitor (celecoxib) significantly inhibits the DprE1 enzyme or the MmpL3 pathway of *Mycobacterium tuberculosis* and can be used to treat tuberculosis. This significant unexpected result will make

the CRW non-obvious and patentable. Similarly, scientists can claim a simple drug's process patent if they prove that using a simple step or a solvent provides significant unexpected results concerning the final product's economic significance, yield, and purity.^[45] The use of milnacipran (an antidepressant) to treat fibromyalgia is another example of unexpected results.^[72] The case of unpredictable drug repurposing and surprising higher potency results may be used to prove unexpected results.^[70]

Industrial application is the third criterion of patentability. Sometimes, an RW is novel and non-obvious but does not have industrial application. This situation may arise due to the different laws of different countries.^[15] For example, a narcotic drug (cocaine) is banned in most countries. Accordingly, using its novel and inventive formulation or composition may not be allowed in those countries. This fact may destroy the third criterion of patentability and make the invention non-patentable. Another example related to the novel and inventive mono-acetonitrile solvate of ceftaroline fosamil. Acetonitrile is a toxic solvent and cannot be used in drug products. Therefore, the USPTO did not grant the claims related to the mono-acetonitrile solvate of ceftaroline fosamil. However, the USPTO granted the mono-acetate mono-hydrate solvate of ceftaroline fosamil.^[57]

The purpose of the patent system is two-fold: to encourage invention and to provide a means of making the results of that innovation available to the public.^[12] Drug development needs extensive research, clinical studies, and regulatory approval. The exclusive right granted by a patent encourages drug developers to invest in research.^[30] However, sometimes, two-fold benefit may not be possible for a pharmaceutical company working on neglected or orphan diseases because of fewer patients. This also leads to limited treatment for these patients at high prices.^[132] The patent system has flexible tools, including research exclusions, compulsory licensing, parallel imports, and monopoly for a limited period to accommodate public interest and health needs.^[132] An unexpired and valid patented invention can be used for research work but not for commercial use.^[132] Researchers can use free patent-related

information to enhance pharmaceutical technologies for better public health. For example, when a drug is invented, other researchers can work on different patentable areas related to pharmaceuticals [Figure 6].

In some cases, there may be demand for drugs, but the patent holder company may not be able to provide a sufficient supply of medicines for public health. In such a case, compulsory licensing may be invoked to meet the demand for the drug for public health and safety.^[133] To reduce the price of a drug, parallel imports are also advocated. It means that an imported can import patented medicine at a lower price and then resell it at an appropriate price but lower than the price of the innovator's product.^[133]

The concept of a generic drug (a relatively cheaper copy of the innovator's pharmaceutical product) is also related to the

patent. After the patent expiry, it becomes public property. This encourages the generic pharmaceutical industries to develop cheaper but bioequivalent copies of the innovator's product. Marketing cheaper generic drugs increases the drug's availability and reduces the financial burden on patients.^[134] A patent is presumed valid by the office unless someone challenges its validity with proof of lack of novelty, obviousness, or non-applicability. In general, a compound patent is difficult to invalidate. Invalidation of evergreen patents (polymorph, new formulations, second indication, etc.) may be possible but still difficult.^[135,136] The patent office can also revoke a patent (cancellation of the patentee's right) under certain conditions.^[137] The invalidation and revocation of patents also motivate the generic pharmaceutical companies to launch their generic product in the market before time. In certain national emergencies, a patent holder can also waive off his rights

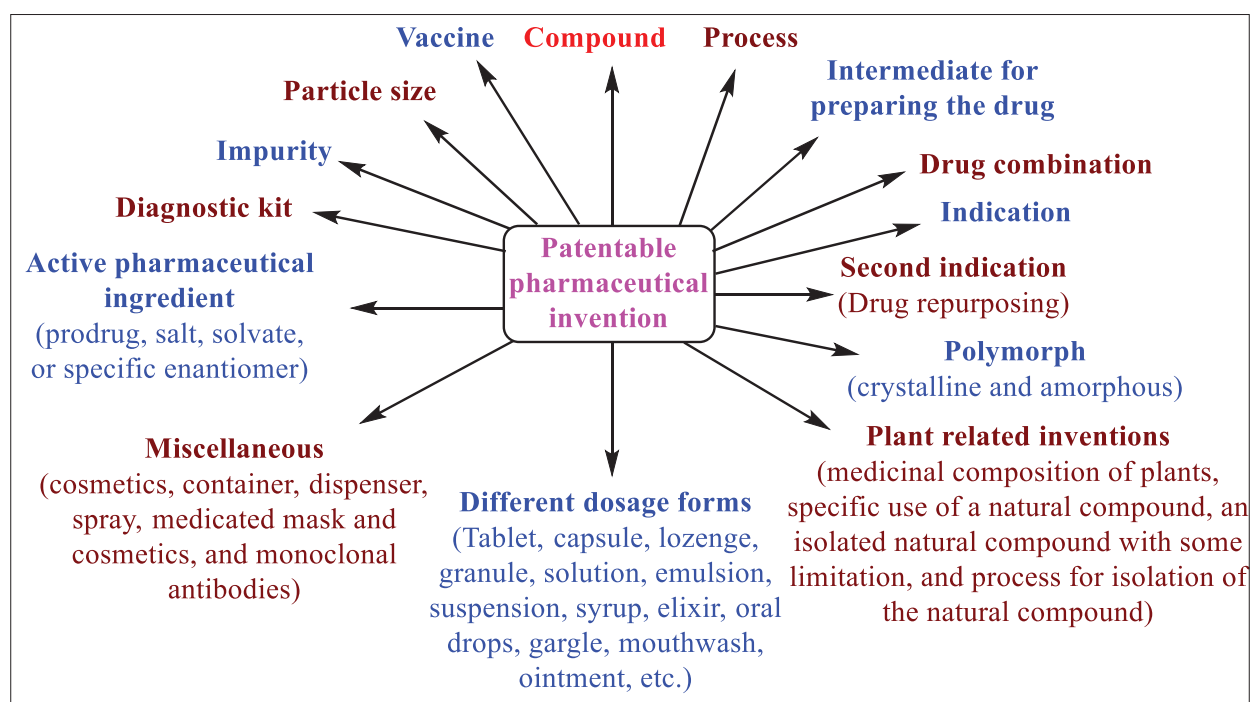


Figure 6: Important patentable pharmaceutical inventions

US10974049B1 (Artificial intelligence systems for quantifying movement disorder symptoms and adjusting treatment based on symptom quantification)	WO2020170165A1 (Use of artificial intelligence to identify novel targets and methodologies for skin care treatment)	US2022301676A1 (Artificial intelligence system for generating pharmaceutical intervention plans based on patient profiles)
KR101839730B1 (Artificial intelligence-based drug treatment system and method of providing drug therapy using the same)	WO2021234522A1 (Filtering artificial intelligence-designed molecules for laboratory testing)	WO2022245062A1 (Method and system for artificial intelligence-based genomic analysis and pharmaceutical substance development)

Figure 7: Artificial intelligence-based pharmaceutical patents/patent applications

on the patent for the public interest.^[138] Pharmaceutical innovators and private sector participation in innovation will be discouraged if they cannot protect inventions. This fact may affect public health and safety in the long term. Therefore, balancing medication access and protecting IPRs are essential.^[139,140]

Finally, the authors would like to highlight the patenting of artificial intelligence (AI)-based inventions. AI (machine learning; deep learning) is an emerging field expediting drug discovery.^[141-145] The AI-based tools reduce the time required for discovering and developing a drug. This helps early delivery of drugs for public health needs. AI-based tools have been employed for target identification and validation, compound screening, drug design, prediction of drug–drug interactions and adverse effects of a drug, clinical trial optimization, drug repurposing, pharmacovigilance, and development of precise medicines.^[142,144] A patent (an IP) is the creation of the mind, whereas AI tools use a computer. Still, AI-based inventions are also patentable if they satisfy the patentability criteria discussed above. Some examples of AI-based patents/patent applications are provided in Figure 7.^[146-151]

Accordingly, the authors trust that scientists developing AI-based pharmaceutical inventions have a great scope in protecting their work as patents.

CONCLUSION

Pharmaceutical research is costly and time-consuming. Patenting of pharmaceuticals is crucial to encourage inventors. The timely delivery of drugs to the public is also essential for the public interest. Most countries' patent laws balance the innovator's benefits and public interest, providing a two-fold benefit. In general, patented pharmaceuticals are expensive. However, the patent system accommodates public interest with provisions such as research exclusions, compulsory licensing, parallel imports, and limited monopoly provided to the patentee. Pharmaceutical technologies are developing at a good pace. All the developed pharmaceutical technologies will be patentable if they satisfy the patentability criteria.

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ETHICAL DISCLOSURE

None required.

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