

Patent Law in Pakistan and the United Kingdom: A Comparative Legal Analysis of Legislative, Judicial and Pharmaceutical Patent Frameworks

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Abstract

This article makes a comparative legal study of the patent law regimes of Pakistan and the United Kingdom. The Patents Ordinance 2000 of Pakistan and the Patents Act 1977 of the United Kingdom have the same statutory structure and have both been designed to comply with the minimum standards set by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and, in the case of the UK, the European Patent Convention. However, a comparative study of the two regimes shows that there is a constant disparity between the formal compliance of Pakistan with the treaties and their effectiveness. This article, using a doctrinal and comparative legal approach, with independently sourced statistical data from the World Intellectual Property Organization and the UK Intellectual Property Office, compares the two jurisdictions on four aspects: the legal framework for patentability, term and compulsory use; the institutional architecture for administering each regime, including comparative filing volumes and Global Innovation Index rankings; the development of patent doctrine through case law; and the specific case of pharmaceutical patents, where the article concludes that Pakistan has never formally granted a pharmaceutical compulsory licence in over two and a half decades of TRIPS membership. The comparative analysis shows that the legislative, institutional and judicial shortcomings in Pakistan are interwoven and the article ends with a calibrated TRIPS-compatible reform programme that is based on, but not uncritically adopted from, the legislative practice of the UK and India.

Keywords: Comparative patent law; Pakistan; United Kingdom; Patents Ordinance 2000; Patents Act 1977; TRIPS; compulsory licensing; access to medicines

Introduction

The seemingly simple role of patent law is to give the public the right to know about an invention in exchange for a monopoly for a limited period of time, based on the theory that the threat of monopoly will motivate investment in innovation.¹ But the worth of that bargain to a particular jurisdiction is not just a function of the existence of a patent statute; it also depends on whether the statute's provisions are sufficiently clear to be applied predictably, whether courts have the power to provide the statute with operative content by interpreting it in case law, and whether the exceptions embedded in the system actually work when public health demands them to. A com-

¹See generally William Cornish, David Llewelyn and Tanya Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (10th edn, Sweet & Maxwell 2021).

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parative study of two jurisdictions with a similar statutory heritage but with very different institutional development can help in identifying which of the three factors is most responsible for the difference between the formal and the effective. This article does just that, it compares the patent law regimes of Pakistan and the United Kingdom on this basis. The Patents Ordinance 2000 (the "Ordinance") was enacted in Pakistan to align the country's patent law with TRIPS after Pakistan joined the World Trade Organization (WTO) under the auspices of the colonial era Patents and Designs Act 1911).² The Ordinance passes the test of the minimum standards set by the treaty: novelty, inventive step and industrial applicability are at the heart of the patentability test, the term is as short as the minimum of the TRIPS, and a compulsory licensing mechanism is in place, broadly following Article 31 of TRIPS.³ The equivalent function is carried out by the United Kingdom's Patents Act 1977 ("PA 1977") which was originally drafted to harmonise UK law with the European Patent Convention (EPC) and has been amended to incorporate TRIPS and the UK's ongoing treaty obligations.⁴ The central question that is addressed in this article is not whether either statute is TRIPS-compliant (both are) but whether formal compliance has led to an effective patent system in practice, and, if not, why not, either because of the text of the statute, because of the institutions and courts under which it is administered, or because of the operation of substantive exceptions in a high-stakes sector like pharmaceuticals. The United Kingdom is chosen as the main comparator not just for convenience. The patent regime in Pakistan is directly linked to the British legal system, which was inherited from the Patents and Designs Act 1911 and the general common law principles of statutory interpretation and precedent that are still followed by Pakistani courts.⁵ The UK also has a well-established precedent-based patent jurisprudence, with a robust appellate structure from the Patents Court to the Court of Appeal to the Supreme Court, and ongoing interaction with the EPC and the European Patent Office (EPO) case law.⁶ This comparator helps to highlight the sources of the compliance-effectiveness gap in the Pakistani context, but does not imply that solutions developed in the UK can or should be imported in full. Throughout, the statutory experience of India, especially in the areas of compulsory licensing and anti-evergreening, is used as a secondary comparator where a more direct comparison can be made with the TRIPS-flexibility architecture in India. The rest of the article goes on as follows. Section 2 examines the current literature on the patent law in Pakistan and places this article in the context of it. In Section 3, the doctrinal and comparative methodology used is outlined. Section 4 contrasts the two jurisdictions' legislation. Section 5 provides a comparison of judicial evolution of patent doctrine in each jurisdiction. Section 6 undertakes a focused comparative case study of pharmaceutical patents. The comparative findings are brought together in Section 7, which also includes a structured tabular comparison across eight criteria. Section 8 outlines a programme for reform. Section 9 concludes.

²Patents Ordinance 2000 (Ordinance No LXI of 2000) (Pakistan), preamble; Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPS Agreement); Marrakesh Agreement Establishing the World Trade Organization (adopted 15 April 1994, entered into force 1 January 1995) 1867 UNTS 154.

³Patents Ordinance 2000, ss 7-10, 23, 58-59; TRIPS Agreement, arts 27(1), 31, 33.

⁴Patents and Designs Act 1911 (British India); Osama Siddique, *Pakistan's Experience with Formal Law: An Alien Justice* (Cambridge University Press 2013).

⁵Patents Act 1977, s 130(7); Convention on the Grant of European Patents (European Patent Convention) (signed 5 October 1973, entered into force 7 October 1977) 1065 UNTS 199.

⁶Senior Courts Act 1981, s 16; Civil Procedure Rules 1998, pt 63; European Patent Convention (n above).

Literature Review

The current academic literature on patent law in Pakistan is relatively sparse compared to the amount of literature on patent doctrine in the UK and the EPO. Allauddin and Anwar's critical analysis of the evolution of patent laws in Pakistan from the Patents and Designs Act 1911 to the Patents Ordinance 2000 reveals that the TRIPS accession process was the main catalyst for the change in the laws, but there was no fundamental change in the institutional culture.⁷ Murtiza and Muhammad discuss the application of TRIPS obligations in Pakistan, and also find that formal compliance has outstripped institutional capacity to implement the resulting framework.⁸ In the international context in which Pakistan's reforms took place, Juma's discussion of intellectual property rights and globalisation places the TRIPS-inspired reform of developing country patent laws, including Pakistan's, in a larger context of externally-driven legislative harmonisation.⁹

The standard doctrinal works, both on the UK side (Cornish and Llewelyn's treatise on intellectual property law and Bently and others' equivalent work), cover the statutory and case-law structure of the Patents Act 1977 in great detail, but neither of them addresses the Pakistani law or provides a comparative overview of the two systems.¹⁰ Siddique's research on the experience of formal law in Pakistan is the most direct scholarly account of the institutional gap examined in this article, which holds that Pakistani courts tend to mechanically apply procedural and evidentiary rules, a tendency he calls "clinging to the text," rather than engaging in the purposive, doctrine-building interpretation that is more common in more developed common law jurisdictions.¹¹ Together, Datzov's discussion of the role of patent (in)eligibility doctrine in fostering or inhibiting innovation and Landes and Posner's economic analysis of judicial precedent provide the theoretical foundation for considering judicial doctrinal development as an independent variable that can influence the effectiveness of the patent system, a proposition this article empirically tests by comparing the case-law of the two systems in Section 5.¹²

As far as pharmaceutical patents and TRIPS flexibilities are concerned, Correa's 2018 article in the Bulletin of the World Health Organization is the most cited account of how compulsory licensing, the research exception and parallel importation work together as a package of TRIPS flexibilities available to WTO members, and his other work has consistently called for "health-sensitive" patent laws to explicitly incorporate these flexibilities into domestic law, rather than

⁷Hina Allauddin and Zahid Anwar, 'Critical Analysis of Patent Laws in Pakistan' (2019) *Journal of Political Studies* 24, 26, 30-31.

⁸Ghulam Murtiza and Ghous Muhammad, 'The Implementation of TRIPS Obligations in Pakistan' (Pakistan journal of law and international affairs).

⁹Calestous Juma, *Intellectual Property Rights and Globalization: Implications for Developing Countries* (Science, Technology and Innovation Discussion Paper, Center for International Development, Harvard University).

¹⁰William Cornish, David Llewelyn and Tanya Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (10th edn, Sweet & Maxwell 2021); Lionel Bently and others, *Intellectual Property Law* (6th edn, OUP 2022).

¹¹Osama Siddique, *Pakistan's Experience with Formal Law: An Alien Justice* (Cambridge University Press 2013).

¹²Nikola L Datzov, 'The Role of Patent (In)Eligibility in Promoting Innovation'; William M Landes and Richard A Posner, 'Legal Change, Judicial Behavior, and the Diversity Jurisdiction' (*Journal of Legal Studies*).

relying on the bare language of TRIPS.¹³ This simple measure of licences granted has been qualified by subsequent public-health scholarship, however, which has shown that the credible threat of compulsory licensing can itself extract price concessions even where a licence is never formally granted; this is addressed directly in Section 6.3 of this article, which relies on the WTO's own formal notification record, rather than anecdotal accounts of negotiated outcomes.¹⁴ Another strand of the public-health literature that has reviewed the post-TRIPS evidence on the effectiveness of compulsory licensing has noted that some developing countries have adopted a different approach to preventing evergreening and maintaining generic competition, namely by setting high standards for patentability, rather than compulsory licensing per se, as this article does in the Pakistani context in Section 6.2.¹⁵ The access-to-medicines literature on supplementary protection certificates (SPCs) – particularly the work of Hu, Eynikel and Boulet and Krikorian on SPCs and access to medicines in Europe – has explored the conflict between market exclusivity and affordable access in the European context, but not yet in the Pakistani compulsory licensing regime.¹⁶

To the best of this article's knowledge, no published study has linked the record of notifications made to the WTO TRIPS Council with Pakistan's own annual reporting to conclude, as an empirical fact, that Pakistan has never formally issued a pharmaceutical compulsory licence, as opposed to inferring this from the statutory text. The principal contribution of this article to the literature is this finding, developed in Section 6 below, and the three-dimensional comparative framework (legislative, judicial and sector-specific) in which it is embedded, as well as the independently sourced comparative filing and innovation-ranking data introduced in Section 4.4, which corroborates the qualitative comparative analysis, and which is sourced from the statistical publications of WIPO and UKIPO, rather than from either jurisdiction's self-reporting.

Research Methodology

The article uses a doctrinal, comparative and, in a limited way, normative method, which is in line with the traditional methods of comparative legal research.¹⁷ The doctrinal element requires careful examination of the key statutory documents in each jurisdiction, namely the Patents Ordinance 2000 and PA 1977, and the delegated legislation, case law and official reports which

¹³Yuanqiong Hu, Diarmaid Eynikel, Pascale Boulet and Gaelle Krikorian, 'Supplementary Protection Certificates and Their Impact on Access to Medicines in Europe' (2020) *Journal of Pharmaceutical Policy and Practice*.

¹⁴Carlos M Correa, 'Flexibilities Provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights' (2018) 96 *Bulletin of the World Health Organization* 148 (DOI: 10.2471/BLT.17.206896) <<https://pmc.ncbi.nlm.nih.gov/articles/PMC5840632/>> accessed 9 August 2026.

¹⁵See 'Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence' (2020) *Journal of Pharmaceutical Policy and Practice* <<https://pmc.ncbi.nlm.nih.gov/articles/PMC7468182/>> accessed 9 August 2026; see also 'TRIPS Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation' (2023) *Journal of Pharmaceutical Policy and Practice* <<https://pmc.ncbi.nlm.nih.gov/articles/PMC10726804/>> accessed 9 August 2026.

¹⁶Yuanqiong Hu, Diarmaid Eynikel, Pascale Boulet and Gaelle Krikorian, 'Supplementary Protection Certificates and Their Impact on Access to Medicines in Europe' (2020) *Journal of Pharmaceutical Policy and Practice*.

¹⁷Jay Dratler Jr and Stephen M McJohn, *Intellectual Property Law: Commercial, Creative and Industrial Property* (Law Journal Press 2023).

provide these statutes with their operative content. The comparative component is based on the functional approach of comparative law scholarship, which compares the two regimes not only on the basis of the corresponding section numbers, but also by examining how each jurisdiction solves the same underlying regulatory issue, such as how each jurisdiction determines the scope of patentable subject matter, or how each jurisdiction balances patent rights with public health concerns.¹⁸ Like the warnings found in the comparative law literature about the dangers of formal doctrinal transplantation, this article does not view UK statutory and case-law solutions as a blueprint for transplantation, but rather as models that can be tested in India, and which are not directly applicable to India because of the differences between the two countries' TRIPS-flexibility positions.¹⁹

The main sources consulted are the text of the Patents Ordinance 2000 and PA 1977, and their delegated legislation, reported case law from the superior courts of Pakistan and the United Kingdom, the TRIPS Agreement, the 2001 Doha Declaration on TRIPS and Public Health, and official reports such as IPO-Pakistan's annual reports and submissions to the United States Trade Representative's Special 301 review process, the WTO TRIPS Council notification database, and reports commissioned by the UK Intellectual Property Office and the UK Department for Business and Trade on the Pakistani IP regime. The academic literature reviewed in Section 2 is considered secondary sources. The empirical claim developed in Section 6 – that Pakistan has never formally granted a pharmaceutical compulsory licence – is supported not by independent empirical fieldwork (such as practitioner interviews, which is not part of the doctrinal method used here and is identified as a direction for future research in Section 9), but rather by the WTO notification record, together with the reporting of IPO-Pakistan, which is of the same evidentiary character as the statutory text itself.

Comparative Analysis of the Legislative Framework

Statutory Architecture and Patentability Criteria

The Patents Ordinance 2000 is a 108-section, twenty-two-chapter code that amends and consolidates patent law and provides domestic implementation of Pakistan's TRIPS commitments.²⁰ It replaced the 1911 Act with its entire provisions and introduced the Controller of Patents and Patent Office as the administering apparatus, which is now under the statutory umbrella of the Intellectual Property Organization of Pakistan (IPO-Pakistan) since 2005.²¹ The Ordinance has been amended thrice since its enactment in 2002, 2007 and 2010, and is supplemented by the Patents Rules 2003.²² In the UK, PA 1977 serves a similar purpose, having been introduced to har-

¹⁸John Henry Merryman, 'Comparative Law and Social Change: On the Origins, Style, Decline and Revival of the Law and Development Movement' (1977) 25 *American Journal of Comparative Law* 457; Otto Kahn-Freund, 'On Uses and Misuses of Comparative Law' (1974) 37 *Modern Law Review* 1.

¹⁹Pierre Legrand, 'The Impossibility of "Legal Transplants"' (1997) 4 *Maastricht Journal of European and Comparative Law* 111; Alan Watson, *Legal Transplants: An Approach to Comparative Law* (2nd edn, University of Georgia Press 1993); Daniel Berkowitz, Katharina Pistor and Jean-Francois Richard, 'The Transplant Effect' (2003) 51 *American Journal of Comparative Law* 163.

²⁰Patents Ordinance 2000, preamble and s 109.

²¹Patents Ordinance 2000, ss 3-4, 106(1); Intellectual Property Organization of Pakistan Act 2012 (Act XXII of 2012).

²²Patents Ordinance 2000, s 105; The Patents Rules 2003 (SRO 1142(I)/2003).

monise UK law with the EPC and predating TRIPS by some seventeen years, but having been amended to include the UK's obligations under TRIPS and to take account of its ongoing treaty-based relationship with the EPO despite its departure from the EU.²³

Both laws share the same patentability structure as stipulated in TRIPS Article 27(1): an invention is patentable if it is new, involves an inventive step and is capable of industrial application.²⁴ These criteria are substantially identical in sections 7-10 of the Ordinance and in sections 1-4 of PA 1977, and both statutes exclude discoveries, scientific theories, mathematical methods, aesthetic creations, and schemes or methods for performing mental acts or doing business from the definition of a patentable invention.²⁵ Both regimes provide for a patent term of 20 years from filing date, which is the minimum term under TRIPS Article 33.²⁶

The comparison, however, is stark on the drafting of precision on the *ordre public* and morality exclusion. Section 7(4) of the Ordinance excludes from patentability inventions whose commercial exploitation would be detrimental to *ordre public* or morality, as well as plant and animal varieties other than micro-organisms, diagnostic and therapeutic methods, and new uses of known products, but provides no guidance on how *ordre public* is to be determined, turning what should be a narrow and exceptional carve-out into a broad discretionary power for individual patent examiners to apply on a case-by-case basis.²⁷ The morality exclusion is more precisely bounded in Section 1(3) of PA 1977 and Schedule A2 to the Act provides specific statutory content to the morality exclusion by enumerating processes involving human cloning, human germ line modification and industrial or commercial use of human embryos.²⁸ The exclusion of methods of diagnosis and of treating the human or animal body by surgery or therapy from patentability is also a separate exclusion, which is drafted with greater precision than the Pakistani equivalent, section 4A of PA 1977.²⁹ A similar structural fault in the compulsory-licensing framework of the Ordinance is that there are two distinct, overlapping paths to non-consensual use of a patent, one based on the Federal Government's determination and the other based on an application to the Controller on non-working grounds, but no clear statutory priority between them.³⁰ The issue is revisited below in Section 6, in the context of pharmaceutical patents, where its implications are most stark.

Institutional Architecture

Compliance-effectiveness is not just about the precision of the legislation; it's also about the capacity of administration to apply it. The UK Intellectual Property Office (UKIPO) is an executive agency of the Department for Science, Innovation and Technology, and, as part of its membership of the EPC, applicants are able to file protection via a centralised European examination

²³Patents Act 1977, s 130(7) (declaring conformity with the European Patent Convention); s 1(1)-(2).

²⁴Patents Ordinance 2000, s 7(1); Patents Act 1977, ss 1(1), 1-4; TRIPS Agreement, art 27(1).

²⁵Patents Ordinance 2000, s 7(2); Patents Act 1977, s 1(2).

²⁶Patents Ordinance 2000, s 31; Patents Act 1977, s 25(1) and (3); TRIPS Agreement, art 33.

²⁷Patents Ordinance 2000, s 7(4).

²⁸Patents Act 1977, s 1(3); sch A2, para 3(b)-(d).

²⁹Patents Act 1977, s 4A.

³⁰Patents Ordinance 2000, ss 58, 59(1)-(2).

process managed by the EPO in addition to the UKIPO route.³¹ The majority of patent litigation in the UK is heard in the specialist Patents Court of the Chancery Division of the High Court, or in lower value disputes, the Intellectual Property Enterprise Court (IPEC), with appeals to the Court of Appeal and in cases of general public importance, the Supreme Court.³² IPO-Pakistan was established as a statutory body under the Ministry of Commerce by the Intellectual Property Organization of Pakistan Act 2012, and has been working on a programme of institutional reform, such as digitisation of some of the opposition process and the establishment of IPR enforcement coordination committees in major cities.³³ IPO-Pakistan's own submission to the United States Trade Representative's (USTR) Special 301 review also admitted that the shortage of human resources had been the main factor for the pendency in the registration process, and that recruitment under the organisation's Service Rules 2022 would only be completed in March 2025.³⁴ The USTR Special 301 Report for 2026 lists seven Specialized Intellectual Property Tribunals in Pakistan as functional by that year, and also notes that additional tribunals are planned for other cities in Pakistan, and Pakistan remains on the USTR Watch List for IP protection and enforcement.³⁵ The eighteen-month examination period and the four-month opposition period as provided in the Ordinance are feasible only if the Patent Office is adequately staffed; the difference between the procedural provisions of the Ordinance and the administrative capacity of the IPO-Pakistan is a structural feature which the original drafting of the Ordinance did not take into account.

International Treaty Participation

The most significant structural difference between the two regimes is not in the text of either statute, but rather that Pakistan is not a member of the Patent Cooperation Treaty (PCT) while the United Kingdom is a member of both the PCT and the EPC.³⁶ A UK applicant who wants protection in multiple jurisdictions may delay the majority of translation and national filing fees for up to 30 months by using a single international PCT application, or can get a single centralised European grant via the EPO. The applicant (or foreign applicant seeking protection in Pakistan) is required to pay the full translation and filing fee for a national application at the time of filing, as there is no national filing route that provides any of the procedural benefits of the PCT.³⁷ The Ordinance does not seek to remedy this, as accession to PCT is a treaty policy issue and not a statutory drafting issue, but it is a limitation that the Ordinance has never been amended to overcome, even though a draft Patents (Amendment) Bill 2024, which was prepared in part

³¹Patents Act 1977, sch A2; UK Intellectual Property Office, 'About Us' (GOV.UK) <<https://www.gov.uk/government/organisations/intellectual-property-office/about>> accessed 9 August 2026.

³²Senior Courts Act 1981, s 16; Civil Procedure Rules 1998, pt 63 and Practice Direction 63.

³³Intellectual Property Organization of Pakistan Act 2012, s 16; Government of Pakistan, Intellectual Property Organization of Pakistan, Annual Report (IPO-Pakistan 2024).

³⁴Government of Pakistan, Intellectual Property Organization of Pakistan, Submission to the Office of the United States Trade Representative 2025 Special 301 Review (IPO-Pakistan 2025) 2.

³⁵Office of the United States Trade Representative, 2026 Special 301 Report (USTR, April 2026).

³⁶Patent Cooperation Treaty (signed 19 June 1970, entered into force 24 January 1978) 1160 UNTS 231; European Patent Convention (signed 5 October 1973, entered into force 7 October 1977) 1065 UNTS 199.

³⁷World Intellectual Property Organization, PCT Applicant's Guide (WIPO, updated 2026) <<https://www.wipo.int/pct/en/appguide/>> accessed 9 August 2026.

to include enabling provisions for eventual PCT accession, was still pending before the Federal Government as of early 2025.³⁸

Comparative Filing Activity and Innovation Outcomes

The above legislative and institutional differences are also evident in the filing and innovation statistics provided by WIPO and UKIPO, which are independently verifiable and are used directly in this article, rather than in the reporting of the patent offices of either jurisdiction. According to WIPO's country statistical profile, resident patent applications increased slowly from 96 in 2012 to 426 in 2021, while resident patent grants were in the low teens in each year during the same period.³⁹ In comparison, the UK Intellectual Property Office's own published facts and figures for 2025 show that UK-based applicants filed 15,443 domestic patent applications in that year alone, which is over 30 times the number of applications filed by all Pakistan's residents in 2021, and a much higher number of applications were filed directly at the EPO by UK-domiciled applicants.⁴⁰ This gap is further supported by the WIPO Global Innovation Index 2025 which shows that the United Kingdom is ranked 6th out of 139 countries in the world (4th in innovation outputs), while Pakistan is ranked 99th out of 139 countries (14th among 37 lower-middle-income countries).⁴¹ The numbers in this article do not, by themselves, prove that the legislative and institutional shortcomings discussed in this article are responsible for the relatively low patenting activity in Pakistan; many other macroeconomic and industrial-structure factors also influence patent filing volumes. They do, however, confirm the qualitative comparative analysis above: a patent system with poorly defined statutory categories and a poorly resourced administering institution is not likely to foster the filing confidence that a well-established, precedent-setting system like the UK's does. None of these is a case where the Patents Ordinance 2000 has been completely unsuccessful. The Ordinance is obviously not deficient in terms of formal TRIPS compliance, and that may be why it has not been replaced in its entirety after over 20 years but has been amended incrementally. The pattern is nevertheless the same, across the statutory, institutional and treaty dimensions explored in this section: the Ordinance establishes the right categories of rule in any modern patent statute and leaves the substance of several of the most controversial categories and the resources required to implement all of them to be added to later by rules, discretion, or reform, which in important respects has not yet come.

Comparative Analysis of Judicial Approaches

The United Kingdom: Sustained Doctrinal Leadership

³⁸Government of Pakistan, Intellectual Property Organization of Pakistan, Annual Report (IPO-Pakistan 2024) 2-3 (noting the draft Patents (Amendment) Bill 2024).

³⁹World Intellectual Property Organization, 'Pakistan: Country Profile, IP Statistics Data Center' (WIPO) <https://www.wipo.int/ipstats/en/statistics/country_profile/countries/pk_content.html> accessed 9 August 2026.

⁴⁰UK Intellectual Property Office, 'Facts and Figures: Patents, Trade Marks, Designs and Hearings 2025' (GOV.UK, 2026) <<https://www.gov.uk/government/publications/facts-and-figures-patents-trade-marks-designs-and-hearings-2025>> accessed 9 August 2026.

⁴¹World Intellectual Property Organization, 'Global Innovation Index 2025: United Kingdom' <<https://www.wipo.int/edocs/gii-ranking/2025/gb.pdf>> accessed 9 August 2026; World Intellectual Property Organization, 'Global Innovation Index 2025: Pakistan' <<https://www.wipo.int/edocs/gii-ranking/2025/pk.pdf>> accessed 9 August 2026.

Patent law is not only defined by the statute, but also by the way novelty, inventive step, scope of the claims and remedies are interpreted in practice, and in common law countries this is done mainly through precedent.⁴² UK courts have been doctrinal leaders on each of these aspects. *Catnic Components Ltd v Hill & Smith Ltd* set out the purposive approach which was later restated in *Actavis UK Ltd v Eli Lilly and Co*, where a variant which is not literally covered by the claim may be infringed if it performs substantially the same function in substantially the same way.⁴³ The four-stage Windsurfing test, as re-stated in *Pozzoli SPA v BDMO SA*, is the framework that is used by the UK courts to determine whether a claim is obvious.⁴⁴ *Regeneron Pharmaceuticals Inc v Kymab Ltd* explained the connection between the scope of a claim and the technical contribution the specification needs to cover in the context of sufficiency of disclosure.⁴⁵ Most recently, and most importantly for the development of UK patent doctrine, the Supreme Court's decision in *Emotional Perception AI Ltd v Comptroller-General of Patents, Designs and Trade Marks* has rejected the two-decade-old *Aerotel* guidance on the statutory exclusion of computer programs "as such" and brought UK practice into line with the EPO's "any hardware" approach to computer-implemented inventions, including artificial neural networks.⁴⁶ The judgment is a typical example of a judicial approach to doctrinal modernisation, achieved by a flexible interpretation of the statute and a focus on international convergence, rather than by independent policy making, which is not bound by the statutory text.

Pakistan: A Constrained and Fragmented Jurisprudence

Pakistani courts have the same formal common law power to elaborate the doctrine of patent, but the extent of elaboration has been significantly less. The number of reported patent case law decisions in Pakistan is relatively low, and a search of reported law reports and freely available databases yields a significantly smaller number of reasoned patent decisions than a search of the UK over a similar period.⁴⁷ The contours of the patent jurisprudence in Pakistan are illustrated by cases such as *Atco Laboratories (Pvt) Ltd v Pfizer Ltd & Ors* (interim injunctive relief), *Novartis AG v Genix Pharma (Pvt) Ltd* (final relief granted on an undefended, ex parte basis), and *Merck & Co Inc v Hilton Pharma (Pvt) Ltd*. They also show a comparative lack of the kind of detailed analytical reasoning that is found in the UK appellate authority.⁴⁸ In *Novartis AG v Genix Pharma*, for instance, the Sindh High Court's reasoning is largely mechanical, relying on the evidentiary-presumption and civil procedure rules, and an un rebutted, ex parte record, instead of substantive engagement with the underlying technical merits of the patent dispute, which is what

⁴²Jay Dratler Jr and Stephen M McJohn, *Intellectual Property Law: Commercial, Creative and Industrial Property* (Law Journal Press 2023).

⁴³*Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 (HL); *Actavis UK Ltd v Eli Lilly and Co* [2017] UKSC 48, [2018] 1 All ER 171.

⁴⁴*Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 (CA); *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588, [2007] FSR 37.

⁴⁵*Regeneron Pharmaceuticals Inc v Kymab Ltd* [2020] UKSC 27, [2021] 1 All ER 1.

⁴⁶*Emotional Perception AI Ltd v Comptroller-General of Patents, Designs and Trade Marks* [2026] UKSC 3; see also [2024] EWCA Civ 825.

⁴⁷Senior Courts Act 1981, s 16; Civil Procedure Rules 1998, pt 63 and Practice Direction 63.

⁴⁸A search of reported Pakistani law reports and freely accessible legal databases (August 2026).

Siddique's study of Pakistani civil litigation calls a tendency of Pakistani courts to "cling to the text" of procedural rules.⁴⁹

The same comparative pattern is seen in enforcement practice. In Pakistan, the application of interim relief in patent cases is more formalistic, with litigants reporting that courts are less inclined to grant search and preservation orders similar to the UK's Anton Piller jurisdiction, while balancing the adequacy of damages, the balance of convenience and the preservation of the status quo.⁵⁰ This is not, on the analysis developed here, a lack of judicial capacity, but rather a lack of institutional capacity, in the sense that the judiciary is not particularly well-trained in complex commercial litigation, that there is a relatively small number of precedents to be drawn on, and that there are docket pressures on complex commercial litigation generally.

Comparative Assessment: Locating the Divergence

Another recent example of this fragmentation is the current litigation before the Sindh High Court in which Novartis Pharma (Pakistan) Ltd and several other multinational and local pharmaceutical companies have asked for declaratory relief from the Federation of Pakistan and the Drug Regulatory Authority of Pakistan (DRAP) regarding the regulatory status of their registered medicines.⁵¹ Although the litigation is correctly described as regulatory, not patent-doctrinal, it is a typical example of the institutional pattern that is found throughout this section: complex, technically sophisticated pharmaceutical cases litigated before a generalist civil court, rather than a consolidated specialist court, with multiple originator and generic manufacturers joined as parties before a single bench.

The comparative picture that emerges is not one of doctrinal inferiority of Pakistani judges as compared to their UK counterparts, but one of the institutional conditions for doctrinal accumulation being much weaker. In Pakistan, patent litigation is referred to the Intellectual Property Tribunals established under the Intellectual Property Organization of Pakistan Act 2012, but in reality, these tribunals operate in a way that is materially similar to general civil courts, and do not have a sufficient number of judges with technical or patent-specific expertise.⁵² The lack of a single national appellate court for IP issues exacerbates the issue: in Pakistan, patent appeals are spread across the High Courts of the provinces, and do not create a consistent body of precedent in the way that a single specialist appellate court, such as the Patents Court and Court of Appeal in the UK, would.⁵³ Judicial and enforcement capacity building has also been identified as a priority area for UK-Pakistan cooperation in the proposals for reform, commissioned jointly by the

⁴⁹Atco Laboratories (Pvt) Ltd v Pfizer Ltd & Ors 2002 CLD 120 (SHC); Novartis AG v Genix Pharma (Private) Ltd, Suit No 1017 of 2011 (Sindh High Court, 11 October 2018); Merck & Co Inc v Hilton Pharma (Pvt) Ltd 2003 CLD 407 (SHC).

⁵⁰Novartis AG v Genix Pharma (Private) Ltd, Suit No 1017 of 2011 (Sindh High Court, 11 October 2018); Osama Siddique, *Pakistan's Experience with Formal Law: An Alien Justice* (Cambridge University Press 2013).

⁵¹Tom Pengelly, Update of the 2020 Pakistan IP Regime Review (UK Intellectual Property Office and Department for Business and Trade, September 2025) <https://assets.publishing.service.gov.uk/media/68a49409cd7b7dcfaf2b5edb/ip_counter_infringement_strategy_review_pakistan.pdf> accessed 9 August 2026; Government of Pakistan, Intellectual Property Organization of Pakistan, National Intellectual Property Strategy (consultative draft, IPO-Pakistan and WIPO, 2024-2026).

⁵²American Cyanamid Co v Ethicon Ltd [1975] AC 396 (HL).

⁵³Intellectual Property Organization of Pakistan Act 2012, ss 15-16.

UK Intellectual Property Office and the UK Department for Business and Trade, and as a priority area for strengthening judicial engagement with patent disputes in IPO-Pakistan's own strategic planning process, in consultation with the World Intellectual Property Organization (WIPO).⁵⁴ The comparative lesson is that legislative modernisation, even legislative modernisation that fills the gaps in the legislation identified in Section 4 above, is not enough to achieve the same doctrinal coherence that can be achieved by a mature, specialised, precedent-conscious judiciary.

Comparative Case Study: Pharmaceutical Patents and Access to Medicines

Why Pharmaceuticals as a Comparative Case Study

The issue of patent protection versus access to medicines is one of the most litigated issues in modern international IP law, and provides an unusually illuminating comparative case study, as the costs of poorly drafted laws and limited institutional capacity are in this area not just commercial, but constitutional and internationally based. Article 38(d) of the Constitution of Pakistan has imposed a duty on the state to provide basic necessities of life to citizens, and in later decisions, the Supreme Court of Pakistan has interpreted the right to life in Article 9 of the Constitution to include the right to a healthy environment and, by clear extension in later decisions and academic commentaries, the right to the conditions necessary to sustain life, including access to essential medicines.⁵⁵ Pakistan is also a signatory to the International Covenant on Economic, Social and Cultural Rights, Article 12 of which states that everyone has the right to the highest attainable standard of health, which the UN Committee on Economic, Social and Cultural Rights has interpreted as the availability of essential medicines.⁵⁶ The TRIPS Agreement does not require the maximisation of patent protection, and WTO members have the full right to apply built-in flexibilities, such as compulsory licensing, to protect public health, as TRIPS itself, through Article 7 and 8, and the 2001 Doha Declaration on TRIPS and Public Health, makes clear.⁵⁷

Two Legislative Gaps: Evergreening and the Bolar Exemption

Two structural deficiencies in the Ordinance's pharmaceutical-specific provisions directly impact access to medicines, and both have a clear comparative response. First, the Ordinance does not have a corresponding provision to the increased efficacy criterion for incremental pharmaceutical innovation in section 3(d) of the Indian Patents Act 1970, as amended in 2005, and upheld by the Indian Supreme Court in *Novartis AG v Union of India* in response to a challenge on the beta-crystalline form of imatinib mesylate.⁵⁸ Section 3(d) provides an exception to patentability for the mere discovery of a new form of a known substance, unless the new form is "significantly different" in terms of therapeutic efficacy. This is a specific exception to prevent "evergreening"

⁵⁴*Perwaiz Ahmed Shaikh v Muhammad Tahir*, High Court Appeal No 289 (Sindh High Court).

⁵⁵Constitution of Pakistan 1973, arts 9, 38(d); *Shehla Zia v WAPDA* PLD 1994 SC 693 (Supreme Court of Pakistan).

⁵⁶International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3, art 12; UN Committee on Economic, Social and Cultural Rights, 'General Comment No 14: The Right to the Highest Attainable Standard of Health' (2000) UN Doc E/C.12/2000/4.

⁵⁷TRIPS Agreement, arts 7-8; WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health (Doha Declaration) WT/MIN(01)/DEC/2 (14 November 2001) paras 4-6.

⁵⁸Patents Act 1970 (India), s 3(d), as amended by the Patents (Amendment) Act 2005 (India); *Novartis AG v Union of India* (2013) 6 SCC 1 (Supreme Court of India).

— the process of extending market exclusivity through minor reformulations that offer no real therapeutic benefit. In contrast, there is no such protection in Sections 7-10 of the Ordinance, which means that the Pakistani patentability standard is open to evergreening as the Indian regime, under the same TRIPS minimum standards, has explicitly closed itself to evergreening.⁵⁹

Second, section 11(4) of the Ordinance only states that the rights of a patentee are not extended to acts for experimental purposes for the subject matter of the invention, which may include regulatory testing for a generic marketing authorisation, but does not explicitly cover it.⁶⁰ The UK equivalent provision, section 60(5)(b) of PA 1977, is supplemented by regulation 49 of the Human Medicines Regulations 2012, which expressly and clearly provides for a Bolar exemption: The making or use of a medicinal product for the purpose of conducting a study, test or trial which is necessary or desirable for the purpose of developing the product and of complying with the requirements of the law does not infringe any patent in respect of the product.⁶¹ The Bolar exemption is generally considered to be a paradigm case of a TRIPS compatible Article 30 exception in WTO dispute settlement practice and in academic commentary.⁶² The section 11(4) of Pakistan does not fully utilise this flexibility as generic manufacturers are not sure on the current wording of the statute whether pre-expiry regulatory testing renders them liable for infringement.

Proving Non-Use: The WTO Notification Record as Primary Evidence

The most significant comparative finding in this case study is the fact that Pakistan's compulsory licensing regime is in operation. Two routes to non-consensual use of a patented invention are provided in sections 58 to 72 of the Ordinance: a Federal Government authorisation route, under section 58, where the public interest so requires, where the patentee has engaged in anti-competitive conduct, or where a licence has been refused on reasonable commercial terms; and a Controller-administered non-voluntary licence route, under section 59, on application no later than four years from filing or three years from grant, to remedy non-working of the patent.⁶³ On their own, both routes are fairly in line with the flexibilities that have been maintained under Article 31 of TRIPS.

The WTO's TRIPS Council notification database is the main official source of evidence of compulsory licensing activity by WTO members. A search of that database shows that Pakistan has not notified any use of TRIPS Article 31 and 31bis in respect of pharmaceutical compulsory licensing, while India, Thailand, Rwanda and Zimbabwe have each notified at least one use of TRIPS Article 31 and 31bis in respect of pharmaceutical compulsory licensing.⁶⁴ This lack is confirmed by the annual reporting of IPO-Pakistan which does not show any formal grant of a pharmaceutical compulsory licence, and by the World Health Organization's evaluation of structural constraints on access to medicines in the Pakistan Pharmaceutical Country Profile.⁶⁵ This

⁵⁹Patents Ordinance 2000, ss 7-8.

⁶⁰Patents Ordinance 2000, s 11(4).

⁶¹Patents Act 1977, s 60(5)(b); Human Medicines Regulations 2012, SI 2012/1916, reg 49.

⁶²TRIPS Agreement, art 30.

⁶³Patents Ordinance 2000, ss 58(1)(a)-(c), 59(1)-(2).

⁶⁴WTO, TRIPS Council Notifications under Articles 31 and 31bis <https://www.wto.org/english/tratop_e/trips_e/who_notif_e.htm> accessed 9 August 2026.

⁶⁵World Health Organization, Pakistan Pharmaceutical Country Profile (WHO 2010); Government of Pakistan, Intellectual Property Organization of Pakistan, Annual Reports (IPO-Pakistan, various years).

helps to establish a specific and, as far as the literature is concerned, hitherto undocumented comparative finding that Pakistan has had a TRIPS-compatible compulsory licensing regime for over two and a half decades, but has never formally exercised it in the pharmaceutical sector, unlike India, where it has been used in practice as discussed immediately below.

This non-use is due to four correctable structural flaws in sections 58-72 of the Ordinance, which act as a system of disincentives: the absence of a definition of what constitutes the "public interest" or a "national emergency" sufficient to trigger section 58; the prior-negotiation requirement, which imposes procedural burden without a corresponding fast-track alternative for emergency situations; the complete absence in section 63 of any statutory formula or guiding factors for determining fair remuneration to the patentee; and the lack of any expedited procedure for public health emergencies.⁶⁶ The comparison with India is instructive because India has a compulsory licensing system with clear thresholds and has shown that it is operationally feasible: In 2012, the Controller General of Patents granted a compulsory licence for sorafenib (Nexavar) under section 84 of the Indian Patents Act 1970, which was later upheld by the Supreme Court of India in *Bayer Corporation v Union of India*.⁶⁷

The Sofosbuvir Case Study and the UK Comparator

The impact of this legislative deadlock is seen in Pakistan's experience with sofosbuvir, a direct-acting antiviral (DAA) developed by Gilead Sciences and marketed as Sovaldi, which is part of combination therapy for chronic hepatitis C virus (HCV) infection. According to the World Health Organization's Global Hepatitis Report (2017), the prevalence of hepatitis C in Pakistan was estimated to be around 7.7 million, which is a matter of acute public health concern as it is very costly to access treatment.⁶⁸ Pakistan did not exercise its statutory compulsory licensing rights under sections 58 to 72 of the Ordinance to obtain access to sofosbuvir at an affordable price, but rather through voluntary generic licensing agreements between Gilead Sciences and the Medicines Patent Pool and Indian generic manufacturers.⁶⁹ Voluntary licensing of this type is not a legal right, but a business decision at the discretion of the patentee, as analysed in the specialist access-to-medicines literature.⁷⁰ A state that does not exercise rights granted by its own Parliament, but instead relies on the private commercial decision of a multinational originator to provide access to pharmaceuticals has, in a meaningful sense, given up the legal protection that the sections 58-72 of the Ordinance were intended to afford.

The UK's compulsory licensing system provides the comparative contrast. Section 48A(1) of PA 1977 sets out concrete statutory grounds for compulsory licensing (non-working, non-meeting reasonable demand, and unreasonable refusal to license) and section 50 provides a reasonable-

⁶⁶Patents Ordinance 2000, ss 58(1)(b), 60, 63.

⁶⁷Patents Act 1970 (India), s 84; *Bayer Corporation v Union of India* (2014) (Supreme Court of India, special leave petition dismissed).

⁶⁸World Health Organization, Global Hepatitis Report 2017 (WHO 2017).

⁶⁹Medicines Patent Pool, 'Gilead Sciences Hepatitis C Licence' (Medicines Patent Pool) <<https://medicinespatentpool.org>> accessed 9 August 2026; Gilead Sciences, 'Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries' (Gilead Sciences, 15 September 2014).

⁷⁰Yuanqiong Hu, Diarmaid Eynikel, Pascale Boulet and Gaelle Krikorian, 'Supplementary Protection Certificates and Their Impact on Access to Medicines in Europe' (2020) *Journal of Pharmaceutical Policy and Practice*.

ness test for remuneration that has been developed in cases such as *Allen & Hanburys Ltd v Generics (UK) Ltd*, which extracted a negotiated willing-licensor-willing-licensee methodology for assessing reasonable royalty rates.⁷¹ Sections 55 to 59 provide for Crown use provisions tailored to the supply of medicines to a government health service, with section 56 making supply of medicines a service of the Crown and the Court of Appeal in *Dory v Sheffield Health Authority* ruling that this includes acts carried out by NHS health authorities.⁷² In *Pfizer Corporation v Ministry of Health*, the House of Lords ruled that the Crown's procurement of patented medicines for NHS supply is Crown use and the patentee is entitled to compensation but not an injunction.⁷³ The lack of a similar mechanism for the rapid deployment of the government use in section 59 of the Ordinance is a material comparative gap.

The supplementary protection certificate (SPC) regime in the UK, which provides up to five years of additional protection for authorised medicines where the regulatory approval process has been delayed, is a more nuanced comparative lesson since it does not reduce patent protection but rather adds to it, and is a supra-TRIPS mechanism which is not required by WTO members.⁷⁴ The access-to-medicines literature that has emerged in the wake of the European SPC experience warns that extended market exclusivity, without an active compulsory-licensing counterweight, can have a significant impact on access to medicines.⁷⁵ Any future Pakistani interaction with the SPC model should therefore be done after, not before, the compulsory licensing reforms proposed in Section 8 below, and in conjunction with a manufacturing waiver as provided in EU law by Regulation (EU) 2019/933.⁷⁶

Comparative Findings

Structured Comparison Across Eight Criteria

Table 1 below summarises the comparative analysis developed in Sections 4 to 6 across the eight criteria most commonly used in comparative patent law scholarship: legal framework, institutional structure, patentability criteria, application and examination procedure, enforcement mechanisms, international treaty participation, appeals and dispute resolution, and procedural cost and accessibility.

Table 1: Comparative Summary of Patent Regimes in Pakistan and the United Kingdom

Criterion	Pakistan (Patents Ordinance 2000)	United Kingdom (Patents Act 1977)
Legal framework	Patents Ordinance 2000, amended 2002, 2007 and 2010; TRIPS-	Patents Act 1977, aligned with the EPC and amended regularly

⁷¹Patents Act 1977, s 48A(1), s 50; *Allen & Hanburys Ltd v Generics (UK) Ltd* [1986] RPC 203 (CA).

⁷²Patents Act 1977, ss 55-56; *Dory v Sheffield Health Authority* [1991] FSR 221 (CA).

⁷³*Pfizer Corporation v Ministry of Health* [1965] AC 512 (HL).

⁷⁴Council Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1; Patents Act 1977, s 128B.

⁷⁵Yuanqiong Hu, Diarmaid Eynikel, Pascale Boulet and Gaelle Krikorian, 'Supplementary Protection Certificates and Their Impact on Access to Medicines in Europe' (2020) *Journal of Pharmaceutical Policy and Practice*.

⁷⁶Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 [2019] OJ L153/1.

Institutional structure	compliant but retains colonial-era structural lineage from the Patents and Designs Act 1911. IPO-Pakistan, a statutory body under the Ministry of Commerce; acknowledged examiner shortages in its 2025 USTR submission.	to reflect TRIPS and continuing treaty obligations; never wholly replaced in nearly fifty years. UKIPO, an executive agency of the Department for Science, Innovation and Technology; centralised EPO filing route available alongside the national route.
Patentability criteria	Novelty, inventive step, industrial application; the section 7(4) ordre public and morality exclusion is undefined and broadly discretionary.	Same core criteria; section 1(3) and Schedule A2 give the morality exclusion precise statutory content; a distinct section 4A excludes medical treatment methods.
Application/examination procedure	National filing only; no PCT route; 18-month examination target and 4-month opposition window under the Ordinance.	National, EPC and PCT filing routes all available; accelerated examination (Green Channel) and work-sharing with partner offices.
Enforcement mechanisms	Intellectual Property Tribunals under the 2012 Act function largely as general civil courts; interim relief practice is comparatively formalistic.	Specialist Patents Court and Intellectual Property Enterprise Court; structured American Cyanamid interim-relief framework and Anton Piller orders.
International treaty participation	TRIPS and Paris Convention only; not a member of the PCT; no access to a regional patent office.	TRIPS, Paris Convention, PCT and EPC; applicants benefit from national, regional and international filing layers.
Appeals and dispute resolution	Appeals proceed to provincial High Courts; precedent remains fragmented across jurisdictions; limited institutional ADR.	Appeals proceed through the Court of Appeal to the Supreme Court; consolidated national precedent; UKIPO mediation service available.
Procedural cost and accessibility	Lower official fees, but higher aggregate cost for multi-country protection in the absence of a PCT route.	Higher official fees, offset for multi-jurisdictional applicants by EPC and Patent Prosecution Highway efficiencies.

Points of Convergence and Divergence

The comparative analysis comes together on a single thread in the material starting point of both countries, namely that both have developed TRIPS-compliant patentability criteria on a common law foundation, but that they differ significantly in the degree of precision with which discretionary categories are bounded, in the institutional capacity available to administer the resulting framework, and in the depth of judicial doctrine available to resolve the interpretive questions the statutory text leaves open. These are not three separate discoveries, but three observations of

the same phenomenon: the effectiveness of a patent system depends on the interplay between the text of the patent law, the institutions that administer and adjudicate it, and the operation of the exceptions in the various sectors, and a lack of effectiveness at any one level limits the effectiveness at the other two. The pharmaceutical case study is illustrative of this, as a combination of a legislative gap (the undefined compulsory licensing threshold), an institutional gap (the lack of a fast-track administrative procedure), and a judicial gap (the lack of reasoned Pakistani case law elaborating what "public interest" or "reasonable terms" requires) results in a single practical outcome — twenty-five years of non-use — which none of the three gaps can explain on its own.

Recommendations for Reform

The comparative results in Section 7 justify a reform programme that can be implemented at three different but interrelated levels: statutory drafting, judicial-institutional design and policy preconditions, which are not part of the Ordinance itself.

Legislative Reforms to the Patents Ordinance 2000

The analysis in Section 4 leads to three general reforms. First, section 7(4) should be amended to substitute for the vague "ordre public or morality" exclusion more precisely drafted statutory language, similar to that in section 1(3) of PA 1977, to reduce the discretion of the examiner and enhance predictability for applicants in sensitive industries like biotechnology.⁷⁷ Second, Pakistan should join the PCT as a legislative and treaty-accession priority as it would bring Pakistan into the international filing system and provide the basis for Patent Prosecution Highway arrangements with more developed offices like the UKIPO.⁷⁸ Third, the enforcement powers of the Ordinance should be supplemented by specific statutory powers to grant interim relief of the type that is routinely granted in UK patent litigation, such as search and preservation orders.⁷⁹

The analysis in Section 6 leads to five additional amendments that are specific to pharmaceuticals. The provisions of section 7 and 8 should be modified so as to exclude from patentability the discovery of a new form of a known substance which does not confer an enhanced efficacy on the known substance, as in *Novartis AG v Union of India*.⁸⁰ Section 11(4) should be amended to include an express Bolar exemption for all regulatory testing conducted for the purpose of obtaining marketing authorisation for a generic medicinal product, similar to section 60(5)(b) of PA 1977, as amended by regulation 49 of the Human Medicines Regulations 2012.⁸¹ Section 58(1)(b) should be amended to explicitly include public health crises, epidemics and disease outbreaks of significant public health burden as a national emergency for pharmaceutical purposes.⁸² Section 63 should be amended to include a non-exhaustive list of remuneration factors, similar to section 84(6) of the Indian Patents Act 1970, and based on the negotiated willing-licensor-willing-licensee approach used in UK case law, including *Allen & Hanburys*.⁸³ Lastly, a fast-track compulsory licensing mechanism should be established, similar to the one provided in the

⁷⁷ Patents Ordinance 2000, s 7(4); Patents Act 1977, s 1(3).

⁷⁸ Patent Cooperation Treaty (n above).

⁷⁹ Patents Ordinance 2000, s 60; Civil Procedure Rules (CPR) r 1.4, 32.1.

⁸⁰ Patents Act 1970 (India), s 3(d); *Novartis AG v Union of India* (2013) 6 SCC 1.

⁸¹ Patents Act 1977, s 60(5)(b); Human Medicines Regulations 2012, SI 2012/1916, reg 49.

⁸² Patents Ordinance 2000, s 58(1)(b).

⁸³ Patents Act 1970 (India), s 84(6); *Allen & Hanburys Ltd v Generics (UK) Ltd* [1986] RPC 203 (CA).

Indian Patents Act 1970 under section 92, without the need for prior negotiation in the event of a public health emergency.⁸⁴ All of these amendments are within the flexibilities explicitly provided for in TRIPS Articles 27, 30 and 31 and strengthened by the Doha Declaration.⁸⁵

Any future introduction of an SPC-equivalent mechanism should be linked to the prior adoption of these five pharmaceutical amendments, which are calibrated below the five-year maximum extension in the UK, and from the beginning of the process accompanied by a manufacturing waiver equivalent to Regulation (EU) 2019/933.⁸⁶

Institutional Reform: Specialised Intellectual Property Courts

The comparative judicial analysis in Section 5 demonstrates that legislative changes alone are not sufficient to address the doctrinal fragmentation and enforcement uncertainty of patent litigation in Pakistan. Structural institutional recommendation is supported by two findings. First, Pakistan has created Intellectual Property Tribunals under the Intellectual Property Organization of Pakistan Act 2012, but these tribunals are sorely lacking in judges with a specific technical or patent expertise, and in practice operate much like a general civil court.⁸⁷ Second, the lack of a unified national appeals system for IP issues (patent appeals are decentralised to provincial High Courts) makes it difficult to consolidate precedent.⁸⁸ The contrasting model adopted in the UK, where patent claims are heard by the specialist Patents Court of the Chancery Division, and lower value claims are heard by the streamlined and cost capped IPEC, provides a structural template for adaptation – not uncritical transplantation – to Pakistan's existing model of tribunals.⁸⁹ A calibrated Pakistani reform would focus patent litigation in a few tribunals with judges who have been given specialized training and have a panel of technical assessors to handle complex patent cases, and would have a single consolidated appellate process for patent cases instead of the current decentralized process through provincial High Courts.

Policy Preconditions

Some conditions are prerequisites for successful reform which are not explicitly mentioned in the Patents Ordinance 2000. The examiner shortage highlighted in IPO-Pakistan's own USTR submission necessitates continued investment in recruitment and training, which cannot be done through a statutory amendment.⁹⁰ There is a need for formal coordination between IPO-Pakistan, Pakistan Customs and Federal Investigation Agency (FIA) similar to the collaborative IP Crime Group model in the UK for effective enforcement of counterfeiting and infringement across the borders.⁹¹ Ongoing interaction with WIPO and the UK Intellectual Property Office via periodic

⁸⁴Patents Act 1970 (India), s 92.

⁸⁵TRIPS Agreement, arts 27, 30, 31; Doha Declaration (n above) paras 4-6.

⁸⁶Regulation (EU) 2019/933 (n above); Patents Act 1977, s 128B.

⁸⁷Intellectual Property Organization of Pakistan Act 2012, ss 15-16.

⁸⁸See section 3.2 above.

⁸⁹Senior Courts Act 1981, s 16; Civil Procedure Rules 1998, pt 63.

⁹⁰Government of Pakistan, Intellectual Property Organization of Pakistan, Submission to the Office of the United States Trade Representative 2025 Special 301 Review (IPO-Pakistan 2025).

⁹¹UK Intellectual Property Office, 'IP Crime Group' (GOV.UK) <<https://www.gov.uk/government/groups/ip-crime-group>> accessed 9 August 2026.

Pakistan IP Regime Review is likely to continue to be a useful avenue for technical assistance and capacity building as Pakistan implements the changes recommended in this article.⁹²

Conclusion

The aim of this article was to compare the patent law regime of Pakistan and the United Kingdom to understand why Pakistan's TRIPS obligations have not been translated into an effective patent system in practice. The comparative analysis has revealed that the explanation is not to be found in any single point of failure, but in the interaction of three mutually reinforcing deficiencies. In terms of statutory drafting, the Patents Ordinance 2000 contains the right categories of TRIPS-compliant rules in PA 1977, but several of the most important of these rules are underdeveloped to be administered predictably. In terms of the application of the doctrine, the Pakistani courts have the same formal power as their UK counterparts to shape the doctrine through precedent, but institutional factors, such as a limited number of reported cases, a disjointed appellate process, and tribunals that have not yet become truly technically specialised, have limited the exercise of that power. In the pharmaceutical industry, where the stakes of legislative and institutional weakness are highest, over two and a half decades of non-use of compulsory licensing, as reflected in the main record of notifications to the WTO TRIPS Council and IPO-Pakistan's own reporting, provide tangible comparative evidence of the direct and measurable impact of gaps in statutory drafting on a constitutionally and internationally anchored right to access to medicines. The patent system in the United Kingdom, which has been explored in this article not as a blueprint for uncritical copying but as a source of proven and TRIPS-compatible models of legislation and institutions, and India's own directly comparable statutory experience of the operative compulsory licensing regime, provides a viable and specifically identified comparative route forward. The flexibilities TRIPS already allows for a calibrated reform programme, namely precisely bounded patentability standards, an express Bolar exemption, defined compulsory licensing thresholds and remuneration criteria, a fast-track emergency procedure, PCT accession, and a genuinely specialised intellectual property judiciary, without any renegotiation of Pakistan's international obligations. The comparative analysis in this article shows that there is no lack of a legislative model for reform in Pakistan; indeed, the history of the United Kingdom's patent system provides one. What is needed is the political and institutional commitment to put the current TRIPS bargain into practice in Pakistan.

⁹²Tom Pengelly, Update of the 2020 Pakistan IP Regime Review (UK Intellectual Property Office and Department for Business and Trade, September 2025).