3D PRINTING AND PHARMACEUTICAL PATENT INFRINGEMENT: EXAMINING LIABILITY FOR DIGITAL DESIGNS USED TO MANUFACTURE PATENTED MEDICINES

Shreyashi Singh, Bharati Vidyapeeth, New Law College, Pune

ABSTRACT

The increasing use of three-dimensional (3D) printing in pharmaceutical industry has sparked important legal concerns, especially regarding patent infringement. These concerns focus on whether the making, sharing, or distribution of digital designs that can be used to create patented medicines could lead to legal consequences. This article explores this issue in the context of the Indian Patents Act, 1970, with a specific look at Section 48. It examines the difference between digital designs and actual patented products, the possible responsibilities of third parties who support unauthorised production, and the shortcomings of the current legal system. By comparing Indian law with American and the European patent laws, the article investigates whether traditional patent principles are sufficient to handle the distinction between digital instructions and physical production. It suggests that sharing a digital file should not always be considered patent infringement. Instead, liability should be determined by the specific patent claims, the role of the digital file, the actions of the involved parties, and the relevant legal rules. The article supports a balanced approach that safeguards genuine pharmaceutical innovation while allowing for legal research, technological advancement, and access to essential medicines.

Keywords: Three-Dimensional (3D) Printing, Pharmaceutical Patent Infringement, Digital Designs, Computer-Aided Design (CAD) Files, Section 48, Indian Patents Act, 1970, Indirect Patent Infringement, Patent Liability, Comparative Patent Law, Access to Medicines.

1. INTRODUCTION

Three-dimensional (3D) printing, often referred to as additive manufacturing, is transforming how products are designed and made. Unlike traditional manufacturing, which relies on fixed production lines and established supply chains, 3D printing allows for the creation of physical objects directly from digital design data using suitable materials and equipment. Because these files can be sent electronically, the design[1] of a product can be separated from the actual production of the item. In the pharmaceutical field, this technology has the potential to enable customised dosages, improved drug release mechanisms, and medicines tailored to specific medical needs.[2]

The United States Food and Drug Administration's approval of Spritam (levetiracetam) in 2015 highlighted the practical potential of 3D printing in drug production.[3] However, the technology also introduces challenges regarding the enforcement of patent rights. Where a medicine can be created using digital instructions, the person who creates or shares these instructions may differ from the person who actually produces or supplies the final medicine. This separation leads to uncertainty about which actions might be considered an infringement and whether legal responsibility can extend beyond the individual who physically makes the medicine.

A major challenge is that a digital design and the medicine produced from it are not always the same in legal terms. A computer-aided design (CAD) file may describe the shape, size, or internal structure of a pill without including the actual drug composition that is protected by a patent. On the other hand, a digital file or set of instructions could be used to make a medicine that is covered by a patent. Therefore, simply creating, uploading, or sharing a file is not enough to determine the legal position. It is necessary to evaluate the patent claims, the role of the file, and the actions of those involved.

The issue becomes even more complex when multiple parties are involved. One person may create the file, another might distribute it online, a service provider could offer printing

[1] Auel, T., Mentrup, A. F. C., Oldfield, L. R., & Seidlitz, A. (2025). "3D printing of pharmaceutical dosage forms: Recent advances and applications." Advanced Drug Delivery Reviews, 217, 115504. https://doi.org/10.1016/j.addr.2024.115504. Reddy, D. P., & Sharma, V. (2020). "Additive manufacturing in drug delivery applications: A review." International Journal of Pharmaceutics, 589, 119820. https://doi.org/10.1016/j.ijpharm.2020.119820.

[2] M., Hatton, G. B., Gaisford, S., & Basit, A. W. (2015). "3D printing of modified-release aminosalicylate (4-ASA and 5-ASA) tablets." European Journal of Pharmaceutics and Biopharmaceutics, 89, 157–162. https://doi.org/10.1016/j.ejpb.2014.12.003.

[3] U.S. Food and Drug Administration, FDA Approves New Medication to Treat Partial Onset Seizures (2015).

facilities, and a manufacturer or healthcare provider could produce the medicine. When these activities occur in different countries, problems related to jurisdiction and applicable laws may arise. Therefore, legal analysis must differentiate between the making of a patented product, the use of a patented process, and the digital activities that might support either of these actions.

Existing scholarship explores the difficulties that digital design files pose for traditional patent infringement rules.[4] Research on 3D printing in healthcare has also looked into the connection between intellectual property protection, technological development, and access to medical technologies.[5] However, Pharmaceutical 3D printing needs careful attention to the specific subject matter of pharmaceutical patents. A file that only describes the shape of a tablet may bring up different legal concerns compared to one that includes technical instructions for making a patented medicine or carrying out a patented production method.

This article looks at the possible legal responsibilities that might come from creating, sharing, distributing, or using digital designs meant to produce patented medicines. It mainly focuses on the Indian Patent Act, 1970, particularly Section 48, and uses US law and the European approach to indirect infringement as reference points. The article argues that a digital file should not be automatically considered an infringing item just because it can help in manufacturing. Instead, the legal analysis should take into account the patent claims, the role of file, the actions of the involved parties, and a valid legal reason for liability. This method aims to safeguard genuine patent rights without unnecessarily limiting research, innovation, and access to medicines.

2. PHARMACEUTICAL 3D PRINTING AND THE LEGAL SIGNIFICANCE OF DIGITAL DESIGNS

2.1 Understanding the manufacturing process

3D printing builds a physical object layer by layer using digital data. In pharmaceutical uses, specific printing techniques and suitable materials can be used to make dosage forms with

[4] Timothy R. Holbrook & Lucas S. Osborn, Digital Patent Infringement in an Era of 3D Printing, 48 U.C. Davis L. Rev. 1319 (2015).
[5] Elton Gatt, Nicolette Sammut Bartolo & Lilian M. Azzopardi, A Systematic Review of 3D Printing of Pharmaceutical Drug Products: Barriers and Enablers, 227 European Journal of Pharmaceutics and Biopharmaceutics 115211 (2026), https://doi.org/10.1016/j.ejpb.2026.115211.

certain structures, strengths, or ways the drug is released. The technology can support tailored dosing and small-scale production, including making medicines closer to where they are needed.

The process may include several key parts: the pharmaceutical formulation, the digital design or manufacturing instructions, and the equipment and processes used to make the medicine. These parts might be controlled by different individuals. For instance, a pharmaceutical company might hold a patent on a formulation, a software developer might create the digital workflow, and a hospital or manufacturing site might use the printer.

This separation has legal importance. In a standard manufacturing setup, the organisation that makes the medicine usually controls the production and distribution. In a decentralised 3D-printing setup, the information needed for production might be sent separately from the materials and equipment used to manufacture the final product. The person who made it possible for production may therefore be different from the person who actually carries it out.

A review of pharmaceutical 3D printing highlights regulatory, technical, and ethical, legal, and social challenges affecting wider use of the technology.[6] These issues show that pharmaceutical 3D printing raises questions not only about how the medicine is made but also about the digital information and the various people involved in the process.

2.2 Digital designs as manufacturing instructions

A CAD file is a digital version of an object. Based on its content, it can describe the shape, dimensions, or internal structure of a product and may be turned into instructions that a printer can process. A file can be made, modified, saved, and shared without the actual physical object being created.

Nevertheless, its legal importance depends on its technical function. A file that only shows the outside shape of a tablet may lack the information needed to reproduce a patented pharmaceutical composition. A file that defines a structure or is a part of a manufacturing process may have a stringer connection to an invention. The analysis may vary depending on whether the patent covers a product, a formulation, or a manufacturing process.

[6] https://www.sciencedirect.com/science/article/pii/S0939641126002328?via%3Dihub

Patent protection is based on what is claimed in the patent, not every peice of information is linked with an invention. A file that can be used to make a medicine is not automatically the same as the patented medicine itself. Likewise, the fact that a file is intangible does not make its role in enabling production is legally unimportant.

Holbrook and Osborn examine this issue in their study of digital patent infringement.[7] They consider whether CAD files that allow the reproduction of patented physical objects should be addressed through current indirect-infringement principles or through theories of direct digital infringement. Their work offers a starting point, but pharmaceutical patents need a separate evaluation because the claimed invention may relate to a chemical composition, formulation, or process rather than the physical shape of an object.

2.3 The relationship between digital designs and pharmaceutical patents

Imagine a situation where a pharmaceutical company has a valid patent for a specific tablet information. A designer creates a digital file that outlines the tablet's shape and size and makes it available online. Another person downloads this file and uses a printer, suitable materials, and the necessary manufacturing information to produce a medicine. Three key questions emerge:

First, does the resulting medicine fall within the claims of the patent? If it does not, simply resembling the patented tablet does not automatically mean there is an infringement of the patent.

Second, if the medicine is covered by the patent, does its unauthorized production fall under the patent holder's exclusive rights under section 48 of the Indian Patents Act, 1970? If the legal requirements are met and there is no applicable authorization or exception, the manufacturer may be directly infringing the patent.

Third, does the designer or distributor face liability just for creating or supplying the file? This is a more complex issue. Liability cannot be automatically assumed because the file was used in the making of a patented product. The legal basis must be clearly identified, and the relevant elements must be confirmed under the applicable laws.

[7] Holbrook & Osborn (2015). "Digital Patent Infringement in an Era of 3D Printing." UC Davis Law Review, 48, 1319–1376. https://scholarship.law.campbell.edu/fac_sw/105/. Ebrahim (2016). "3D Printing: Digital Infringement and Digital Regulation." Northwestern Journal of Technology and Intellectual Property, 14, 37–80. https://scholarlycommons.law.cwsl.edu/fs/323/. (Osborn & Holbrook, 2015)

The main challenge is therefore to link digital actions to the specific invention protected by the patent without expanding the patent holder's rights beyond the legal scope of protection.

3. THE INDIAN PATENT FRAMEWORK: SECTION 48 AND THE LIMITS OF EXISTING RIGHTS

3.1 Rights conferred by Section 48

Section 48 of the Patents Act, 1970, explains the rights given to someone who holds a patent. For a product patent, the patent holder has the sole right to stop others from making, using, offering for sale, selling, or importing the patented product in India. For a process patent, the patent holder can stop others from using the patented process and from doing specific acts involving the product that comes directly from that process.[8] These rights serve as the basis for understanding how pharmaceutical 3D printing might relate to patent law. If a person makes a medicine that is covered by the claims of a valid Indian product patent, using a 3D printer does not automatically mean the activity is outside the scope of the patent. The key question is whether the final product falls within the patent claims, not whether it was made with traditional euipment or using additive manufacturing.

However, Section 48 does not clearly say that every act like creating, sharing, or distribution of a digital design that can make a patented product is an act of infringement. So when considering digital files under section 48, it is important to carefully review the patent claims and the actual actions taken.

For instance, a file that only describes the shape of a tablet might not include all the features of a patented medicines. If such a file is treated as the patented product, it could wrongly extend the patent protection beyond what was originally claimed. On the other hand, if a file has specific technical instructions designed to reproduce the claimed invention, distributing it may raise questions about whether the distributor's actions fall within a legal basis for liability.

The right approach is to clearly separate three things: the existence or transfer of a digital file, the actual making or using of the patented invention, and the actions of someone who may have helped in making or using the invention.

[8] The Patents Act, 1970, No. 39 of 1970, § 48 (India), available at https://www.ipindia.gov.in/acts/patent-act-1970/section-48.

3.2 The importance of patent claims

Patent claims set the boundaries of the invention that is protected. Therefore, they are essential in determining whether a medicine made through 3D-printed infringes a patent. A patent that covers a specific active pharmaceutical ingredient does not automatically cover every dose form that includes that ingredient. A patent focused on a particular formulation may not cover a different formulation that goes beyond the limits of its claims. Similarly, where a process is patented, it is necessary to check if the actual process used falls within the claims.

This distinction is important because 3D printing can be used to create new dosage forms from known pharmaceutical ingredients. The resulting medicine might be a patented invention, or it may not fall under the relevant patent.

In *Novartis AG v. Union of India*, the Supreme Court looked at Section 3(d) of the Patents Act and the conditions for patenting of a new form of a known substance, including the requirement of increased effectiveness.[9] However, this decision did not involve 3D printing or digital files. Thus, it should not be treated as authority for cases involving digital-file infringement. Its relevance is more limited: pharmaceutical patent protection depends on the statutory requirements and the invention claimed, not on the fact that the product is in a different form.

Therefore, using a new manufacturing method does not by itself prove either patentability or infringement. The outcome depends on the actual claims and the product or process involved.

3.3 Direct infringement and the digital file

Direct infringement is the most straightforward situation when someone physically makes or uses a patented product without permission. If the product falls under the claims of a valid patent, unauthorised production may fall within the exclusive rights of the patent holder under Section 48.

The situation is more complicated when someone only creates or shares a digital file. The file itself may not be the patented product but may help make it. Therefore, it's not safe to assume that sharing the file automatically means it is a direct infringement under Section 48.

[9] Novartis AG v. Union of India, (2013) 6 SCC 1.

This does not mean that digital files are never relevant to legal cases about infringement. Instead, the legal ground for the case must be identified, not assumed. Depending on the facts, the case may involve the scope of the claims, the use of a patented process, or whether the actions of a person who helped in making the product are covered by known legal principles.

The current legal structure raises an important issue that needs further clarification by the courts or legislature: how should responsibility be determined when digital instructions are shared before the actual patented physical product is created? Any solution must maintain the difference between actions that are clearly covered by the law and other types of liability that need a separate legal foundation.

4. DIGITAL-FILE DISTRIBUTION AND THE PROBLEM OF INDIRECT INFRINGEMENT

4.1 Why indirect infringement matters

Direct infringement involves unauthorised actions related to a patented item or method. Indirect-infringement comes into play when someone does not personally carry out the final infringement but instead helps or provides tools that allow another person to do so. In the case of pharmaceutical 3D printing, a digital file can link the patented invention to the individual who eventually produces it. The designer might not own a printer, the distributor might not provide pharmaceutical materials, and the manufacturer could have no direct link to the patent owner. Despite this, the file can still play a major role in enabling production process.

The legal challenge lies in determining when such assistance is closely enough linked to infringement to justify holding someone accountable. A rule that covers every file that could be used to make a patented product might limit lawful research, education, and general technical services. On the other hand, excluding digital files from legal consideration in all cases could make it hard to deal deliberate attempts to support unauthorised manufacturing.

A balanced approach must therefore differentiate between the technical abiliuty of a file, how it is actually used, and the legal standards for holding the person who provided it responsible.

4.2 The United States approach

United States patent law offers a helpful comparison because 35 U.S.C. § 271 outlines several

types of infringement. Section 271(a) deals with unauthorised production, use, offer to sale, selling, or importation of a patented invention. Section 271(b) addresses active inducement of infringement, while Section 271(c) addresses certain supplies of components or materials that satisfy the statutory requirements for contributory infringement.[10]

These provisions recognise that liability may, in specified circumstances, extend beyond the person who physically manufactures the patented product. However, they do not establish that every digital file used in an infringing process is automatically actionable. The requirements of the relevant provision must still be met, including the need for an underlying infringing act where required and the applicable conditions concerning the defendant's conduct and knowledge.

A person who actively encourages another to manufacture a patented medicine without authorisation may present a different case from a software provider that supplies a general-purpose tool with substantial lawful uses. Similarly, a file designed specifically to facilitate a particular infringing act may raise different issues from a platform that neutrally hosts a wide range of user-generated designs.

The US framework is therefore useful for identifying possible approaches to secondary liability. It cannot, however, be imported directly into Indian law without an independent legal basis.

4.3 The Indian position and the need for clarity

The Indian Patents Act does not set out a separate, comprehensive statutory regime for inducement and contributory infringement in the same express terms as 35 U.S.C. § 271(b) and (c). This creates uncertainty when a person facilitates infringement without personally carrying out the acts specified in Section 48.

That uncertainty should not be resolved by automatically treating digital-file distribution as infringement. Nor should it be assumed that a person who knowingly and deliberately facilitates unauthorised manufacture can never be held responsible under any applicable legal principle. The relevant statutory provisions, claims, facts, and available causes of action must be

[10] 35 U.S.C § 271(a)-(c), available at https://www.law.cornell.edu/uscode/text/35/271.

examined carefully.

A clearer framework could distinguish deliberate assistance directed towards a specific infringing act from the ordinary provision of technology that has substantial lawful applications. Such clarification would help balance patent enforcement with legitimate innovation. Until the legal position is authoritatively clarified, however, proposed approaches to secondary liability should be described as questions for interpretation or reform, rather than as settled Indian law.

5. ASSESSING LIABILITY ACROSS THE DIGITAL MANUFACTURING CHAIN

5.1 The digital-design creator

A designer may create a digital file for education, research, product development, or authorised manufacture. The act of creating a design should not, by itself, establish patent infringement merely because the design resembles a patented medicine.

A different question arises where a designer knowingly creates a file specifically intended to reproduce a patented pharmaceutical product without authorisation and supplies it to facilitate that manufacture. The designer's role may become relevant to an applicable claim, depending on the patent claims, the conduct involved, and the legal basis relied upon.

The analysis must remain claim-based. A file describing only a tablet's shape may not reproduce a patented composition. A file that forms part of a process specifically designed to produce the claimed invention may raise a different issue. Intention may be relevant to certain forms of secondary liability, but intention alone cannot replace the legal elements required to establish liability.

5.2 The person distributing the file

A distributor may make a digital design available to many users, potentially enabling repeated manufacture of a patented product. This raises a legitimate concern that the economic value of patent protection may be undermined where digital distribution enables unauthorised production.

Nevertheless, distribution should not automatically be treated as infringement. A file may have substantial non-infringing uses, may not reproduce the claimed invention, or may be distributed under a valid licence. Relevant considerations include the content and technical function of the file, the purpose and circumstances of distribution, the distributor's conduct, and the applicable law.

The legal distinction should be between the neutral distribution of information and conduct that satisfies the requirements of a recognised form of infringement or other legally established liability.

5.3 Online platforms and intermediaries

Online platforms may enable digital designs to be distributed across borders. Some platforms merely host files uploaded by users, while others may select, modify, promote, or actively distribute particular designs. Their role should be examined on the facts rather than assumed solely from the presence of a file on the platform.

India's information-technology framework may be relevant to intermediary responsibilities, but intermediary status does not by itself resolve every patent-infringement question. Equally, the upload of a file by a user should not automatically make a platform liable for patent infringement.

Any proposed framework should distinguish neutral hosting from active participation in conduct that facilitates a specific infringing act. Questions of knowledge, participation, and response to credible complaints may be relevant, but they must be considered within the applicable statutory framework. This approach would address deliberate facilitation without imposing indiscriminate liability on all digital platforms.

5.4 Software developers and printer manufacturers

Software developers and printer manufacturers provide tools that may be used for lawful or unlawful purposes. A printer may be used to manufacture a licensed medicine, a non-patented formulation, a research prototype, or a product that potentially infringes a patent.

The supply of general-purpose equipment should not ordinarily be equated with participation in every infringement committed by a user. A different question may arise where a supplier

knowingly configures or promotes a system to facilitate a particular infringing activity, provided that the elements of an applicable legal basis for liability are satisfied.

Patent infringement must also be distinguished from manufacturing defects. An inaccurate digital design or faulty printer may result in an unsafe medicine, but that fact does not automatically establish patent infringement. It may instead raise questions of regulatory compliance, contractual responsibility, professional duties, or product liability.

5.5 Pharmacies, hospitals, and healthcare professionals

Pharmacies and hospitals may use 3D printing to produce medicines suited to individual patients. A clinical purpose does not automatically exempt the activity from patent law, but it is relevant to the broader policy debate.

The legal questions include whether the medicine falls within a valid patent claim, whether the institution is authorised to manufacture it, and whether a statutory exception applies. Patient-specific production should not be presumed to be infringing in every case, but it should not become a blanket justification for systematic unauthorised commercial manufacture.

A balanced framework should allow legitimate clinical and research activity within the limits of applicable law, while maintaining appropriate safeguards for patent rights, medicine quality, and patient safety.

6. PATENT EXCEPTIONS, RESEARCH, AND ACCESS TO MEDICINES

Patent protection and public health are not necessarily opposing objectives. Exclusive rights may encourage investment in drug discovery, formulation development, and manufacturing. At the same time, uncertainty or excessively broad enforcement may obstruct legitimate research, personalised treatment, and access to medical technologies. Research on 3D printing during the COVID-19 pandemic has examined the relationship between intellectual property protection and access to essential healthcare technologies, including medical equipment and replacement parts. This literature is relevant to the broader policy debate, but it should not be treated as direct authority establishing that pharmaceutical 3D printing is exempt from patent infringement. The legal treatment of medical devices and replacement parts may differ from that of patented pharmaceutical compositions.

6.1 Research and experimental use

Research involving a patented medicine or a printing technique may serve legitimate scientific purposes. However, the existence of a research objective does not automatically place every activity outside patent law.

Section 107A of the Patents Act provides a limited exception for specified acts involving patented inventions that are reasonably related to the development and submission of information required under laws regulating products.[11] The provision must be applied according to its language and does not establish a general exemption for every form of pharmaceutical research or 3D printing.

Clear guidance on the boundary between permitted research and unauthorised manufacture would assist researchers, pharmaceutical developers, and healthcare institutions in determining when additional authorisation may be necessary.

6.2 Private and non-commercial activity

Private and non-commercial use raises a further question. An individual may use a printer for a limited personal purpose, while another person may distribute the same design widely or operate a service producing patented products for multiple customers. These activities may differ significantly in scale, purpose, and commercial impact.

The European framework provides a comparative example. Article 27 of the Agreement on a Unified Patent Court identifies certain exceptions to patent rights, including acts done privately and for non-commercial purposes.[12] This provision does not automatically apply in India and should not be presented as a rule of Indian patent law.

The broader policy question is whether carefully defined exceptions could protect certain limited non-commercial activities without creating a route for widespread commercial substitution. In the pharmaceutical context, any such approach would also need to consider patient safety, medicine quality, and applicable regulatory requirements.

[11] The Patents Act, 1970, No. 39 of 1970, § 107A (India).
[12] Agreement on a Unified Patent Court, art. 27(a) (exceptions to the rights conferred by a patent), https://www.unifiedpatentcourt.org/en/court/legal-documents.

6.3 Compulsory licensing and public-health flexibility

India's compulsory-licensing framework provides a mechanism for addressing specified public-interest concerns. Section 84 of the Patents Act allows an application for a compulsory licence on statutory grounds, including where the reasonable requirements of the public have not been satisfied, the patented invention is not available at a reasonably affordable price, or the patented invention is not worked in India, subject to the statutory conditions.[13]

In *Bayer Corporation v. Union of India*, the Bombay High Court considered issues arising from the compulsory licence granted to Natco in relation to Bayer's patented cancer medicine sorafenib tosylate.[14] The dispute illustrates the role of statutory public-interest considerations in pharmaceutical patent law.

The Doha Declaration on the TRIPS Agreement and Public Health also recognises the importance of interpreting and implementing the TRIPS Agreement in a manner supportive of public health and access to medicines.[15]

These mechanisms do not create a general right to manufacture patented medicines through 3D printing without permission. Rather, they demonstrate that public-health concerns should be addressed through legally recognised mechanisms. Access to medicines should not automatically excuse infringement, but patent enforcement should not be considered in isolation from legitimate public-health objectives.

7. COMPARATIVE ANALYSIS: THE UNITED STATES AND EUROPE

The United States and European approaches offer useful insights into the legal treatment of digital designs, although neither is binding authority in India.

United States law expressly addresses direct infringement, active inducement, and contributory infringement under 35 U.S.C. § 271. This provides a statutory basis for addressing certain conduct by parties who facilitate another person's infringement. However, the existence of these provisions does not mean that every digital file, printer, or software product used in an

[13] The Patents Act, 1970, No. 39 to 1970, § 84 (India).
[14] Bayer Corporation v. Union of India, AIR 2014 Bom 178.
[15] World trade Organisation, Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2 (Nov. 14, 2001).

infringing activity automatically attracts liability. The statutory requirements must be satisfied.

The European framework raises a related question. Article 26 of the Agreement on a Unified Patent Court addresses the supply of means relating to an essential element of a patented invention, where the supplier knows or should know that those means are suitable and intended for putting the invention into effect. [16]In the context of digital manufacturing, an important question is whether a particular CAD file can qualify as such a means. The answer depends on the nature of the file and the legal requirements of the provision; it should not be assumed that every digital design falls within it.

The comparative academic literature on 3D printing identifies separate activities in the digital manufacturing chain: creating or uploading a design, distributing or downloading it, and physically producing the patented product.[16] It also highlights the difficulty of enforcing territorial patent rights when these activities occur in different jurisdictions. This literature helps identify the legal problem, but scholarly analysis should be distinguished from binding legal authority.

Three lessons emerge from the comparison. First, the law should clarify the circumstances in which a digital design may be relevant to the facilitation of patent infringement. Second, it should distinguish deliberate assistance from neutral distribution of technology with legitimate uses. Third, it should provide a clearer basis for analysing liability when digital distribution and physical manufacture occur in different locations. The appropriate lesson is not that India should simply copy the US or European approach. Rather, the separation between digital instructions and physical production requires careful legal treatment. Any Indian response should be grounded in the structure of the Patents Act and should clearly distinguish established statutory rights from proposed reforms.

8. CRITICAL ANALYSIS AND RECOMMENDATIONS FOR LEGAL REFORM

The preceding analysis reveals a distinction between the legal position concerning the physical manufacture of a patented medicine and the uncertainty surrounding digital files distributed before manufacture. Section 48 provides a basis for addressing unauthorised acts involving a patented product or process where the statutory requirements are met. The more difficult

[16] Agreement on a Unified Patent Court, art. 26.

question is how the law should address persons who create or distribute digital means that facilitate manufacture.

Treating every digital file as infringing would risk extending patent rights beyond the invention actually claimed. It could also create uncertainty for researchers, educators, platforms, and suppliers of general-purpose technology. Conversely, refusing to consider the role of digital files in every case could make it difficult to address deliberate attempts to facilitate unauthorised manufacture.

The appropriate response is targeted clarification rather than an unlimited extension of patent rights.

8.1 Clarify the relationship between digital files and patent claims

The law or authoritative guidance should clarify that the mere existence or transfer of a digital design does not automatically establish infringement. The analysis should consider the scope of the patent claims, the technical content and function of the file, and its relationship to the claimed invention.

Where a file describes only the external shape of a tablet, it should not automatically be treated as the patented pharmaceutical composition. Where a file is specifically configured to reproduce the claimed invention, its role may require closer legal examination. In either case, the patent claims must remain the starting point.

8.2 Clarify liability for deliberate facilitation

The law should clarify the circumstances in which a person who knowingly and purposefully facilitates unauthorised manufacture may incur liability. Any proposed rule should distinguish deliberate assistance from the ordinary supply of general-purpose printers, software, or technical information.

Knowledge and the nature of a defendant's participation may be relevant, but they should not replace the need to establish the elements of an applicable legal basis for liability. If legislative reform is considered necessary, it should define the required connection between the defendant's conduct and the infringing act, together with appropriate limits and safeguards.

8.3 Preserve legitimate research and non-infringing uses

Existing statutory exceptions should remain available within their lawful scope. Section 107A should be applied according to its terms, and any further exception for research or non-commercial activity should be carefully defined.

The objective should be to avoid unnecessary barriers to legitimate research and patient-specific treatment without creating an unrestricted route for unauthorised commercial production of patented medicines. Any proposed exception should also be considered alongside medicine-quality and safety requirements.

8.4 Encourage licensing and authorised digital workflows

Voluntary licensing can provide a practical route for authorised pharmaceutical 3D printing. A licence may specify which digital designs may be used, which equipment and materials are permitted, what quality-control procedures must be followed, and which institutions may manufacture the medicine.

Such arrangements may enable patent holders to protect their commercial interests while permitting authorised use in hospitals, pharmacies, and research settings. They may also clarify the responsibilities of designers, technology suppliers, and manufacturers. Licensing is not a complete substitute for legal clarification, but it can reduce uncertainty in particular settings.

8.5 Improve accountability without confusing legal responsibilities

Patent infringement, medicine quality, and professional responsibility are related but distinct issues. A person may be authorised to use a patented technology but manufacture an unsafe medicine. Conversely, a medicine may meet applicable quality standards while still infringing a patent.

A sound framework should therefore distinguish patent liability from regulatory and professional responsibility. Traceability of digital designs, manufacturing parameters, materials, and final products may support accountability, but it should not replace the legal test for infringement.

8.6 Maintain public-health flexibility

Where access concerns arise, existing statutory mechanisms, including compulsory licensing where the legal requirements are satisfied, should remain available. At the same time, access to medicines should not be treated as an automatic defence to every infringement claim.

The objective should be a proportionate framework that protects genuine pharmaceutical innovation while allowing legitimate research and clinically justified uses within the limits of applicable law. The legal framework should respond to demonstrated problems

without presuming that every participant in the digital manufacturing chain is an infringer.

Taken together, these recommendations seek to reduce uncertainty surrounding digital-file liability while preserving the distinction between existing law and proposed reform. The central objective is to make the legal treatment of digital pharmaceutical manufacturing more predictable without extending patent protection beyond its justified scope.

9. CONCLUSION

Pharmaceutical 3D printing challenges conventional patent enforcement because it separates the digital information used to manufacture a medicine from the physical medicine itself. A design can be created and distributed before a product exists, while the eventual manufacture may be undertaken by a person who has no direct relationship with the designer or the patent holder. This separation creates uncertainty about the relevant infringing act and the responsibility of each participant.

Indian patent law provides a basis for addressing unauthorised acts involving patented products and processes. Where a 3D-printed medicine falls within the claims of a valid patent, the use of additive manufacturing does not automatically remove it from the scope of patent protection. The more difficult issue concerns the creation or distribution of digital designs before the physical medicine is produced.

The appropriate conclusion is neither that every digital file constitutes infringement nor that digital distribution can never attract liability. The analysis must depend on the patent claims, the technical function of the file, the conduct of the person involved, and the applicable legal framework. The liability of designers, distributors, platforms, software developers, and

manufacturers should be assessed individually rather than presumed merely from their participation in the manufacturing chain.

The comparative analysis demonstrates the value of clearer rules concerning certain forms of facilitation, while also highlighting the danger of expanding patent liability without adequate limits. Public-health considerations further show why legitimate research, personalised treatment, and access to healthcare technologies should be considered when developing a legal response. These considerations, however, do not automatically exempt pharmaceutical 3D printing from patent law.

Ultimately, the challenge is to align patent enforcement with the realities of digital manufacturing. A balanced framework should protect genuine pharmaceutical innovation, address deliberate facilitation of unauthorised manufacture where the law

permits, and preserve legitimate research and treatment. Greater clarity on digital-file liability would improve predictability while reducing the risk that legal uncertainty becomes an unnecessary barrier to technological development and access to medicines.

REFERENCES:

Legislation and international instruments

- The Patents Act, 1970 (India), §§ 48, 84 and 107A.
- 35 U.S.C. § 271.
- Agreement on a Unified Patent Court, arts. 26–27.
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 30.
- World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (2001).

Cases

- *Novartis AG v. Union of India*, (2013) 6 SCC 1.
- *Bayer Corporation v. Union of India*, AIR 2014 Bom 178.
- *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000).

Secondary sources

- Timothy R. Holbrook & Lucas S. Osborn, *Digital Patent Infringement in an Era of 3D Printing*, 48 U.C. Davis L. Rev. 1319 (2015).
- Gatt, Sammut Bartolo & Azzopardi, *A Systematic Review of 3D Printing of Pharmaceutical Drug Products: Barriers and Enablers*, European Journal of Pharmaceutics and Biopharmaceutics 227 (2026), article 115211, https://doi.org/10.1016/j.ejpb.2026.115211.
- Sagili et al., *Intellectual Property Issues in Pharmaceutical 3D Printing*, in *Precision 3D Printing in Pharmaceutical Sciences* (2025), https://doi.org/10.1002/9781394337576.ch11.
- Anuja Saraswat, *3D Printing in Pharmaceutical Industry*, IIPRD (Apr. 8, 2022), https://www.iiprd.com/3d-printing-in-pharmaceutical-industry/.