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BANGLADESH'S PATENT ACT– ALIGNING WITH GLOBAL STANDARDS OR FALLING SHORT? A COMPARATIVE STUDY

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Abstract: The Bangladesh Patents Act 2023 marks a pivotal reform in the nation's intellectual property framework, replacing outdated laws to align with modern standards. This research provides a comparative analysis of the Act, focusing on its potential to foster innovation while safeguarding public interests. The study identifies strengths and limitations in the legislation by comparing Bangladesh's framework with the patent systems of India, the United Kingdom, Australia, Pakistan, and the United States.

Key provisions, including patentable subject matter, compulsory licensing, and patent duration, are assessed against international best practices. The analysis highlights the Act's emphasis on novelty, inventive steps, and industrial applicability while identifying gaps such as insufficient safeguards against "evergreening" and weak procedural mechanisms for opposition.

Although the Act introduces measures to address public health concerns and support innovation, its implementation and institutional capacity remain challenges. This article argues that stronger compulsory licensing frameworks, enhanced opposition procedures, and stricter patentability criteria are crucial. It concludes with recommendations to reform Bangladesh's patent system, ensuring it supports economic growth, public health, and global competitiveness.

Keywords: Bangladesh Patents Act 2023; Intellectual property rights; Comparative patent analysis; Patent law reform; Innovation and public health; Compulsory licensing

1 INTRODUCTION

Intellectual Property Rights (IPRs) are fundamental to fostering innovation, as they grant creators and inventors exclusive control over their inventions and creative works, allowing them to benefit commercially from their ideas. Patents, one of the primary types of IPR, provide inventors with a temporary monopoly over the production, use, or sale of their innovations. This exclusivity encourages investment in research and development (R&D) by offering a legal framework that protects against unauthorized use or duplication by competitors. For many businesses, particularly those in technology, pharmaceuticals, and agriculture, patents serve as a crucial incentive, ensuring that R&D efforts have the potential for returns on investment. This incentive structure also drives competition and collaboration in the marketplace as firms strive to improve upon existing technologies or develop new ones, fueling ongoing advancements in science and technology.

Furthermore, patents have a significant role in economic growth. Studies have shown that companies holding IP rights, especially small and medium enterprises (SMEs), experience higher revenue and growth compared to those without such protections. By allowing companies to secure and commercialize their technological advancements, IPRs benefit individual inventors and contribute to broader economic development by promoting a continuous culture.

This article presents a comparative analysis of the Bangladesh Patent Act, 2023, alongside the patent laws of India, the United Kingdom, Australia, and the United States. It examines key aspects such as patentability criteria, compulsory licensing, and patent duration to assess the Act's alignment with global standards. The analysis aims to identify strengths and gaps in the legislative framework, offering insights into whether Bangladesh's patent regime effectively supports innovation goals while adhering to international best practices.

1.1 Bangladesh's Transition to the Patents Act, 2023

Bangladesh's patent legislation has undergone significant reform over recent years, aligning it more closely with global IP standards. The original *Patents and Designs Act, 1911* (Act No. II of 1911) governed patents and designs for decades, until the enactment of the *Patents Act, 2022* (Act No. V of 2022), which repealed the 1911 law to establish a modernized patent framework. However, to further refine and improve the patent system, the *Patents Act, 2023* (Act No. 53 of 2023) was introduced, repealing the 2022 Act and thereby solidifying the legal infrastructure to support innovation and compliance with international standards better, particularly the TRIPS Agreement.

2 RESEARCH METHODOLOGY

The research methodology employed in this study is a doctrinal comparative approach [1], which analyzes the legal frameworks governing patent systems in multiple jurisdictions to evaluate the strengths and weaknesses of The Bangladesh Patent Act, 2023. This methodology integrates qualitative legal analysis with theoretical evaluation to provide a comprehensive understanding of how the Act aligns with international standards and practices.

The study is structured as a comparative legal analysis, focusing on the patent laws of Bangladesh, India, the United Kingdom, Australia, Pakistan, and the United States. By examining these jurisdictions, the research identifies key areas where Bangladesh's patent law aligns with or diverges from international norms, with a particular emphasis on TRIPS compliance.

The research relies on primary and secondary legal sources:

- Primary Sources: Statutory texts, including the Bangladesh Patents Act, 2023; India's Patents Act, 1970; the UK Patents Act, 1977; the Australian Patents Act, 1990; the Patents Ordinance, 2000 (Pakistan); and the America Invents Act (AIA, 2011).
- Secondary Sources: Scholarly articles, case law, international legal instruments such as the TRIPS Agreement, official reports from organizations like WIPO and WTO, and legal commentaries, accessed through trusted databases.

3 KEY PROVISIONS IN BANGLADESH'S PATENTS ACT, 2023

The Patents Act, 2023, of Bangladesh aligns the country's patent provisions with international intellectual property standards. This summary highlights key aspects, including patentable subject matter, application processes, patent duration, rights, exceptions, and international patents.

3.1 Patentable Subject Matter

The 2023 Act defines patent eligibility criteria to align with global standards while retaining certain exclusions unique to Bangladesh's legal framework and public policy.

3.1.1 Entitlement to apply for a patent (Section 4)

Eligible applicants include:

a) The original inventor, their assignee, or legal representative.

b) Joint inventors with shared patent rights.

c) The first applicant in cases of identical independent inventions.

d) Employers, when inventions arise from employment contracts or use of company resources (unless otherwise specified).

e) Patent rights may be transferred or inherited.

3.1.2 Exclusions (Sections 6 &7)

The Act excludes certain categories from patentability, such as:

a) Scientific Discoveries & Methods: Including scientific principles, theories, mathematical methods, and business methods.

b) Medical Processes: Methods of treatment or diagnostics applied to humans or animals.

c) Biological & Natural Resources: Plants, animals, biological resources in nature (unless artificially modified microorganisms).

d) Morality & Public Order: Inventions harmful to public order, morality, or health.

e) Traditional Knowledge: Combinations based solely on traditional knowledge or known properties.

f) Frivolous or Simple Arrangements: Inventions that lack technical interaction, such as mere aggregations of known elements.

g) Artistic & Informative Works: Including artistic works, broadcasts, and purely informational descriptions.

h) Atomic Energy: Inventions related to the production or control of atomic energy are non-patentable.

i) *Additional TRIPS Council Exclusion*: Patents on pharmaceutical and agrochemical products remain excluded as per TRIPS Council decisions, with government discretion for timeframe adjustments.

3.2 Application Process and Formalities

The Act details a structured application process with specific requirements for granting patents, which is overseen by the Department of Patents, Industrial Designs, and Trademarks (DPDT).

3.2.1 Authority (Section 3): The DPDT is the certifying body for patents, responsible for examining, granting, and maintaining patents. This centralization aims to ensure consistency and efficiency in patent registration.

3.2.2 Filing the Application (Section 8)

a) Single Application: Each invention requires a separate application, filed with the Department of Patents on the prescribed form.

b) Details and Documentation:

- Applicant and inventor information, with a declaration if the applicant is not the original inventor.
- Power of Attorney (for applications via representatives) and assignment documentation if rights are transferred.
- Certified copy for priority claims, if applicable.

c) Specifications:

- Either a provisional or complete specification can be filed initially; a complete specification must follow within 12 months if a provisional was filed.

- The complete specification must include a detailed description, the best-known method of performing the invention, precise claims, and a summary limited to 300 words, along with diagrams if required.

3.2.3 Publication (Section 17)

a) The application is published for public inspection 18 months after filing, including details like the inventor's and applicant's information, title, classification, and summary.

b) Early publication can be requested with a fee, but the application remains confidential until officially published.

3.2.4 Pre-grant opposition (Section 19)

a) Within six months following publication, any interested party may oppose the patent before it is granted, citing grounds like prior public knowledge, lack of novelty, insufficient disclosure, or non-patentable subject matter.

b) The Director-General conducts a hearing, allowing both the applicant and opponent to present evidence. Decisions may include rejection, modification, or continuation of the application.

3.2.5 Post-grant opposition (Section 20)

a) After a patent is granted and published, interested parties have 24 months to oppose it by filing a notice with supporting evidence.

b) Grounds for post-grant opposition are similar to pre-grant, including issues like prior public knowledge, non-patentable claims, and incomplete disclosure.

c) The DG issues a notice of opposition, conducts a hearing, and makes a decision based on evidence. Both parties are informed within one month whether the patent is upheld, amended, or revoked.

3.2.6 Withdrawal and reapplication (Section 10)

a) Applicants can withdraw their application at any point before the grant.

b) If withdrawn before publication, without priority claims or ongoing proceedings, the applicant may reapply for the same invention, though priority from the first application cannot be claimed.

3.3 Patent Duration and Maintenance

The Act specifies the duration of patents and establishes rules for maintaining patent rights through renewals.

3.3.1 Duration of Patent (Section 28)

A patent remains valid for up to 20 years from the filing date or, if applicable, the priority date, as long as it does not expire or lose effectiveness earlier [2]. A patent can be renewed by paying the annual fee. The renewal process requires the fee of the preceding year to be paid in order to renew the patent for the following year [3].

3.3.2 Provisions for Expiration

a) If the renewal fee is not paid within the prescribed period (including any extended time), the patent's effectiveness will be canceled [4].

b) If the renewal fee is not paid within the given time (or extended time), the patent holder will lose their rights to the subject matter of the patent [5].

c) If the renewal fee is not paid on time, but the patent holder has a reasonable justification for the delay, they may apply for restoration of the patent within 2 years of the renewal deadline by paying the necessary renewal and restoration fees [6].

3.4 Rights and Obligations of Patent Holders

The 2023 Act outlines a range of exclusive rights granted to patent holders along with certain obligations.

3.4.1 Exclusive rights (Sections 25):

The patent holder has exclusive rights to-

a) For Products: The patent holder has the exclusive right to prevent third parties from producing, using, selling, offering for sale, or importing the patented product in Bangladesh without permission.

b) For Processes: The patent holder has the exclusive right to prevent third parties from using, offering, selling, or importing products produced using the patented process without consent.

3.4.2 Transferability and Licensing (Section 31):

The original patent holder may choose to transfer their rights to another party. This could happen through an assignment of the patent, where the ownership of the patent is transferred permanently to another entity or individual.

a) The ownership of the patent or any changes in its application must be recorded in writing and submitted to the Director-General's office.

b) This change will only be effective after being publicly notified on the website or through other means by the Director-General.

c) Until such a record is made, the change will not be effective against third parties.

3.4.3 Licensing agreements (Section 31 (2)):

Any patent-related license agreement must be submitted to the Director-General. The content of such agreements will remain confidential, and they will not be effective against third parties until recorded.

3.5 Exceptions and Limitations

The Act includes several important exceptions to the exclusive rights of patent holders.

3.5.1 Compulsory licensing (Section 36):
Under specific circumstances, the government can issue compulsory licenses for patented inventions without the patent holder's consent. This includes cases where:
a) Public Interest - For national security, nutrition, health, or economic development.
b) Anti-Competitive Practice - When the court or executive authority finds the invention's use anti-competitive by the patent holder or licensee. Explanation: Includes abuse of dominant position or refusal to license on reasonable terms.
c) Abuse of Exclusive Rights - When the patent holder abuses their exclusive rights. Explanation: Includes: failing to meet reasonable public demand; making the invention unaffordable for the public; failing to enable local use without imports and failing to prove feasibility for partial or full local production.
d) Subsequent Patent Dependency - When a second patent depends on a prior patent and cannot be practiced without it, if the second patent has significant economic and technical advancement.
e) Denial of License without Justified Reason - When the patent holder refuses to grant a license within four months without a valid reason.
f) Essential Services and Combinations - To ensure access to essential services, including fixed-dose combination medicines for production and distribution.
3.5.2 Government use (Section 40):
Even after the patent is granted, the government can use a patented invention for public purposes, including public health, nutrition, and environmental needs. This includes addressing high prices and ensuring access to essential medicines. Individuals can apply to the government, which must make a decision within 60 days following a hearing with the patent holder. The government may grant permission for the production, use, or sale of the invention or import-related equipment or pharmaceuticals. The patent holder is entitled to fair compensation, up to 4% of the net sales.
3.5.3 Exceptions to patent rights (Section 62):
The following activities are exempt from the application of patent rights:
a) Personal or Non-Commercial Use: Activities performed for personal or non-commercial purposes are exempt from patent infringement.
b) Educational, Testing, or Research Purposes: Activities carried out for educational, experimental, or research purposes do not violate patent rights.
c) Medical Preparations: Work conducted in pharmacies or by medical professionals to prepare medicines as prescribed by doctors is not covered by patent rights.
d) Pre-Application Activities: Actions performed in good faith before the filing of a patent application or, if priority is claimed, before the date of the application, are exempt from patent rights.
e) Use by Foreign Transport: Temporary use of patented inventions on foreign vessels, aircraft, or vehicles operating within Bangladesh is exempt from infringement.

3.6. Cancellation and Revocation of Patents

3.6.1 Cancellation
Under Section 32, any interested party can apply to the court to cancel a patent if it fails to meet the requirements of Sections 8(3) and (4), or if the patent holder is not the actual inventor or successor. The court may cancel specific claims or transfer ownership in disputes. The Director-General must be notified of the final decision, and patent holders can apply for cancellation or withdrawal.
3.6.2 Revocation
Section 33 of the Act outlines grounds for patent revocation by the District Court, including prior valid claims, improper entitlement, non-patentability, lack of novelty, inoperability, insufficient disclosure, or misrepresentation of biological sources. Patents may also be revoked if they replicate indigenous knowledge. Notices must be issued to relevant patent holders as per the Director-General's requirements.
3.6.3 Public interest revocation
Section 34 empowers the government to revoke patents if they threaten public health or public interest. The patent holder is granted a hearing opportunity before the government issues a revocation declaration in the official gazette, which immediately renders the patent null and void.

4 INTERNATIONAL COMPARISON AND ANALYSIS

4.1 India

4.1.1 Patentable subject matter
The Indian Patents Act, 1970 [7], which was significantly amended in 2005, outlines strict guidelines for patentable inventions, particularly when it comes to pharmaceutical products. Section 3(d) of the Act is one of the most crucial aspects of Indian patent law, as it specifically addresses incremental innovations in the pharmaceutical sector. This section prohibits the patenting of new forms of known substances unless they demonstrate a significant enhancement in efficacy. This clause effectively prevents the practice known as "evergreening," which involves making slight modifications to existing drugs to extend their patent life, a common practice in the pharmaceutical industry that could otherwise lead to higher prices for consumers.

India's application of Section 3(d) reflects its public health-centered intellectual property (IP) policy, aimed at ensuring that essential medicines remain affordable and accessible to the population. For example, in the case of the *Novartis AG v. Union of India* (2013), the Supreme Court of India upheld the denial of a patent for the beta crystalline form of imatinib mesylate, a cancer drug, on the grounds that the new form did not demonstrate any significant therapeutic efficacy over the existing version. India's position is clear: public health needs take precedence over patent monopolies.
In addition to Section 3(d), the Patents Act also includes provisions for expedited examination (Rule 24 of the Patents Rules, 2003), allowing applicants to fast-track the examination process for certain patent types. This is designed to reduce delays in the patent process, enhancing the efficiency of the system for both applicants and the public.

4.1.2 Compulsory licensing

The Indian Patents Act includes a significant provision for compulsory licensing, as outlined in Sections 84 to 92A. This mechanism allows the government to grant a license to produce and sell a patented product without the patent holder's consent under specific conditions. It is particularly vital in the pharmaceutical sector, enabling the government to ensure access to essential medicines during public health crises, especially when patented drugs are unaffordable or in short supply.
In 2012, India made headlines by granting its first compulsory license for the cancer drug *Nexavar*, produced by Bayer [8]. The government argued that the drug was priced too high and that there was a public health emergency. The decision underscored India's commitment to ensuring access to life-saving medicines, especially for chronic diseases like cancer. This move reflects India's broader intellectual property policy, which strives to balance the promotion of innovation with the protection of public health, ensuring that patents do not hinder access to critical treatments.

4.1.3 Public interest and IP policy

India's approach to IP is embedded in its broader public health strategy, as reflected in its patent law. The government emphasizes balancing patent protection with the public interest, particularly in the pharmaceutical sector. This is evident in Section 3(d), which limits the patentability of incremental innovations that do not substantially improve the therapeutic efficacy of a known drug.
The Patents Act, along with the Patents Rules, 2003, provides a transparent process for handling patent applications, oppositions, and compulsory licensing [9]. These rules ensure that patenting is not used to exploit the public but promotes welfare. The Indian IP system allows opposition to patents that do not meet the required standards of innovation or could result in an unjustifiable monopoly. This system has been instrumental in preventing the patenting of drugs not sufficiently different from existing treatments, ensuring essential medicines remain accessible [10].
India's IP approach reflects a model where the rights of patent holders are balanced against the public's needs, especially regarding health and affordable medicines. This contrasts with countries like the United States, where patent rights are more strongly protected.

4.2 Pakistan

4.2.1 Patentable subject matter

Pakistan's patent law is governed by the Patents Ordinance, 2000, along with the Patent Rules, 2003. These laws provide a framework for patentability, compulsory licensing, and public interest considerations, ensuring alignment with global intellectual property norms while reflecting Pakistan's domestic priorities.
Section 7 of the Ordinance outlines the criteria for patentability, requiring that an invention must be novel, involve an inventive step, and have industrial applicability. Novelty ensures that the invention is not part of the prior art, while the inventive step prevents obvious innovations from receiving protection. Industrial applicability ensures that the invention can be practically utilized in a relevant industry. Despite these broad criteria, certain categories are explicitly excluded from patentability under Section 7(4). These include scientific discoveries, mathematical methods, business processes, and substances occurring in nature unless modified to demonstrate new utility. Furthermore, methods for medical or surgical treatments and inventions that could harm public morality, order, or the environment are excluded, ensuring that patent rights do not conflict with societal values [11].

4.2.2 Compulsory licensing

Compulsory licensing provisions under Sections 58 and 59 of the Patents Ordinance, 2000 allow patent exploitation without the patent holder's consent under specific conditions, such as addressing public health emergencies, ensuring essential goods availability, or preventing monopoly abuse. A license can be requested after three years from the grant of the patent or four years from the filing date, whichever is later. The Federal Government can directly exploit a patent or authorize third-party use for public welfare, national security, or health crises, ensuring patents serve the public interest [12].

4.2.3 Public interest and IP policy

Pakistan's patent law reflects a careful balance between protecting intellectual property rights and serving public interest needs. By including provisions for compulsory licensing and government use, the law ensures that patented innovations can be accessed during emergencies or to address national priorities. Section 7 also reinforces public interest by excluding inventions whose exploitation would harm public order, morality, or the environment. For example, methods related to genetic modification that conflict with ethical standards may be excluded from patent protection. Furthermore, the law promotes local innovation by requiring patents to be "worked" within the country, preventing foreign entities from holding unused patents that could stifle domestic development. These features demonstrate Pakistan's commitment to fostering innovation while safeguarding public welfare.

4.3 United Kingdom

4.3.1 Patentable subject matter

The United Kingdom's patent system is governed by the Patents Act 1977, incorporating aspects of European Union law and international agreements, particularly the TRIPS Agreement. The UK's patent law aligns with global standards and additional guidelines from the European Patent Convention (EPC) [13]. To qualify for a patent, an invention must meet three criteria: novelty, inventive step, and industrial applicability. The UK follows the EPC's definition, excluding discoveries, scientific theories, and mathematical methods from patentability.

The UK has strict exclusions, especially in biotechnology and pharmaceuticals. Patents are granted only for new, inventive products with specific industrial applications. The human genome and natural processes or organisms cannot be patented, reflecting the country's commitment to ethical IP standards. This is particularly significant in pharmaceuticals, where the UK plays a major role in biopharmaceutical and genetically modified organism development [14].

The examination process ensures that only inventions meeting these criteria are patented. Incremental innovations, often in pharmaceuticals, undergo additional scrutiny to assess true inventiveness or simple modifications of existing technologies. This approach maintains a balance between promoting innovation and protecting public access.

4.3.2 Compulsory licensing

The UK allows for compulsory licensing under Section 48 of the Patents Act 1977, in cases where the availability of a patented invention does not serve the public interest. While the UK's approach is more restrictive than India's, it still allows for the use of a patented invention without the consent of the patent holder under exceptional circumstances. These include cases where the patent holder refuses to exploit the invention within a reasonable period, or where there is insufficient supply of the product to meet demand. The compulsory licensing provisions in the UK are less commonly invoked than in countries like India, which has more robust mechanisms for ensuring access to life-saving medications.

Additionally, the UK follows the Bolar exemption, which allows for the use of patented inventions to conduct research and obtain regulatory approval for generic drugs. This exception supports competition in the pharmaceutical market, allowing generics to enter the market as soon as the patent expires. The Bolar exemption has been a significant factor in maintaining the balance between IP protection and public health interests in the UK [15].

4.3.3 Public interest and IP policy

In the UK, intellectual property law is designed to foster innovation while balancing it against the needs of society, particularly with respect to public health [16]. The compulsory licensing provisions, while not as commonly used as in countries like India, reflect the underlying principle that patents should serve the public interest and not lead to monopolies that harm consumers.

Moreover, the UK's involvement in the European Patent Convention and its adherence to TRIPS guidelines emphasize its commitment to maintaining international standards in patent law. The UK's IP policy is typically aligned with its strong support for innovation and research but remains vigilant about ensuring that patents do not restrict public access to critical goods, especially in healthcare.

4.4 Australia

4.4.1 Patentable subject matter

Australia's patent law is governed by the Patents Act 1990, which aligns with international standards, particularly the TRIPS Agreement. For an invention to be patentable in Australia, it must meet novelty, inventive step, and usefulness requirements. Unlike some jurisdictions, Australia does not permit the patenting of abstract ideas, scientific principles, or natural phenomena unless they are transformed into practical applications [17].

A distinctive feature of Australia's approach is its broad interpretation of inventive step. The Australian Patent Office has been known to grant patents for incremental innovations, especially in the pharmaceutical and biotechnology sectors, which may not be patentable in other countries like India. This approach has raised concerns about patent "evergreening," where minor modifications are made to extend patent life.

Case law, such as *Research Affiliates LLC v. Commissioner of Patents* (2014) [18], has emphasized that inventions must offer genuine improvements over existing methods to be patentable, not merely applying common knowledge. This ensures that patents granted in Australia reflect true innovation rather than trivial modifications.

4.4.2 Compulsory licensing

Australia includes provisions for compulsory licensing in its Patents Act, notably under Section 133. These provisions allow for the government to issue a compulsory license if the patentee does not exploit the invention within a reasonable period, or if the patent is being used in a way that restricts competition or negatively affects the public. While the provisions for compulsory licensing are not as frequently used as in India, they still provide an important mechanism for ensuring that patents do not hinder market access to critical products.

One key feature of Australia's compulsory licensing provisions is their focus on competition law. Under the Competition and Consumer Act 2010, the Australian Competition and Consumer Commission (ACCC) can investigate instances where patents are being used to restrict competition or abuse market power [19]. This law plays a critical role in ensuring that patent holders do not use their exclusive rights in ways that harm public welfare, particularly in sectors like pharmaceuticals and biotechnology.

4.4.3 Public interest and IP policy

Australia's IP policy strikes a balance between encouraging innovation and ensuring public access to essential products. The system supports a competitive market, particularly in technology, pharmaceuticals, and biotechnology, while maintaining safeguards to prevent patents from being used to exploit consumers or restrict access to vital goods.
As a signatory to international IP agreements, including the TRIPS Agreement, Australia's laws are influenced by global standards. However, concerns persist that its permissive stance on patentability, especially for incremental innovations, could pose challenges in healthcare sectors where access to affordable medicines is crucial.

4.5 United States of America

4.5.1 Patentable subject matter
In the United States, patent law is governed by the Patent Act of 1952 (Title 35 of the U.S. Code). The US broadly defines patentable subject matter, aligned with international standards, but with notable exceptions, particularly in biotechnology and software. The USPTO grants patents based on novelty, non-obviousness, and utility, consistent with the TRIPS Agreement. However, the definition of "non-obviousness" has been subject to case law clarification .
A key feature is the exclusion of "abstract ideas," particularly in the biotechnology and software sectors, as seen in *Mayo Collaborative Services v. Prometheus Laboratories* (2012) [20] and *Alice Corp. v. CLS Bank International* (2014) [21]. These cases established a test for abstract ideas, limiting software patents, especially in business methods and algorithms. The US system requires practical application, leading to greater scrutiny in some tech sectors.
The America Invents Act (AIA) of 2011 transitioned the US from a "first-to-invent" to a "first-to-file" system, emphasizing patent filing over proving prior invention.
4.5.2 Compulsory licensing
The US patent system does not have extensive compulsory licensing provisions like countries such as India. The US is largely pro-patent, favoring patent holders' rights. However, there are exceptions allowing the government to override patents in specific situations, particularly in public health emergencies. Under 35 U.S.C. Section 203, the government may invoke "march-in rights" to use patented inventions without the patent holder's consent if the patent is not commercially exploited or if there are public health concerns. One notable example of this provision was the Bayh-Dole Act (1980) [22], which allowed the government to license federally funded research patents to third parties if the patent holder failed to commercialize the invention within a reasonable time.
4.5.3 Public interest and IP policy
Public interest considerations in the United States are addressed through competition law, the patent misuse doctrine, and patentability exclusions. The patent misuse doctrine prevents holders from unreasonably extending monopolies or restricting competition. The FTC (Federal Trade Commission) and DOJ (Department of Justice) regulate anti-competitive practices, focusing on industries like pharmaceuticals where misuse can harm public welfare.
In the pharmaceutical sector, *evergreening*—the practice of slightly modifying existing drugs to secure new patents and delay generics—poses challenges. The Hatch-Waxman Act of 1984 [23] enables generic manufacturers to challenge such patents through an abbreviated process, helping combat patent thickets and ensuring affordable access to essential medicines.
While adhering to international IP treaties like TRIPS, the U.S. sets a high standard for patent protection globally. These treaties reinforce the balance between fostering innovation and public access. Through its legal framework, the U.S. aims to curb misuse while supporting innovation, reflecting a commitment to competitive markets and public welfare.

5 COMPARATIVE INSIGHTS

5.1 Incremental Innovation and Patentability Criteria

The Bangladesh Patents Act, 2023 requires inventions to meet the criteria of novelty, inventive step, and industrial applicability. However, the Act lacks provisions restricting patents on incremental innovations, such as minor modifications to pharmaceuticals that do not substantially improve efficacy. This omission may facilitate "evergreening," where minor changes extend patent life without genuine advancements, delaying generics and raising healthcare costs.
India's Patents Act, 1970, under Section 3(d), limits the patentability of incremental pharmaceutical innovations by requiring significant enhancement in efficacy. This provision, upheld in *Novartis AG v. Union of India* (2013), prevents minor modifications from receiving undue protection, ensuring public health priorities and access to affordable generics.
In Pakistan, patentability is based on novelty, inventive step, and industrial applicability, with exclusions for discoveries, natural substances, and therapeutic methods.
The United Kingdom's Patents Act 1977 and Patents Rules 2007, aligned with the European Patent Convention (EPC), exclude scientific discoveries, therapeutic methods, and certain biotechnological processes. Ethical restrictions limit patenting of natural biological materials unless specifically modified for new utility, indirectly curbing incremental innovations.
Australia's Patents Act 1990 historically allowed "innovation patents" for incremental inventions, now being phased out due to quality concerns. The Raising the Bar amendments (2013) introduced stricter standards for inventive step, clarity,

and disclosure, enhancing patent quality while allowing broader patentable subject matter compared to India's strict efficacy requirements.

In the United States, Section 101 of the Patent Act sets high patentability standards, refined by cases like *Alice Corp. v. CLS Bank* (2014) to exclude abstract ideas and natural products, particularly in software and biotechnology. The America Invents Act (AIA) of 2011 emphasizes "first-to-file" principles, but the U.S. lacks explicit measures to restrict incremental pharmaceutical patents, relying instead on judicially driven limits to promote genuine innovation.

Table 1 Comparative Overview of Patentable Subject Matter and Exclusions

Country	Patentable Subject Matter	Key Exclusions	Notable Provisions
Bangladesh	Novelty, Inventive Step, Industrial Applicability	Scientific principles, natural phenomena, therapeutic methods	General exclusions without specific pharmaceutical limitations
India	Novelty, Inventive Step, Industrial Applicability	Section 3(d) limits incremental innovation in pharmaceuticals	Section 3(d) prevents evergreening; public health focus
Pakistan	Novelty, Inventive Step, Industrial Applicability	Natural substances, unless modified, discoveries, aesthetic works	Excludes new uses of known products and methods of treatment .
United Kingdom	Novelty, Inventive Step, Industrial Applicability	Human cloning, biotechnological patents that conflict with ethics	Ethical exclusions under EPC, Rule 53
Australia	Novelty, Inventive Steps, Usefulness	Abstract ideas, scientific principles, and natural phenomena	Raising the Bar amendments for quality control
United States	Novelty, Non-obviousness, Utility	Abstract ideas, laws of nature (as clarified by case law)	Alice Corp. v. CLS Bank limits software/business method patents

5.2 Compulsory Licensing

Bangladesh's Patents Act permits compulsory licensing for public health emergencies or when patented products aren't affordable. However, it lacks detailed criteria for issuing these licenses, which could lead to inconsistent applications. India's system, on the other hand, provides a more comprehensive framework for compulsory licensing. India has invoked compulsory licensing in cases of unaffordable essential drugs, such as Bayer's cancer drug Nexavar, making it a model for how public health interests can be integrated into patent law. Patents Ordinance of 2000 provides clear grounds for compulsory licensing, including public health emergencies, failure to work the patent, and unreasonably high prices. Strengthening Bangladesh's licensing provisions could enhance accessibility to life-saving medications and offer clearer pathways for public health-driven exceptions to patent exclusivity.

Table 2 Compulsory Licensing Provisions in Comparison

Country	Grounds for Compulsory Licensing	Public Interest Focus
Bangladesh	Public health, national emergency, unaffordability	Public interest in general
India	Affordability, public health, failure to work patent	Detailed criteria for affordability
Pakistan	Public health, national security, failure to work patent, high prices	Explicit timeline; detailed public welfare provisions.
United Kingdom	Insufficient supply, public interest, abuse of monopoly	Balances IP rights with public interest
Australia	Anti-competitive practices, lack of reasonable use	Competition law focus
United States	March-in rights (for government use in emergencies)	Rarely invoked; focused on incentivizing innovation

5.3 Pharmaceutical Patent Extensions

In its current form, Bangladesh's law doesn't provide supplementary protection certificates (SPCs) or patent term extensions, which are offered in jurisdictions like the United States. The U.S. system allows up to five years of additional patent protection to compensate for delays in regulatory approval [24]. This approach balances public access to affordable medicine with incentives for pharmaceutical R&D. Bangladesh could explore implementing SPCs to support domestic innovation and investment in the pharmaceutical industry without compromising the availability of affordable drugs.

5.4 Patent Application Process and Opposition Mechanisms

India provides a robust opposition structure through Rule 24 (expedited examination) and Rule 55 (pre- and post-grant opposition) of the Patents Rules, 2003. This allows detailed third-party challenges on grounds such as novelty and inventive step, improving patent quality and public oversight.

Pakistan's patent application process, governed by the Patents Ordinance, 2000, is overseen by the Intellectual Property Organization (IPO) and involves filing, publication, examination, and granting. Pre-grant opposition allows third parties to challenge applications based on criteria like lack of novelty or inventive step before the patent is granted, providing transparency and public oversight. Post-grant opposition further enables challenges after issuance, focusing on grounds like insufficient disclosure or over-broad claims.

The United Kingdom also incorporates structured opposition under the Patents Act 1977 and The Patents Rules 2007, with Rule 24 detailing pre-grant opposition, as well as a formal appeals process. These mechanisms offer greater transparency than in Bangladesh, enhancing accountability by permitting public and legal scrutiny at multiple stages.

Australia's system under the Patents Act 1990 and Patents Regulations 2016 offers both pre- and post-grant opposition, particularly after the Raising the Bar amendments, which heightened requirements for inventive steps and disclosure. This structured approach aims to maintain patent quality and reduce low-quality filings, contrasting with Bangladesh's less rigorous framework.

The USA does not have a pre-grant opposition. Still, it offers post-grant review mechanisms, including *inter partes review* (IPR) under the America Invents Act (AIA) of 2011 and Title 37 of the Code of Federal Regulations (CFR). This strong post-grant review process provides structured avenues to challenge patents, especially within nine months of the grant, ensuring high standards in patent quality.

Bangladesh's patent application and opposition framework broadly align with international norms but lacks the procedural rigor and detailed opposition grounds in other jurisdictions like India, the UK, Australia, and the U.S. The Bangladesh Patents Act of 2023 authorizes pre-grant and post-grant opposition processes managed by the Department of Patents, Industrial Designs, and Trademarks (DPDT). However, its opposition procedures are relatively underdeveloped, with limited specific criteria and procedural details, which may reduce transparency and public engagement.

Implementing more detailed opposition procedures like those in India, the UK, and Australia could improve transparency and public engagement in Bangladesh's patent system, strengthening patent quality control.

Table 3 Comparative Overview of Patent Application Processes and Opposition Mechanisms

Country	Application Process	Pre-Grant Opposition	Post-Grant Opposition	Unique Features
Bangladesh	DPDT oversight; examination and publication	Available	Available	Streamlined but with limited criteria
India	Expedited examination available (Rule 24)	Available (Rule 55)	Available	Detailed opposition procedures
Pakistan	IPO oversight; filing, publication, examination	Available	Available	Specific grounds for revocation and invalidity
United Kingdom	Detailed process under Patents Rules 2007	Available (Rule 24)	Available	Structured appeals and SPCs
Australia	Standard and innovation patent processes	Available	Available	Quality focus post-Raising the Bar
United States	Regulated by Title 37 CFR	Not explicitly available	Inter Partes Review (IPR)	Strong post-grant review system

6 RECOMMENDATIONS

6.1 Adoption of Best Practices

To make its patent law more robust and aligned with international standards, Bangladesh could incorporate practices from countries with well-developed IP frameworks, such as the UK, USA, and Australia:

6.1.1 Clear Guidelines on Patent Eligibility:

Bangladesh could benefit from adopting the UK's approach to patent exclusions, particularly in sensitive sectors like biotechnology and software, to prevent the patenting of overly broad or abstract inventions. The UK and European Union prohibit patents on natural biological processes and unmodified genes, helping prevent monopolies in essential fields.

6.1.2 Pre-and Post-Grant Opposition Procedures

Implementing a more accessible opposition system, similar to India's pre- and post-grant procedures, would allow third parties to challenge patents before and after they are granted. This system promotes transparency and ensures that patents are granted only for genuine innovations, aligning with TRIPS and protecting public interesting

6.1.3 Term Extensions for Pharmaceuticals

The USA provides supplementary protection certificates (SPCs) for pharmaceutical patents, allowing for extensions when regulatory approval delays market entry. Bangladesh could introduce similar protections, helping attract pharmaceutical investments while balancing incentives for local generic production.

6.2 Patent Quality and Accessibility

Balancing innovation incentives with public accessibility is key to building an effective IP system. To this end, Bangladesh could consider these policy amendments:

6.2.1 Stricter Patentability Standards for Pharmaceuticals

Following India's Section 3(d), which prevents "evergreening" by barring patents on minor modifications unless they show significantly enhanced efficacy, would help ensure that only genuine improvements are patented. This could keep drug prices affordable and stimulate generic production.

6.2.2 Developing Licensing Criteria

Establishing a clear framework for issuing compulsory licenses for life-saving drugs would help address public health needs while aligning with TRIPS flexibilities. This would ensure accessibility without discouraging pharmaceutical innovation.

6.2.3 Accessible Patent Info Base

As seen in the USA and UK systems, a public database with patent application statuses and granted patents could increase transparency. This would help researchers and businesses access essential information, promoting collaboration and reducing infringement risks.

6.3 Strengthening Institutional Frameworks

To implement these legal advancements effectively, Bangladesh requires a supportive institutional framework:

6.3.1 Improved Patent Office Resources and Training

Enhancing the capabilities of the Bangladesh Patent Office through technical resources, training, and efficient electronic processing systems would streamline application reviews and improve patent quality. The USA's Patent and Trademark Office (USPTO) provides a model with rigorous examiner training programs and online patent filing systems that could be adapted in Bangladesh.

6.3.2 Establishing a Dedicated IP Tribunal

An IP tribunal could streamline patent disputes and reduce the backlog, as seen in India and the UK. Establishing such a tribunal would support faster resolution of IP-related cases and improve enforcement, giving inventor's confidence that their patents will be protected.

6.3.3 Integration with Competition Policy

Including IP-related provisions, like those in Australia's Competition and Consumer Act, could help prevent monopolistic practices. Such integration would ensure that patents do not unduly restrict market competition, fostering a fair business environment that benefits consumers and local industries alike.

7 CONCLUSION

Overall, while Bangladesh's Patent Act of 2023 takes significant steps toward aligning with international norms, there remain gaps, particularly in incremental innovation, compulsory licensing, and patent term extensions. These gaps may hinder the country's ability to fully capitalize on the benefits of patent protection while balancing public health interests and fostering innovation. For instance, without a robust compulsory licensing provision, Bangladesh may struggle to guarantee access to life-saving drugs at affordable prices, which is a cornerstone of many global patent systems, especially in India and Brazil. Similarly, the absence of SPCs might limit the incentives for innovation, particularly in the pharmaceutical sector.

The increasing emphasis on data exclusivity and global patent harmonization might prompt future reforms, including enhanced transparency in patent opposition and more flexible compulsory licensing provisions, ensuring greater public access to new technologies while stimulating local innovation. Furthermore, global trade agreements and continued compliance with TRIPS flexibilities will likely push Bangladesh to refine its patent system, particularly in the healthcare sector, where access to affordable medicines remains a critical issue.

As Bangladesh continues to navigate the balance between protecting intellectual property and serving the public interest, it is essential that future reforms consider both global IP trends and domestic needs, ensuring that the country remains competitive on the world stage while also prioritizing public health and local development.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose.

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