To
The Office of Controller General of Patents, Designs & Trade Marks (CGPDTM)
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Subject: Comments on the 'Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals (2026)'.

This submission presents comments on the "Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, 2026" ("2026 Draft Guidelines") released by the Office of Controller General of Patents, Designs & Trade Marks, Ministry of Commerce & Industry, Government of India.

The submission is divided into two parts- General Comments and Specific Comments on the 2026 Draft Guidelines.

As a preliminary comment, and as already submitted by 2 of our authors here to the DPIIT,[1] a 15-day submission window is extremely short and insufficient to provide in-depth feedback. Due to this extremely inadequate timeline, we were forced to choose between the present 2026 Draft Guidelines and the Draft Guidelines for Examination of Patent Applications in the Field of Biotechnology, 2026 ("2026 Draft Biotech Guidelines") which were released on the same day and subject to the same consultation period. Once again, we ask that a more substantial amount of time be given, should the office of the CGPDTM genuinely be seeking feedback on these important guidelines, and to prevent mere namesake public consultations.

This submission was made on September 19, 2026 within the deadline prescribed for comments, i.e. fifteen days from the publication of the 2026 Draft Guidelines (September 4, 2026).

The Submission is authored by: Ambika Aggarwal, Swaraj Paul Barooah, Praharsh Gour, Maneesha Gupta, Rishabh Upadhyay, Harini Srinivasan.[2] Thanks to Bharathwaj Ramakrishnan for his input and Sunidhi for research assistance.

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[1] Ambika Aggarwal, 'General Comment on the IPO's Draft Pharmaceutical Guidelines (2026)' (SpicyIP, 10 September 2026) Available at https://spicyip.com/2026/09/general-comment-on-the-ipos-draft-pharmaceutical-guidelines-2026.html

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Part A: General Comments

1.1 Insufficient Time for Stakeholders to Send their Comments

The timeframe of 15 days for submission of specific comments on the 2026 Draft Guidelines[3] is insufficient for the serious stakeholder deliberation that such guidelines deserve and require.[4]

It must be noted that the 2026 Draft Guidelines are the first update to the existing 2014 Guidelines. In the period of twelve (12) years, significant jurisprudential as well as technological changes have taken place in the domain of pharmaceutical patents. A mere 15-day window to study and comment on the cumulative changes of more than a decade is a patently inadequate consultation period.

These Guidelines are an important reference point to the IP Office's patent prosecution procedure and offer critical information to stakeholders across the board, from drug originator companies to generics producers, and affect the rights of patient groups, as well as society at large. We thus reiterate that adequate time must be allotted for the review of the 2026 Draft Guidelines in order for the subject matter to be reviewed with the seriousness and importance that it deserves.

Recommendation: We recommend that the public consultation process should provide adequate and reasonable time to stakeholders to submit their comments. Although stated in the context of legislations, India's Pre-Legislative Consultation Policy recommends a period of minimum of 30 days for a legislation to be kept in public domain and invite comments from the

[3] For convenience of reference and comparison where required, the Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, 2026 will be referred to as the "2026 Draft Guidelines", and the Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, 2014 will be referred to as the "2014 Guidelines".

[4] Two of the authors of this draft, i.e., Ambika Aggarwal and Praharsh Gour, had also sent an email requesting for a reasonable time period to be given, via email to the O/o CGPDTM on 10th September 2026. It is available here https://spicyip.com/wp-content/uploads/2026/09/Comments-on-the-Draft-Guidelines-for-Examination-of-Patent-Applications-in-the-Field-of-Pharmaceuticals-2026.pdf

public on the same.[5] For 106 page draft guidelines on an area that would impact so many stakeholders including with regards to life-saving medicines, along with the fact that it has been 12 years since the last set of guidelines were issued, we strongly recommend that at least 45 more days (i.e., total of 60 days) are given.

1.2 Clarifying the Hierarchy and Interplay with Other Guidelines

The Scope of the 2026 Draft Guidelines (Page 5) states,

> *"The guidelines as set out below are supplemental to the practices and procedures followed by the Patent Office as published in the "Manual of Patent Office Practice and Procedure", "Guidelines for examination of patent applications in the field of Pharmaceuticals - 2014", "Guidelines for Examination of Biotechnology Applications for Patent - 2013" and "Guidelines for Examination of Ayush Related Inventions-2025"."*

The 2026 Draft Guidelines however do not refer to how they should interact in areas of divergences, gaps, overlaps, or inconsistencies with the other guidelines and documents issued by the same office.

One such document that does not find mention is the ***'Guidelines for the Use of Artificial Intelligence in Patent Examination Procedures, 2026'*** released by the office of the CGPDTM on August 7, 2026.[6] It is well recognised that the use of Artificial Intelligence (AI) models in pharmaceutical innovation is creating new legal challenges in the assessments of core patentability criteria on novelty, inventive step, prior art, PSITA and inventorship.[7] Similarly, the Office is contemplating using AI platforms as tools for assistance with examining patent applications. The absence of information on this overlap, or how these tools play into the examination processes, creates uncertainty and possible gaps or inconsistencies in the patent examination process, especially when patent law is intersecting with new technologies in real time.

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[5]Committee of Secretaries, 'Pre-Legislative Consultation Policy (PLCP)' (2014)
[6] The Guidelines for the Use of Artificial Intelligence in Patent Examination Procedures (2026), https://ipindia.gov.in/storage/uploads/docs-operator/ade11dcd-c118-41f4-ab58-cc150f47a736.pdf
[7] Janet Freilich & Arti K. Rai, 'Patents on AI-derived Drugs: Empirical Evidence and Legal Challenges', (2026) 44 Nat Biotechnol, https://fordhamipinstitute.com/wp-content/uploads/Freilich_et_al-2026-Nature_Biotechnology.pdf.

The inter-relationship between the 2026 Draft Guidelines and the 2026 Draft Biotech Guidelines[8] released on the same day, also needs to be addressed. The substantive portions on Section 3 are similar in both Draft Guidelines, with differences in applications in their illustrations. In the absence of explicit scoping of subject matter, for instance, on 'bioavailability and therapeutic efficacy', there is a potential for stakeholders to use or argue for using differing interpretations of the two sets of Guidelines in areas of potential subject matter overlap.

Recommendation: We recommend that the 2026 Draft Guidelines should be explicitly cognisant of the overlap in subject matter with existing Guidelines of the IP Office. The 2026 Draft Guidelines should reflect how AI-assisted pharmaceutical inventions will be examined. The incoherence between the 2026 Draft Guidelines and the 2026 Draft Biotech Guidelines should be rectified.

1.3 Structural and Substantive Inconsistencies within the 2026 Draft Guidelines

Within the 2026 Draft Guidelines, the placements of certain concepts are repetitive beyond their designated subheadings. Certain editorial decisions make the draft internally incoherent or inconsistent. Indicatively, we have noted:

- Chapter 5 on Prior Art Search contains no illustrations in the chapter text. At the same time, certain illustrations pertaining to novelty and inventive step, in the Annexure are found to be discussing prior art instead. Similarly, despite a dedicated heading on 'Markush Claims' in Chapter 4 (page 8), contradicting substantive information and illustrations are found scattered in Chapters 11 and 12. We have detailed this in the submission below.

- In Chapter 9 on 'Industrial Applicability', reliance has been placed on "*the study material on 'Intellectual Property Rights - Laws and Practice' published by the Institute of Company Secretaries of India (ICSI)*" to delineate which inventions are considered

[8] The Draft Guidelines for Examination of Patent Applications in the Field of Biotechnology (2026), https://ipindia.gov.in/storage/uploads/patents/HYDWX57qp7DRZHpSGrWlz11sQDJqFfb3A80CFH1T.pdf

industrially applicable. The said text is not an authoritative text on intellectual property. The study material booklet of an adjacent field of work should not be used when there is no dearth of case law on the subject. We have elaborated on this point in detail in the submission below.

- Throughout the 2026 Draft Guidelines, we have noted instances of removal of references to decisions of the Intellectual Property Appellate Board (IPAB). The IPAB is an erstwhile IP dispute resolution body that was dissolved on April 4, 2021. Its decisions, however, continue to be utilised and cited in judgments of High Courts. Similarly, we have noticed that the 2026 Draft Guidelines have removed references to a few case laws from different Courts which were previously mentioned in the 2014 Guidelines. For instance the 2026 Draft Guidelines has removed the references to *Ram Pratap* v. *Bhabha Atomic Research Centre,* (1976) IPLR 28 (Page 34 of the 2014 Guidelines) and *Raj Prak[a]sh* v. *Mangatram Chowdhury*, AIR 1978 Del 1 at 9 (fn 25, page 38 of the 2014 Guidelines). We also note that *Raj Prak[a]sh* continues to be relied upon in the 2026 Draft Biotech Guidelines, issued by the same Office, on the same day, which suggests that their removal from the 2026 Pharma Guidelines was not inadvertent. These removals make it unclear if the Patent Office is indicating that these orders are to no longer be considered valid precedent. If this is so, the Patent Office should say so directly / explain the divergence where required.

- The 2026 Draft Guidelines appear to have at least one of what appears to be an ‘internal note’ still present in its published form. Under the example of Pharma-IE-34 (Page 81), the following line appears: *"Prior art teachings & study needs to be elaborated for comparison."* This indicates that the draft guidelines may not have been completed or verified before publishing. The same illustration also misspells the drug as 'Letemovir' in one place, which reinforces this concern.

Several illustrations in the Annexure are found lacking in legal and scientific merit. Some illustrations have been noted as misconstruing patentability tests, reaching the wrong conclusions and being incomplete in factual scenarios; while many others have been found lacking in reasoned decisions. We have elaborated on this point in detail in the submission below.

Recommendation: We recommend that the 2026 Draft Guidelines should be substantially reworked and reverified to correct defective illustrations, remove diverging definitions of the same concepts, ensure that all substantive information about a concept is provided within its designated subheading, proper authorities are cited and citation to credible authorities is not removed without reason.

1.4 Acknowledging the Patent Bargain and Flexibilities as provided for in the TRIPS Framework

Much of the phrasing of the 2026 Draft Guidelines reads the statutory provisions merely as technicalities to the prosecution. We believe that this emphasis on a mechanistic interpretation detracts from the role of certain provisions as substantive policy levers. The 'Introduction' to the 2026 Draft Guidelines makes references to the TRIPS Agreement, 1995 only in the context of product patents, mail-box provisions and exclusive marketing rights. Even when discussing the COVID-19 Pandemic, the Introduction reduces the understanding of patents to a 'numbers game' of manufactured vaccine units.

We emphasise that the 2026 Draft Guidelines should explicitly be beholden to the ethos of Articles 7 and 8 of the TRIPS Agreement.[9] The 2026 Draft Guidelines should accept and accommodate the TRIPS-compliant viewpoint that the patent prosecution structure behind "the pharmacy of the world" is so powerful because it builds our patent framework while being cognisant of socio-economic welfare and promotion of public interest.

Recommendation: We recommend that as an official document of constant reference and guidance to the examiners and stakeholders, the 2026 Draft Guidelines should embody the

[9] The TRIPS Agreement, Article 7, Objectives
"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."
The TRIPS Agreement, Article 8 (1), Principles
"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

socio-economic welfare and public interest-centric policy obligations of the TRIPS Agreement, 1995 and refrain from an overly mechanistic and technical interpretation of patent law.

Part B: Specific Comments

2. Dealing with Chapter 3: Relevant Provisions

2.1. Correction of Clerical Error in Section 3(p) Citation

The cited draft text under Section 3(p) (page 7) contains a clerical error in the concluding part of the Section. It reads “components or components”, whereas Section 3(p) in the Act reads as “component or components”; i.e., singular followed by plural of component.

Recommendation: We recommend the text to be corrected to: “***Section 3(p): an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components***.”

2.2 Inclusion of Section 8 under Relevant Provisions: Information and Undertaking Regarding Foreign Applications

Section 8 of the Patents Act, 1970 read with Rule 12 of the Patents Rules, 2003 requires patent applicants in India to furnish information about the processing of corresponding foreign patent applications for the same or substantially the same invention via Form 3. Additionally, Rule 12(3) states that the Controller may use accessible and available databases for considering information filed in these jurisdictions. Considering that Rule 12 of the Patent Rules, as recently amended, changes the method, frequency and burden of how Controllers are to ask and receive information regarding patent applications from other countries, it is pertinent that the 2026 Draft Guidelines clarify on how the Section 8 information is to be sought by the Patent Office.
(Detailed relevance and reasoning is expanded upon later on at Section 4.4 of this document).

Despite the critical role in the patent examination process, Section 8 and Rule 12 are absent under “Relevant Provisions” of the 2026 Draft Guidelines.

Recommendation: We recommend the addition of Section 8 of the Patents Act, 1970 and Rule 12 of the Patent Rules, 2003 in the “Relevant Provisions” of the 2026 Draft Guidelines.

2.3 Inclusion of Section 25 under Relevant Provisions: Opposition to the Patent

Section 25 of the Patents Act, 1970 covers provisions related to both pre-grant and post-grant opposition. It is noted that in the 2026 Draft Guidelines, opposition provisions are mentioned cursorily in-

- Introduction (Paragraph 1.11), Page 3, and
- Illustrative example, Pharma-IE-13 for Section 3(d), Page 39.

The 2026 Draft Guidelines do not mention Section 25 under “Relevant Provisions” and consequently lack further guidance on how Controllers and Examiners should conduct and adjudicate opposition proceedings under Section 25 read with Rules 55-62 of the Patents Rules, 2003.

Recommendation: We recommend the addition of Section 25 of the Patents Act, 1970 in the “Relevant Provisions” of the 2026 Draft Guidelines. (Detailed relevance and reasoning is expanded upon at Section 11 of this document).

3. Dealing with Chapter 4: Claims of Pharmaceutical Inventions

3.1 Concerns with the 2026 Draft Guidelines' Explanation of Markush Claims[10]

The definition of Markush Claims in the 2026 Draft Guidelines is a modest expansion over the 2014 Guidelines. Restricting the conversation expressly to pharmaceutical inventions, the definition in the 2026 Draft Guidelines seems to be more examination oriented in terms of full breadth of the claims. The definition in the 2026 Draft Guidelines also seems to build on the one given in 2014 Guidelines by adding considerations of clarity and support alongside patentability, sufficiency, and unity. However, the 2026 Draft Guidelines do not address the issue of a later patent application claiming a compound already covered by an earlier Markush claim. Specifically, the 2026 Draft Guidelines do not clarify whether broad coverage of a specific subject matter within a genus or Markush claim would be included as prior claiming. This question assumes particular significance in the context of Section 13(1)(b) of the Patents Act, 1970, where an earlier-filed application may be considered for prior claiming despite being published only after the filing of the later application.

Furthermore, Chapter 7 of the Draft Guidelines refers to paragraph 09.03.02 in the Manual for Patent Office Practice and Procedure (2019) for the test of novelty. The Manual cites *Novartis AG* v. *Union of India*[11] for the proposition that a compound including its pharmacological properties, already disclosed in an earlier patent, is not a new invention. Despite the reliance on *Novartis*, the draft does not clarify how this disclosure requirement is to be reconciled with determining novelty or prior claiming where the claimed subject matter merely falls within the broad, notional coverage of an earlier genus or Markush claim, but is not specifically disclosed or exemplified therein.

Unsettled Jurisprudence: Since 2014, the Delhi High Court has looked into a number of ongoing cases dealing with this issue.[12] However, law propounded in all of these cases pertains

[10] Markush claims are also dealt with by the 2026 Draft Guidelines in Chapter 7 (Assessment of Novelty). Accordingly, our comments also deal with it in that section. See Section 5 of this document.
[11] Novartis AG v. Union of India, (2013) 6 SCC 1(Supreme Court of India, 1 April 2013).
[12] AstraZeneca AB & Anr. v. Intas Pharmaceuticals Ltd., FMC Corp. and Anr. v. Best Crop. Science LLP and Anr., Boehringer Ingelheim Pharma GMBH & Co. KG & Anr. v. Vee Excel Drugs and Pharmaceuticals Pvt. Ltd. & Ors., and, most recently, the Division Bench decision in F. Hoffmann-La Roche AG & Anr. v. Natco Pharma Limited.

to the interim stage. As per the Supreme Court in *State of Assam* v. *Barak Upatyaka D.U. Karmachari Sanstha*, findings at the interim stage are *prima facie* in nature and do not constitute binding precedent for final adjudication.[13] With the volume of interim orders to final orders being lopsided, there is a risk of interim orders being cited. As such, it would be useful for the Guidelines to explicitly reiterate that interim orders do not serve as precedent.

Recommendations

1. We recommend that the 2026 Draft Guidelines clarify whether and when a specific compound falling within the scope of an earlier Genus or Markush claim is considered to have been claimed or disclosed for the purpose of Section 13(1)(b).
2. We recommend that the 2026 Draft Guidelines clarify (perhaps with an illustration) the treatment of 'earlier filed' but 'later published' applications under Section 13(1)(b), where the later claimed compound falls within the earlier Markush claim, but is not specifically identified.
3. We recommend the 2026 Draft Guidelines to provide guidance on the Novartis disclosure standard for the Markush claims, including whether mere coverage of a compound within a genus is sufficient, or whether compound must be specifically disclosed or otherwise made available by earlier application.
4. The 2026 Draft Guidelines must expressly provide clarity on the use of interim judicial orders in patent examination. Given that the recent Markush and genus-species set of orders stems from interim orders which do not have precedential value, the 2026 Draft Guidelines must clarify that interim orders are not to be relied upon to raise or waive objections.

3.2 Inconsistent Interpretation

Language in the 2026 Draft Guidelines: Markush Claims are discussed inconsistently in other places of the 2026 Draft Guidelines. In Chapter 11 (Sufficiency of Disclosure, Clarity and Support of the Claims - Page 56) it is provided (underlined emphasis our own):

[13] State of Assam v. Barak Upatyaka D.U. Karmachari Sanstha, AIR 2009 SC 2249 para 10 (Supreme Court of India, 17 March 2009).

“the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:
A) all alternatives have a common property or activity; AND
B) (1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR
B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.”

In Chapter 12 (Unity of Invention - Page 61) immediately before Pharma-IE-22, it is provided:

"The Markush group of alternative chemical compounds can be regarded as being of a similar nature is subjected to the fulfilment of the following conditions:
a) They have a common property or activity,
b) All of the Compounds derived from Markush Formula should have common structure."

As can be seen, the text present in Chapter 12 does not contain the recognised chemical class alternative (B(2)) from Chapter 11. Chapter 11 provides that alternatives in a Markush group may be considered to be of a similar nature where they have a common property or activity and either share a significant structural element or, where a common structure cannot be the unifying criterion, belong to a recognised class of chemical compounds. This formulation is consistent with (in fact a verbatim reproduction of) paragraph 10.17 of the PCT International Search and Preliminary Examination Guidelines.[14]

It is unclear why there is a change in Chapter 12 to remove the alternative limb for recognised classes of chemical compounds. Further, the worked examples in Chapter 12, particularly Pharma-IE-22 and Pharma-IE-23, similarly proceed on the basis of a common structural element, without recognising the alternative limb. This creates an internal inconsistency and may result in a narrower test being applied under the Guidelines than the test reflected in the PCT Guidelines, particularly where the alternatives share a common property or activity and belong to a recognised class but do not share a common structural element.

[14] World Intellectual Property Organization, 'PCT International Search and Preliminary Examination Guidelines', para 10.17 https://www.wipo.int/en/web/pct-system/texts/ispe/10_11_19 accessed 17 September 2026.

Defects in Markush concerned Illustrations: Pharma-IE-68 (mentioned in the Annexures, page 100) and Pharma IE-19 (Page 56) reach opposite conclusions on near identical fact patterns.

The invention under Pharma-IE-68 relates to a novel class of kinase inhibitor genus with a markush structure disclosed as claiming the invention. The claim of the illustration defines R^2 as selected from two categories: “(i) Piperidinyl, morpholinyl, or azepanyl optionally substituted with hydroxyl or carboxylic acid; (ii) A heterocyclic ring selected from pyrazolyl, imidazolyl, or thiazolyl."

These are structurally unrelated categories. Category (i) consists of saturated nitrogen-containing rings, and category (ii) of aromatic heterocycles, and there is no shared scaffold identified anywhere in the claim or description. The illustration's analysis nonetheless concludes that “the claim is supported by the description, and each alternative is enabled” and that “no objections arise with respect to sufficiency of disclosure.” The description, however, discloses only 5–10 individual compounds of unspecified composition, with the single worked example confined to R^2 = piperidin-4-yl, which falls within category (i) only. No example, property data, or synthetic route is shown for category (ii).

Meanwhile, Pharma-IE-19 treats an identical fact pattern as grounds for an objection on sufficiency and support. It draws the distinction that support requires the scope of the claims to be justified by, and correspond to the technical contribution disclosed in the specification, while sufficiency of disclosure requires that the invention be described in a manner sufficiently clear and complete for a person skilled in the art to perform it over the whole scope of the claims, and finds that where the specification only enables compounds having R1 = phenyl, the absence of disclosure for the remaining claimed alternatives also gives rise to a prima facie objection regarding sufficiency of disclosure, in addition to the objection that the claims lack adequate support. Pharma-IE-68 presents a claim under which the description enables only R^2 category (i), but does not apply this distinction and reaches the opposite conclusion.

Recommendations:

1. We recommended that the Unity of Invention test for Markush Claims in Chapter 12 (Page 61) be reconciled with Chapter 11 by replacing the current text with the following:

"the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:

A) all alternatives have a common property or activity;

AND

B) (1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR
B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains."

Illustrations IE- 22 and IE-23 should also be reconsidered in light of this clarification.

2. We recommend that the 2026 Draft Guidelines should rework the Pharma-IE-68 so that its analysis is consistent with the standard applied in Pharma-IE-19. It can be achieved by either supplying representative examples, properties, and test data for R^2 category (ii), or by concluding that an objection as to sufficiency and support arises in respect of that category. Moreover, the illustration should address the unity-of-invention question raised by the R^2 definition.

4. Dealing with Chapter 5: Prior Art Search

4.1 "Iterative" Search

The Chapter contains 3 paragraphs (5.1 - 5.3) that are materially unchanged from paragraphs 5.1 - 5.3 of the 2014 Guidelines, apart from the addition of the word "iterative" to the search-strategy requirement in paragraph 5.1. (Additionally, paragraph 5.4 of the 2014 Guidelines have been removed completely from the 2026 Draft Guidelines and this is dealt with separately in Section 4.5 of these Comments below).

Para 5.1 currently states:

> *"While conducting a prior art search, the Examiner should design or formulate a comprehensive search strategy by combining various search parameters including keywords, International Patent Classification (IPC), compound searches, etc. A thorough*

*and **iterative** search should be carried out in patent as well as non-patent databases." **(emphasis added)***

The 2026 Draft Guidelines do not define what would count as sufficient iteration.

Moreover, unlike the Disclosure, Unity of Invention, and Section 3(d) Chapters, the Prior Art Search Chapter contains no illustrations. Given that the 2026 Draft Guidelines otherwise rely on 70 illustrations for practical guidance, the absence of any worked example here leaves examiners without guidance on how the 'iterative' search standard in paragraph 5.1, or the INN-based search in paragraph 5.3, are to apply in practice.

Recommendation: We recommend that the 2026 Draft Guidelines should add illustrations to the Prior Art Search Chapter showcasing the application of an iterative, INN-based search strategy to a second-use or new-form claim.

4.2 No Reference to Specific Databases for Prior Art Search & Omission of the UNDP Methodology on Patent Searches for Essential Medicines:

Paragraph 5.1 mandates a search in patent as well as non-patent databases, however, it fails to specify which databases. In pharmaceutical patent examination, generic non-patent database searches are insufficient. An iterative search involving CAS Registry Numbers and structural formulas requires specialized databases, e.g., STNext, SciFinder, PubChem, DrugBank, ChEMBL, or the WIPO PATENTSCOPE chemical search function. Leaving various databases undefined introduces significant uncertainty regarding the baseline rigor expected of an examiner's prior art search.

For example, the United States Patent and Trademark Office (USPTO) utilizes the Scientific and Technical Information Center (STIC) to equip examiners with access to databases like SciFinder (CAS Registry), STN, and MARPAT specifically to support complex chemical structure and Markush searching.[15]

[15] United States Patent and Trademark Office, 'Commercial Databases Available at USPTO' https://www.uspto.gov/learning-and-resources/support-centers/scientific-and-technical-information-center-stic/commercial accessed 17 September 2026.

Paragraph 5.2 of the 2026 Draft Guidelines retains the five compound search methods from the 2014 Guidelines: Molecular formula, IUPAC, CAS, INN, and IPC. However, it removes footnote 1 of the 2014 Guidelines, which cross-referenced these methods to the *Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries by UNDP.*[16] Part 3 of the said document provides exhaustively the methodology for searching for medicine patents and the challenges associated with it while providing for specific databases like MARPAT, and Beilstein Online among others, to be relied upon while developing a methodology for medicine patent search.[17] Part 4 and 5 then also provides how by relying on sources like FDA Orange Book, Health Canada listings and with determination of patent landscape, a methodology with minimum cost and without any reliance on paid databases can be developed to be an efficient tool in developing countries for medicine patent searches.[18]

By removing the reference to this internationally recognized, public-health-oriented methodology of the UNDP document, the Draft Guidelines not only severs paragraph 5.2 from its contextual anchor, but also misses an opportunity to develop an efficient and low cost methodology for medicine patent searches by examiners.

Recommendations: We recommend that while the 2026 Draft Guidelines must specify the specialized commercial databases such as STN, SciFinder, MARPAT required for complex chemical and Markush structure searches, the Indian Patent Office need not rely exclusively on costly platforms. Acknowledging the financial and technical barriers highlighted in the UNDP methodology, the Guidelines should fashion an alternative, cost-efficient search protocol tailored specifically for developing nations, drawn from Parts 4 and 5 of the UNDP document. This would ensure that even when access to premium databases is limited, examiners have a standardized, highly effective, zero-cost methodology to trace pharmaceutical patents.

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[16] United Nations Development Programme, *Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries* (UNDP) https://www.undp.org/sites/g/files/zskgke326/files/publications/Patent%20Information%20and%20Transparency.pdf accessed 17 September 2026.

[17] United Nations Development Programme, *Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries* (UNDP), pt 3, 24–28 https://www.undp.org/sites/g/files/zskgke326/files/publications/Patent%20Information%20and%20Transparency.pdf accessed 17 September 2026.

[18] United Nations Development Programme, *Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries* (UNDP), pts 4 and 5, 29–45 https://www.undp.org/sites/g/files/zskgke326/files/publications/Patent%20Information%20and%20Transparency.pdf accessed 17 September 2026.

4.3 Known Substance Question

The 2014 Guidelines also contained a further paragraph, 5.4, addressed to second-use, new-indication, and new-form claims:

> *"5.4: In case it is found that the applicant claims the second use/indication in the form of a product claim of an already known pharmaceutical compound/new form of a known substance or compound, the examiner should follow the same methodology and ask the applicant to inform the INN of the said pharmaceutical substance. If the applicant does not inform the INN even on the request, the examiner should try to find out the INN and use the same in the search strategy."*

This paragraph does not appear in the 2026 Draft Guidelines, and nothing has been put in its place to identify the known substance in second-use and new-form cases.

The omission is relevant to the Guidelines' own discussion in the Section 3(d) Chapter, which relies on *DS Biopharma Limited* v. *The Controller of Patents and Designs,*[19] for the proposition that "the one specific known substance is to be identified" for the purposes of a Section 3(d) objection. Identifying that known substance, which the deleted paragraph 5.4 may secure through INN disclosure at the search stage, is the evidentiary basis on which examiners can meet the standard *DS Biopharma* sets. *DS Biopharma* itself relied on *Fresenius Kabi Oncology Limited* v. *Glaxo Group Limited*,[20] later confirmed in *Taiho*,[21] for a three-part test requiring identification of (i) the specific known substance, (ii) how the claimed substance is a derivative or new form of it, and (iii) the basis for asserting shared known efficacy.[22] A search strategy that does not require identification of the known substance's INN at the outset makes it harder for examiners to satisfy limb (i) at the examination stage.

Recommendations:

[19] DS Biopharma Ltd v. Controller of Patents and Designs and Anr, C.A. (COMM.IPD-PAT) 6/2021, 2022/DHC/003563 (Delhi High Court, 30 August 2022).
[20] Fresenius Kabi Oncology Limited v. Glaxo Group Limited, ORA 22 of 2011/PT/KOL (Intellectual Property Appellate Board, 27 July, 2013).
[21] Taiho Pharmaceutical Co Ltd v. Controller of Patents, C.A. (COMM.IPD-PAT) 6/2022 (Delhi High Court, 15 May 2025).
[22] As highlighted in our comments on Section 3(d) (See Section 8.1 of this document), the wrong paragraph has been relied upon in DS Biopharma.

1. We recommend that the 2026 Draft Guidelines should reinstate the former paragraph 5.4 from the 2014 Guidelines, thereby, requiring the examiner to request the applicant's disclosure of the INN of the known substance in case of second-use, new-indication, and new-form cases, and to independently ascertain it where the applicant does not comply.
2. We recommend that the 2026 Draft Guidelines, under the Prior Art Search Chapter, should cross-reference the identification requirement drawn from *Fresenius Kabi* and *Taiho*, so that the search-methodology requirement and the Section 3(d) identification requirement are drafted as connected obligations.

4.4 Section 8 Disclosures:

Patent applications in the field of pharmaceuticals routinely involve multiple patent applications on similar inventions filed across different jurisdictions. Looking at these applications is extremely beneficial for the examiner while assessing the Indian application as it would enable the office to make informed decisions based on any developments/ objections which these offices might have raised.

The purpose of Section 8 can be traced back to reasoning given in the Ayyangar Committee Report (1959)[23]. In the report, it was stated:

> *"It would be of advantage therefore if the applicant is required to state whether he has made any application for a patent for the same or substantially the same invention as in India in any foreign country or countries, the objections, if any, raised by the Patent Offices of such countries on the ground of want of novelty or unpatentability or otherwise and the amendments directed to be made or actually made to the specification or claims in the foreign country or countries up to the date of acceptance of the application."*

In *Fresenius Kabi Oncology Limited* v. *Glaxo Group Limited* (2013)[24], the IPAB noted the importance of this provision in keeping a check on the developments pertaining to the foreign application corresponding to the Indian application. Indicatively, the patent office had relied on

[23] Report of Shri Justice N Rajagopala Ayyangar on the Revision of the Patents Law (1959) para 350.
[24] Fresenius Kabi Oncology Limited v. Glaxo Group Limited, ORA 22 of 2011/PT/KOL (Intellectual Property Appellate Board, 27 July, 2013).

the information about foreign patent applications to reject a secondary patent application for Bedaquiline.[25]

Given the central role of Section 8 in enabling the Indian Patent Office to meaningfully examine patent applications, the 2026 Draft Guidelines should expressly clarify how such disclosures are to be evaluated.

Recommendations:

1. We recommend that 2026 Draft Guidelines include a dedicated section on Section 8 explaining how information relating to corresponding foreign applications should be evaluated during examination.
2. We recommend that the 2026 Draft Guidelines provide guidance on the evidentiary value of foreign proceedings, clarifying that a grant or favourable search/examination report from a foreign office does not, by itself, establish patentability in India.
3. We recommend that the 2026 Draft Guidelines emphasise on independent examination under Indian law, while requiring examiners to meaningfully consider relevant findings from corresponding foreign applications.
4. We recommend that the 2026 Draft Guidelines provide illustrations/examples showing how information from foreign prosecution should be considered when assessing novelty, inventive step, sufficiency, and other grounds of patentability.

5. Dealing with Chapter 7: Assessment of Novelty

5.1 Inherent anticipation

The 2026 Draft Guidelines make a significant departure from the 2014 Guidelines by removing the phrase “inherent anticipation” from the Assessment of Novelty and also removing the reference to Para 58 of the IPAB decision in *Enercon Ltd.* v. *Aloys Wobben*,[26] which explained inherent anticipation as ‘a necessary consequence of what was deliberately intended in the invention’. The 2014 Guidelines had clarified that it is not necessary that a person of ordinary

[25] Indian Patent Application No. 1220/MUMNP/2009.
[26] Enercon (India) Ltd. v. Aloys Wobben, [ORA/08/2009/PT/CH] Order No. 123 of 2013, paragraph 58 (Intellectual Property Appellate Board, 12 June 2013).

skill in the art at the relevant time would have recognised the inherent disclosure, but the result is necessary for what is intended by the invention.

With this removal, the 2026 Draft Guidelines no longer distinguish inherent anticipation from implicit disclosure, even though the 2014 Guidelines treated them as separate concepts warranting separate explanation. As per the 2014 Guidelines, implicit disclosure asks what a skilled reader would draw out from the document as written; while inherent anticipation asks whether a claimed feature is a necessary and automatic consequence of practising the prior art, regardless of whether the skilled reader or the author of the prior document, recognised that consequence at the time. Collapsing both into a single word "inherently," with no explanation, denies examiners a workable standard for examining anticipation in such a manner.

This has significant consequences for pharmaceutical patents, as the narrowed understanding of anticipation can lead to increased evergreening patents. Inherency is the doctrine that helps prevent as being claimed as new, for eg, the metabolite necessarily produced when a known drug is administered; the polymorph necessarily obtained by following a prior process; the enantiomer necessarily present in a disclosed racemate; the degradation product necessarily formed on storage. This in turn pushes the burden to Section 3(d), on a different test, with the applicant now able to argue that inherency is not required in the Indian examination process.

Recommendations:

1. We recommend that in the 2026 Draft Guidelines the paragraph explaining inherent anticipation and citation to *Enercon*, should be reinstated entirely, along with retaining the clarification that recognition by the skilled person at the relevant time is not required.
2. We recommend that in the 2026 Draft Guidelines a note should also be added which distinguishes inherent anticipation from implicit disclosure so that the examiners do not require recognisability of the disclosure, which pertains to implicit disclosure. The appropriate test pertaining to inherent anticipation is whether the result necessarily follows from practising the prior art or not.

5.2 Generic Disclosure vis-à-vis Specific Disclosure

While the 2026 Draft Guidelines state that a generic disclosure in the prior art may not necessarily take away the novelty of a specific disclosure, they do not clarify the circumstances in which such generic disclosure may nevertheless be relevant to the novelty of the specific disclosure. Further, the example provided is unhelpful insofar that it relates to a mechanical example (metal spring, copper spring), instead of a chemical example. In pharmaceutical inventions, functional equivalence or structural equivalence (wherever appropriate) may be a relevant consideration; however, the example of copper and metal does not clarify what particular aspect of the specific disclosure would be sufficient to take away the novelty of the generic disclosure. Further, even a simple metallic compound may fall within different categories, and it is unclear which category or characteristic of the specific disclosure is to be considered for the purpose of destroying novelty. This is particularly problematic for chemical and pharmaceutical inventions involving Markush claims, structural or functional relationships, and different chemical forms. The 2026 Draft Guidelines should supplement these examples with pharmaceutical examples that explain what constitutes sufficient disclosure for the purposes of novelty.

Recommendation: We recommend that the 2026 Draft Guidelines should clarify whether, and to what extent, the teaching or direction contained within the same generic disclosure may be relevant in determining whether the specific subject matter has been disclosed. This clarification would be particularly relevant in the context of pharmaceutical inventions, where a broad generic disclosure may encompass a large number of compounds while also containing specific teachings or directions concerning particular compounds (while filing a species patent out of genus patent).

5.3 Combination & Composition Claims

The chapter on novelty at page 16 states "*Claims relating to a combination of two or more known active ingredients may be considered allowable where the applicant establishes that the claimed combination produces an unexpected technical effect, such as a synergistic effect, in the treatment of a disease or such condition. The asserted effect should be supported by appropriate experimental or clinical data demonstrating the effect of the claimed combination in comparison with the effects produced by the individual known active ingredients when*

administered separately." However, it is to be noted that synergistic effect, supported by data or otherwise, is not relevant to novelty.

The 2014 Guidelines had a straightforward approach towards assessing novelty in context of combinations by stating that "*it may happen that the combination has already fallen in the public domain and hence, should be dealt under novelty also*." Therefore, to assess novelty of such claims, the test will be to see whether the composition/ combination would be a part of a single prior art or not. Whereas, the requirement to establish an unexpected or synergistic technical effect through experimentation or clinical data fall under the purview of Section 3(e) assessment. Here too, the 2026 Draft Biotech Guidelines have retained the 2014 Guidelines sentence quoted above. It is to be noted that the removal of this from pharmaceuticals would amount to removing it for fixed-dose combination claims

The two worked illustrations Pharma-IE-3, Examples 1 and 2, in fact confirm the understanding from the 2014 Guidelines: both are decided purely on whether the prior art discloses the same composition, with no reference to synergy or comparative data at all. The stated principle and its own illustrations are therefore inconsistent with each other.

Recommendation: We recommend that the requirement of synergy or unexpected-effect or comparative-data requirement for combination/composition claims should be removed and instead the 2026 Draft Guidelines should reinstate the 2014 Guidelines framing for combination/composition claims while adopting the principle of anticipation-by-identical-disclosure rule, which will go hand in hand with the two illustrations.

5.4 Inconsistency in Understanding Over Elements in Prior Art.

The 2026 Draft Guidelines on Point 2 (page 13) states that "*A prior art is considered for anticipating novelty if all the features of the invention under examination are present in the single cited prior art document.*" However, the Guidelines also state, while quoting the decision in *Ericsson (Publ)* v. *Lava*[27] (Page 15), "*...Based on the analysis, issue a formal decision, if the invention* ***or any of its claimed elements*** *is found in the prior art, the invention is not novel. Conversely, if the invention is not disclosed by the prior art, it is considered novel*." This indicates that if any, i.e., if even a single element is found in prior art, the invention would be

[27] Telefonaktiebolaget LM Ericsson (PUBL) v. Lava International Ltd, CS(COMM) 65/2016 and connected matters (Delhi High Court, 28 March 2024).

anticipated. The quoted passage thus creates an inconsistency with the 2026 Draft Guidelines' earlier statement that anticipation of novelty requires all the features of the invention to be present in a single prior-art document.

Recommendation: We recommend that the 2026 Draft Guidelines delete the above quoted portion from *Ericsson* v. *Lava*, as it conflicts with the Guidelines' stated test for novelty.

5.5 Lack of Clarity on the Applicable Novelty Test

Chapter 7 of the 2026 Draft Guidelines refers examiners to multiple frameworks to assess novelty. This includes reference to Chapter 9, Para 09.03.02 of the Manual for Patent Office and Practice, the "*Seven Stambhas Approach"* in *Ericsson (Publ)* v. *Lava International Ltd* (para 87-88) and the six points checklist in the 2026 Draft Guidelines (Page 13). Pointing to different authorities does not clarify the role, order or hierarchy of these tests/ checklists, or framework which should prevail when the approaches in these resources diverge. An instance of this occurring was clearly explained above in point 5.4.

Recommendations

1. We recommend that the 2026 Draft Guidelines clarify the hierarchy and relationship between these authorities, tests and framework to determine Novelty.
2. We recommend that the 2026 Draft Guidelines specify which test or framework will prevail where the approaches in these different frameworks differ.

5.6 Omission of "Prior Use" from the Meaning of "Prior Art"

At page 13 of the 2026 Draft Guidelines the explanation of prior art does not expressly include prior use which is not published, unlike the 2026 Draft Biotech Guidelines which expressly state that prior art includes "*all information and knowledge relating to the invention, which is available in any publication or* ***used in the country or elsewhere in the world*** *before the date of priority of the patent application"* (Section 7). This divergence is significant for traditional knowledge and other forms of knowledge which might not have been documented in published documents.

Recommendations:

1. We recommend the 2026 Draft Guidelines to keep the definition/ explanation of prior art consistent with the Biotech Guidelines and include prior use, prior knowledge within the meaning of prior art.
2. We recommend the 2026 Draft Guidelines to clarify that prior use may constitute relevant prior art even when the use has not been recorded in a published document, to include traditional knowledge within the meaning of prior art.

5.7 Deletion of the Enablement Requirement

The 2014 Guidelines, while discussing assessment of novelty under relevant date of a prior document, stated that a prior art document must be enabling, and required a clear and unmistakable direction for the invention. This requirement does not appear anywhere in the 2026 Draft Guidelines. Expressly stating this requirement would enhance coherence and certainty by establishing a clear threshold for when a prior art disclosure is sufficiently complete to constitute an anticipation.

Recommendations: The 2026 Draft Guidelines should include enablement requirement in the assessment of novelty and it should adopt the 2014 Guidelines' language identically: "The prior art document must be enabling, i.e., there should be a clear and unmistakable direction for the invention in the prior art."

6. Dealing With Chapter 8: Assessment of Inventive Step

6.1 Clarity on Cited Case Laws

The 2026 Draft Guidelines reiterate that the person skilled in the art is an unimaginative skilled technician, relying on the 1972 UK judgement in *General Tire & Rubber Company* v. *The Firestone Tyre and Rubber Company Limited*.[28] However, in *Rhodia Operations* v. *Assistant Controller of Patents,*[29] the Madras High Court has adopted a more inclusive approach towards interpreting the person skilled in the art, recognizing that such a person may possess

[28] General Tire & Rubber Co v. Firestone Tyre and Rubber Co Ltd, [1972] RPC 457 (CA).
[29] Rhodia Operations v. Assistant Controller of Patents and Designs, (T) CMA (PT) No.88 of 2023 (Madras High Court, 25 June 2024).

imagination and creativity of a real-world skilled practitioner. The Court explained that such a person possesses skills greater than those of an average person in the industry, while not being omniscient, and emphasised the need to identify the relevant field of endeavour. The judgment further provides an approach for determining whether the person skilled in the art should comprise a team where the invention involves multiple disciplines, This point was also stated in by the Madras High Court in *Galatea* v. *Controller of Patents*.[30]

Furthermore, the 2026 Draft Guidelines in paragraph 8.5 deleted the distinction between the "obviousness person" and the "enablement man," which was previously detailed in paragraph 8.6 of the 2014 Guidelines. To explain the distinction the guidelines had relied on *Enercon (India) Ltd.* v. *Aloys Wobben*,[31] and had also clarified that the skilled person is not to be a person who is "super skilled" but also not a skilled person who can carry out only basic instructions. The Enercon ruling provided a yardstick to examiners regarding the modicum of creativity of the skilled person while judging obviousness which would be more than the enablement person while judging sufficiency of disclosure.

The Guidelines state both– Delhi High Court's four-step approach laid down in *Lava International Ltd* v. *Telefonaktiebolaget LM Ericsson*[32] and the five-step approach in *F Hoffmann-La Roche Ltd* v. *Cipla Ltd*[33], towards determining obviousness. Later, the Guidelines also acknowledge the position adopted in *Sulzer Mixpac AG* v. *Assistant Controller of Patents and Designs*[34] wherein a Division Bench of the Delhi High Court observed that the five-step test is not "commandments cast in stone". However, the Guidelines have missed the 2025 Delhi High Court Division Bench order in *Tapas Chatterjee* v. *Assistant Controller of Patents & Designs & Anr*[35]., where the Court took a stricter approach towards following the five-step test in a sequential manner and how it would essentially ensure a proper evaluation of obviousness. This view was also supported by the Delhi High Court in *Energeo Works India Private Limited* v.

[30] Galatea Ltd. v. The Controller of Patents, [(T)CMA(PT)/19/2023], paragraph 37 - 40 (Madras High Court), 15 April 2024).
[31]Enercon (India) Ltd. v. Aloys Wobben, [ORA/08/2009/PT/CH] Order No. 123 of 2013, paragraph 30 (Intellectual Property Appellate Board, 12 June 2013).
[32] Telefonaktiebolaget LM Ericsson (PUBL) v. Lava International Ltd, CS(COMM) 65/2016 and connected matters (Delhi High Court, 28 March 2024).
[33] F Hoffmann-La Roche Ltd v. Cipla Ltd 2015 (Delhi High Court, 27 November 2015).
[34] Sulzer Mixpac AG v. Assistant Controller of Patents and Designs, LPA 545/2024 (Delhi High Court, 1 July 2026).
[35] Tapas Chatterjee v. Assistant Controller of Patents and Designs LPA 836/2023 (Delhi High Court, 6 October 2025).

Assistant Controller of Patents[36], where the Court opined for a sequential application of the five-steps test.

It is to be noted that the sequential application of these tests would provide a structural framework for assessing the obviousness and would ensure consistency in how applications are assessed.

Recommendations

1. We recommend that the 2026 Draft Guidelines should expressly discuss the interpretation of Person Skilled in the Art, laid out by the Madras High Court in Rhodia Operations v Asst. Controller of Patents, for it is a contemporary and relevant ruling on the concept.
2. We recommend that the 2026 Draft Guidelines should be updated with the missing jurisprudential developments on the application of tests of inventive step.
3. We recommend that the 2026 Draft Guidelines should also state that in order to ensure consistency the examiner should sequentially apply these tests and if they are partially applying these tests, then they should clearly explain the reasons for the same.
4. We recommend that the 2026 Draft Guidelines should reinstate the *Enercon (India) Ltd.* v. *Aloys Wobben* citation and the distinction between the "obviousness person" and the "enablement man" in Clause 8.5 of the 2026 Draft Guidelines (as previously contained in Clause 8.6 of the 2014 Guidelines), or explicitly clarify the rationale for its removal for examiners to accordingly proceed upon.

6.2 Clarity on the Illustrations

The Annexure provides illustrations for conducting the obviousness analysis under Pharma-IE-30, IE- 31, and IE- 32. The illustrations appear to adopt an incomplete approach to assessing patentability, particularly in distinguishing the requirements of novelty, inventive step, and the exclusions under Section 3.

In Pharma-IE-31, the conclusion that the claimed compound is non-obvious appears to rely substantially on the fact that the compound is not disclosed in D1-D3 and that it requires further

[36] Energeo Works India Pvt Ltd v. Assistant Controller of Patents, C.A. (COMM.IPD-PAT) 21/2025 (Delhi High Court, 30 January 2026).

structural modifications, while the improved IRAK4 inhibition is noted without explaining how or why such improvement establishes an inventive step.

In Pharma-IE-32, the conclusion of inventiveness appears to rely, inter alia, on the fact that none of the cited documents disclose the claimed process, which primarily addresses novelty rather than the separate inquiry under Section 2(1)(ja).

In Pharma-IE-30, the Guidelines conclude that the substitution of selenium with sulphur would have been obvious through routine experimentation, despite noting that the cited prior art itself indicates that the sulphur analogue had little activity and suggests that selenium is essential for the relevant activity. The illustration does not adequately address how such teaching in the prior art affects the obviousness inquiry.

Recommendation: We recommend that the analysis in the illustrations should expressly examine the differences between the claimed invention and the prior art and, where relevant, address factors such as motivation to modify or combine the prior art, reasonable expectation of success, teaching away, and any demonstrated unexpected technical effect.

7. Dealing with Chapter 9: Industrial Applicability

7.1 Reliance on Informal Study Material: Non-Binding in Nature

It is noted that the 2026 Draft Guidelines have updated guidance on evaluating "Industrial Applicability" under Section 2(1)(ac) of the Patents Act, 1970. Defining "industry" *in its broadest sense as encompassing practical and useful activity beyond purely intellectual or aesthetic pursuits (pg. 31)* - the inclusion of this foundational concept is a welcome improvement over the 2014 Guidelines.

However, the cited reference for this part is not authoritative and is a study module prepared by the Institute of Company Secretaries of India (ICSI) on *"Intellectual Property Rights-Laws and Practice" (Pg. 31).* The module lacks statutory authority and binding legal value, and is seemingly inaccurate in parts. For instance, the cited study material provided a three-prong test for the criteria of "industrial application". One of them is the invention "can be made (TANGIBLE)". This is not completely accurate. The term "tangible" specifically does not take into consideration that industrial processes, chemical methods, and manufacturing steps that

are intangible in nature fully meet the requirement of being "made" or executed in an industry.[37] While the other two criteria derived from this material that an invention must be used in an activity (useful) and reproduced with consistent characteristics (concrete) are conceptually helpful, citing non-authoritative study guides dilutes the legal rigor of the examination framework. It is also noted that the hyperlink footnoted to access the ICSI module is not to be found accessible.

Recommendation: We recommend that reference to non-binding study material, i.e., the ICSI module along with its footnote from the Chapter 9 of the 2026 Draft Guidelines, be removed.

8. Dealing with Chapter 10: Inventions not patentable

Given the limited 15-day period provided for submitting comments on the document, our comments in this section are confined to the discussion of Section 3(d), even though this portion in the Guidelines also includes Sections 3(b), 3(c), 3(e), 3(i), 3(j), and 3(p). Each of these are significant provisions and it is quite unfortunate that sufficient time has not been provided to submit comments on these.

8.1 Missing reference to IPAB Decisions

The substantive content on Section 3(d) under Chapter 10 (“Inventions Not Patentable”) of the 2026 Draft Guidelines is substantially similar to the 2014 Guidelines, with *Fresenius Kabi Oncology Limited* v. *Glaxo Group Limited*[38] replaced by *DS Biopharma Limited* v. *The Controller of Patents and Designs,*[39] and references to the IPAB orders being removed.

One such removed reference is the description of the patent prosecution procedure cited from *Fresenius Kabi Oncology Limited* v. *Glaxo Group Limited*[40]

[37] Advika Singh Malik, ‘SpicyIP Tidbit: Beyond Abstract Ideas: Understanding Process Patentability for a Progressive Innovation Ecosystem’, (*SpicyIP,* 21 April 2025) https://spicyip.com/2025/04/spicyip-tidbit-beyond-abstract-ideas-understanding-process-patentability-for-a-progressive-innovation-ecosystem.html.
[38] Fresenius Kabi Oncology Limited v. Glaxo Group Limited, ORA 22 of 2011/PT/KOL (Intellectual Property Appellate Board, 27 July, 2013).
[39] DS Biopharma Ltd v. Controller of Patents and Designs and Anr, C.A. (COMM.IPD-PAT) 6/2021, 2022/DHC/003563 (Delhi High Court, 30 August 2022).
[40] Fresenius Kabi Oncology Limited v. Glaxo Group Limited, ORA 22 of 2011/PT/KOL, paragraph 56 (Intellectual Property Appellate Board, 27 July, 2013).

"… But in a revocation the applicant must plead and prove that it is hit by S.3(d) and that it has the same therapeutic efficacy as the known substance. Then the respondent will counter it either by proving that it is not a derivative of a known substance or by proving that though it is only a new form of a known substance he has shown that it has enhanced therapeutic efficacy. In the present case, there are no such pleadings. It is not enough to plead that because Ex1 and 2 are admitted prior arts, this is only a new form of those compounds. That is vague. It is only when the pleadings show how the invention is one kind of a derivative of known substance the patentee will have to explain how the grant of patent is justified because of the enhancement of therapeutic efficacy."

This reference has been substituted with the Delhi High Court's decision in *DS Biopharma Limited* v. *The Controller of Patents and Designs,*[41]

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

Placing reliance on this particular excerpt from *DS Biopharma* is not an optimal choice. When read without context, it seems to imply a reduced burden where a "brief" description from the patent examiner might be found satisfactory. This would lead to a disturbing trend of unsubstantiated FERs, especially when the threshold of "enhanced therapeutic efficacy" remains highly context-specific.

DS Biopharma had in fact relied on *Fresenius*, with the court observing that information on three criteria was not supplied by the patent examiner; the criteria were subsequently confirmed in *Taiho*[42] –

"(i) What is the specific 'known' substance in question?

(ii) How and why the claimed molecule(s) or substance(s) is a derivative or is otherwise a new form of a known substance?

[41] DS Biopharma Ltd v. Controller of Patents and Designs and Anr, C.A. (COMM.IPD-PAT) 6/2021, 2022/DHC/003563 (Delhi High Court, 30 August 2022).
[42] Taiho Pharmaceuticals Co. Ltd. v. The Controller of Patents, C.A. (COMM. IPD-PAT) 6/2022.

(iii) Basis to assert that the alleged 'known' substance and the claimed molecule or substance have the same 'known' efficacy?"[43]

Reference to this succeeding portion of the judgment for the formulation of guidelines incorporating such specific requirements for the patent examiners would provide more certainty and clarity to all stakeholders on the patent prosecution requirements. The scope of the 2026 Draft Guidelines admits to the "dynamic nature" of case law. While this is an apt observation, any reference that is made to judicial decisions should incorporate the substantive portions of the rulings, especially when they have been cited approvingly in other judgments and directly relate to the patent prosecution procedure.

Recommendations:

1. We recommend that the 2026 Draft Guidelines should reconsider its references to judicial decisions and take note of substantive parts of the judicial decisions that it seeks to rely on.
2. We recommend that the 2026 Draft Guidelines should formulate into guidelines such directions that create a comprehensive patent filing and examination protocol instead of emphasising on 'brief' mentions of information in patents and related documents.

8.2 Clarity on Examination of Combination Claims

The 2026 Draft Guidelines remove the reference to IPAB's explanation of the term 'combination' cited from *Ajanta Pharma Limited* v. *Allergan Inc. and Others*,[44]:

The term "combination" as appearing in Section 3(d) has been explained by IPAB as "The combination mentioned in the Explanation can only mean a combination of two or more of the derivatives mentioned in the Explanation or combination of one or more of the derivatives with the known substance which may result in a significant difference with regard to the efficacy"

[43] DS Biopharma Ltd v. Controller of Patents and Designs and Anr, C.A. (COMM.IPD-PAT) 6/2021, 2022/DHC/003563, paragraph 15 (Delhi High Court, 30 August 2022).
[44] Ajanta Pharma Limited v. Allergan Inc. and Others ORA/21/2011/PT/KOL of Order no. 173 of 2013, Paragraph 84 (Intellectual Property Appellate Board, 8 August 2013).

While this definition has now been removed, the Guidelines should provide greater clarity in examination of combination claims. In particular, the Guidelines should clarify that characterizing an invention as a combination does not, by itself, take its individual claims and components outside the scope of Section 3(d), and that the claimed combination as a whole would additionally be required to satisfy the requirement of Section 3(e).

Recommendation: We recommend that the 2026 Draft Guidelines clarify that, where a combination or composition claim involves a new form of a known substance, each relevant component must independently satisfy the requirements of Section 3(d), while the combination or composition as a whole must additionally satisfy the requirements of Section 3(e).

8.3 Defects in Illustrations

Although the 2026 Draft Guidelines specify that the illustrations contained therein “are not intended to exhaust the manner in which the relevant guidelines are to be applied in practice” and the examiners should “examine applications on a case-by-case basis, without being prejudiced by the specific illustration being provided”, it is reasonable to expect that in practical application these 70 (seventy) illustrations will be used for reference and clarity by the examiners.

19 illustrations from Pharma-IE-34 to Pharma-IE-52 have been dedicated to cover several prongs of the Section 3(d) assessment. Special attention should have been given to the content of said illustrations. Unfortunately, several of the new illustrations included in the 2026 Draft Guidelines follow a pattern where the description of therapeutic efficacy is given in a “brief manner”; consequently, some illustrations suffer from scientific and legal incompleteness, while at least 4 (four) of the illustrations appear to be potentially mistreating the legal requirements of Section 3(d). It has also been observed that for some of these illustrations, the compounds and their properties refer directly to existing patents which have not been cited in the 2026 Draft Guidelines.

i. Pharma-IE-39: Ether of a known substance

This illustration refers to an ether converting GABA α5 negative allosteric modulator (NAM) into positive allosteric modulator (PAM). The Analysis states that his conversion is proof of enhanced

therapeutic efficacy. In view of the given set of information, this conclusion could be scientifically unsound.

Briefly, NAM demonstrates a reduced response of the receptor to GABA and PAM increases it. Both pharmacological mechanisms are directionally opposite. Going from NAM to PAM is not always a better therapeutic response. In some medical conditions, the reverse, i.e. going from increased to decreased uptake might also be beneficial. The illustration makes this mistake of over-simplification, where a negative to positive change in direction is itself considered an enhancement of therapeutic activity, while providing no direct assessment of the same,

> "*The compound disclosed in prior art are negative allosteric modulators ("NAMs") of GABA α5, while the compounds of the present invention are positive allosteric modulators ("PAMs"). Therefore the claimed ether derivative compound shows enhanced therapeutic efficacy over the prior document.*"

The change from NAM to PAM could simply be a change in pharmacology. In the absence of any comparative evidence, it cannot be said whether PAM activity is a potential improvement and demonstrates better therapeutic outcomes. The illustration is, thus, too hasty in reaching its conclusion.

ii. Pharma-IE-43: Metabolite of a known substance

The illustration could be conceptually sound, but its phrasing creates internal confusion between what the parent compound is, what is the salt of the metabolite, specific identification of Formula 1 and Formula 2 and the comparator. Section 3(d) analysis specifically requires the identification of what is being compared. Further, the illustration appears to be inspired by an existing patent, EP31880001B1,[45] and has not been cited appropriately.

iii. Pharma-IE-47: Isomer of a known substance

The illustration seems to equate safety with enhanced therapeutic efficacy,

> "*... applicant shows that S-isomer of norketotifen shows better therapeutic efficacy than the racemic mixture of norketotifen with less side effects. Thus, the claim satisfies the requirements of Section 3(d)...*"

[45] EP3180001B1 - Active metabolite of 1-[(2-bromophenyl) sulfonyl]-5-methoxy-3-[(4-methyl-1-piperazinyl) methyl]-1h-indole dimesylate monohydrate and dimesylate dihydrate salt of active metabolite, available at https://patents.google.com/patent/EP3180001B1/en.

Decreased side effects are generally not solely sufficient to satisfy the Section 3(d) scrutiny. The illustration does not provide supporting information on whether “less side effects” contribute to better therapeutic value in treating the disease. Thus, the conclusion of satisfaction of the requirements of Section 3(d) is unsubstantiated.

iv. Pharma-IE-49: Complex of a known substance

The illustration pertains to a “*zinc-curcumin complex which shows better therapeutic efficacy towards antioxidant property over curcumin.*” This illustration does not use any comparative data, nor does it justify why an increase in antioxidant properties contributes to enhanced therapeutic efficacy. Thus, the conclusion that the requirements of Section 3(d) are met is unjustified.

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

This illustration conceptually confuses Section 3(d) with Section 2(1)(j). Section 3(d) is concerned with “*the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*” Novelty of the process used is not a requirement to be assessed under Section 3(d). This illustration submits such subject matter to a Section 3(d) assessment that is beyond the statutory ambit. In any event, the example’s analysis cannot be reconciled with the Explanation to Section 3(d), as a new crystalline form of the same substance (i.e., a polymorph), is deemed to be the ‘same substance’ as per the Explanation, unless it differs significantly with regards to efficacy. The illustration does not refer to any such data. Similarly, Pharma IE-9 in the same Draft Guidelines also points out that a mere modification in physical size is treated as obvious.This illustration is wrong on all points of its analysis.

Recommendations:

1. We recommend that the illustrations included in the 2026 Draft Guidelines be reworked to remove implied and obvious defects.
2. We recommend that suggestive illustrations should be explicit and clear on substantive legal tests, prosecution procedure and requirements, and construct factual applications in a manner that is useful.
3. We recommend that where the illustrations are referring to existing patents, such patents should be adequately cited.

9. Dealing with Chapter 11: Sufficiency of Disclosure, Clarity and Support of the Claims

The substantive content under this heading largely carries forward the 2014 Guidelines with certain changes which need attention.

9.1 Absence of a Stated Distinction Between the Four Requirements Bundled under Sections 10(4) and 10(5)

The Chapter treats enablement (Section 10(4)(a)), best mode (Section 10(4)(b)), fair basis (Section 10(5)), and clarity/succinctness (Section 10(5)) as one undifferentiated inquiry, without indicating that these requirements do not carry the same consequences at every stage of examination.[46] Stating the distinction would ensure an objection is raised, and can be sustained, at the correct stage: enablement under Section 10(4)(a) is available as a ground under both Section 25(1)(g) and Section 25(2)(g), whereas best mode under Section 10(4)(b) and fair basis under Section 10(5) are not listed opposition grounds and become available only as grounds for revocation under Section 64(1)(h)-(i).

Recommendation: We recommend that the 2026 Draft Guidelines add a paragraph stating that enablement under Section 10(4)(a) is a ground available at both pre-grant opposition under Section 25(1)(g) and post-grant opposition under Section 25(2)(g), whereas best mode under Section 10(4)(b) and fair basis under Section 10(5) are not listed opposition grounds and are enforceable only as grounds for revocation under Section 64(1)(h)-(i).

9.2 Incorrect Statutory Citation

The Chapter cites Section 10(4)(ii)(d) as the basis for requiring disclosure of the source and geographical origin of biological material. The correct citation, as also used under the head “Deposition of Biological Material” on page 58 of the 2026 Draft Guidelines is Section 10(4)(d)(ii). Correcting this typing error removes an internal inconsistency within the Chapter's own text which has been carried forward unchanged from the 2014 Guidelines.

[46] Adarsh Ramanujan, Ramanujan’s Patent Law (1st edn, OakBridge Publishing 2025) 323-325.

Recommendation: The 2026 Draft Guidelines should correct the citation “Section 10(4)(ii)(d)” to Section 10(4)(d)(ii) wherever it appears in the Chapter.

9.3 The Risk of Importing Inventive Step Evidentiary Standard into Sufficiency Inquiry

This Chapter requires that for substance, composition, or combination claims, “*detailed report pertaining to the test, such as in vitro or in vivo, conducted and experimental results with inference of such a test shall be provided in the description*.” As worded, this does not distinguish between two categories of data: data needed to enable a person skilled in the art to work the invention and to substantiate the use or effect asserted for it, which is properly a matter of sufficiency under Section 10(4)(a); and comparative data establishing technical advancement over the prior art, which is a matter of inventive step under Section 2(1)(ja).

The Chapter relies on *Saint Gobain Glass France* v. *Assistant Controller of Patents and Designs & Anr.*,[47] for the proposition that Section 10 sufficiency and Section 2(1)(ja) inventive step operate in distinct spheres. The judgment illustrates the distinction on its own facts. The Court held, at paragraph 42, that the Controller “*did not raise an objection of insufficiency of disclosure under Section 10 of the Act. The data in the Complete Specification was considered adequate for the limited purpose of disclosure*,” and that the separate objection concerned only the absence of comparative data proving technical advancement under Section 2(1)(ja). The same specification was thus treated as sufficient for disclosure while being inadequate for inventive step. Confining the detailed report and experimental results requirement to data needed for enablement and for substantiating the asserted use would keep the sufficiency inquiry within its own sphere rather than extending into the enquiry of inventive step.

Recommendation: We recommend that the 2026 Draft Guidelines should confine the requirement of “detailed report... experimental results with inference” to data necessary to enable a person skilled in the art to work the invention and to substantiate the use or effect asserted for it, and should clarify that comparative data establishing technical advancement over the prior art remains a distinct requirement of inventive step under Section 2(1)(ja), as

[47] Saint Gobain Glass France v. Assistant Controller of Patents and Designs & Anr. C.A.(COMM.IPD-PAT) 13/2024 (Delhi High Court, 11 September 2025).

recognised in *Saint Gobain Glass France* v. *Assistant Controller of Patents and Designs & Anr.*, paragraphs 42-43.

9.4 Deletion of Instrumental Part from 2014 Guidelines

Two passages present in the 2014 Guidelines have been removed from the 2026 Draft Guidelines without any indication of the reason for their removal or any substitute being provided.

1. The 2014 Guidelines relied on the IPAB's observation in *Enercon (India) Ltd.* v. *Aloys Wobben*[48] to distinguish between the person skilled in the art (the obviousness person) and the person who has average skill (enablement man). This distinction served the purpose of providing a legal standard for examiners while evaluating an application for enabling disclosure requirements. This distinction is not stated anywhere in the 2026 Draft Guidelines, irrespective of the fact that it remains a good law and offers a judicially recognised standard against which sufficiency has to be measured. While the 2026 Draft Guidelines introduce the Saint Gobain standard to caution an examiner against confusing sufficiency with inventive step, the removal of the Enercon standard leaves the examiners to follow a legal boundary without any guidance on how to follow it.

2. The 2014 Guidelines, at paragraph 11.4, also carried a paragraph on claims that seek to protect subject matter "*not identified by the applicant at the time of filing the application, but that may be identified in the future by carrying out the applicant's process.*" This paragraph addressed what is commonly termed a reach-through claim. This has been dropped from the 2026 Draft Guidelines, even though the corresponding 2026 Draft Biotech Guidelines (Part C, Section 19) retain the identical principle. The result is an unexplained inconsistency between two guidance documents issued by the same Office in the same cycle, addressing the same statutory requirement.

Recommendations:

[48] Enercon (India) Ltd. v. Aloys Wobben, [ORA/08/2009/PT/CH] Order No. 123 of 2013, paragraph 30 (Intellectual Property Appellate Board 12 June 2013).

1. We recommend that the 2026 Draft Guidelines should restore the passage from Enercon (India) Ltd. v. Aloys Wobben, distinguishing the notional addressee for enablement from the notional addressee for obviousness, in substantially the same form as in the 2014 Guidelines.

2. We recommend that the 2026 Draft Guidelines should restore the reach-through claims paragraph from the 2014 Guidelines, in a pharmaceutically appropriate form, to maintain consistency with the 2026 Draft Biotech Guidelines.

9.5 Defects in Illustrations

Pharma-IE-67 concerns a Markush claim in which terms such as "substituted or unsubstituted heteroaryl" are used without disclosing the identity of the heteroatom, the number of heteroatoms, the point of attachment, or the substitution pattern. The 'Analysis' attributes this defect to Section 10(4)(c) alone. Section 10(4)(c) requires a complete specification to end with a claim or claims defining the scope of the invention for which protection is claimed. This is a requirement about the presence and structure of claims. The separate requirement that claims be clear and succinct is set out in Section 10(5). The FER record in two of the judgments relied upon in this Chapter shows that the Patent Office does not treat these two provisions as alternatives, but raises them together: in Saint Gobain Glass France, the FER dated 25th April 2019 raised "Lack of clarity under Section 10(4)(c) and 10(5) of the Act," repeated in the subsequent hearing notice; and in *OpenTV Inc.* v. *The Controller of Patents and Designs*,[49], the FER raised "insufficiency of disclosure and definitiveness in the claims, under Sections 10(4)(c) & 10(5) of the Act." Aligning Pharma-IE-67 with this practice, by citing both provisions together and explaining why an indefinite substituent fails to define the scope of the invention under Section 10(4)(c) would make the illustration consistent with how the Office itself frames such objections.

Pharma-IE-69 concerns a composition claim that fails to identify the active pharmaceutical ingredient and describes its preparation only as standard pharmaceutical techniques. The concern in this illustration lies in the general text discussed above, which requires "detailed report... experimental results with inference" for all substance, composition, or combination

[49] OpenTV Inc. v. The Controller of Patents and Designs C.A.(COMM.IPD-PAT) 14/2021 (Delhi High Court, 11 May 2023).

claims without qualification. The Intellectual Property Appellate Board, in *TATA Global Beverages Ltd.* v. *Hindustan Unilever Ltd.*,[50] held that the sufficiency requirement is met if at least one way of working the invention is clearly indicated enabling the skilled person to carry out the invention, and that it is not necessary for the purpose of Section 10(4) that the disclosure of a patent be adequate to enable the skilled person to carry out all conceivable ways of operating the invention, since disclosure of the best method known to the patentee satisfies the requirement.

Recommendations:

1. We recommend that the 2026 Draft Guidelines should correct Pharma-IE-67 to cite Section 10(4)(c) together with Section 10(5), the clarity/succinctness limb of that provision, as distinct from the unity-of-invention limb addressed in the separate Chapter on that subject which is consistent with the Office's own practice recorded in Saint Gobain Glass France case, and *OpenTV Inc*. v. *The Controller of Patents and Designs*, and should add a sentence explaining why an indefinite Markush substituent fails to define the scope of the invention for the purposes of Section 10(4)(c).
2. We recommend that the 2026 Draft Guidelines should replace the words “shall be provided” in the text preceding Pharma-IE-69 with words to the effect that such data “should ordinarily be provided, to the extent necessary to enable a person skilled in the art to work the invention without undue experimentation," as per the ruling in *TATA Global Beverages Ltd*. v. *Hindustan Unilever Ltd.* to confirm that disclosure of the best method known to the applicant satisfies Section 10(4).

10. Dealing with Chapter 12: Unity of Invention

10.1 Clarification on a Posteriori Determination of Unity

The 2026 Draft Guidelines state that lack of unity may be evident in an application through *a posteriori* assessment, i.e., after a search of the prior art, if the shared technical feature fails to make a contribution over the prior art. However, the illustration IE-20 appears to assess unity

[50] Tata Global Beverages Limited v. Hindustan Unilever Limited and Anr. TRA/1/2007/PT/MUM (Intellectual Property Appellate Board, 18 October 2012).

primarily by examining whether the claims share a common structural or special technical feature, without illustrating how consideration of the prior art leads to a finding of lack of unity.

Further, the existing illustrations concerning intermediate and final products (IE-24) may clarify how the contribution of the shared technical feature is to be assessed against the prior art, particularly where the same intermediate gives rise to multiple final products, for the purpose of determining unity of invention.

Recommendations:

1. We recommend that the 2026 Draft Guidelines clarify the test for determining whether the shared technical feature makes a contribution over the prior art for the purposes of assessing a posteriori lack of unity.
2. We recommend that the 2026 Draft Guidelines revise the IE-24 illustration concerning intermediate and final products to explain how this assessment should be undertaken where the same intermediate gives rise to multiple final products.
3. We recommend that the 2026 Draft Guidelines consider including a separate example specifically illustrating a posteriori finding of lack of unity, where the shared technical feature initially appears to establish unity but is subsequently found not to make a contribution over the prior art.

10.2 Removal of Clarification Regarding Additional Properties or Activities of Intermediates

The earlier 2014 Guidelines expressly stated that, where unity of invention is recognised, the fact that an intermediate also exhibits other properties or activities should not affect the unity of invention. This clarification has been removed in the present 2026 Draft Guidelines. The Guidelines may clarify whether the removal of this proposition is intended to alter the position concerning the effect of additional properties or activities of an intermediate on the determination of unity of invention.

Recommendation: We recommend that the 2026 Draft Guidelines may clarify whether the removal of the above proposition is intended to alter the position concerning the effect of additional properties or activities of an intermediate on the determination of unity of invention.

11. Pre- and Post-Grant Opposition

Pre-grant opposition proceedings under Section 25(1) read with Rule 55 aid the Controller during examination of patent applications in the field of pharmaceuticals by bringing forward vital technical evidence, prior art, and Section 3(d) objections. Such opposition also plays a key role in preventing frivolous patents from being granted as demonstrated in the rejection of secondary patent application for Bedaquiline[51] and Tenofovir[52] (establishing a lack of inventive step and failure to meet Section 3(d) threshold), as well as Imatinib[53] (establishing failure to meet Section 3(d) threshold). As per Rule 55 of the Patent Rules, 2003, following the Patent (Amendment) Rules, 2024, the Controller must conduct a prima facie assessment of the opposition, with one month window for the opponent to seek a hearing in case the opposition is rejected, before issuing the notice to the applicant. The 2026 Draft Guidelines should therefore clarify how these hearings interact with FERs and ensure consistent timelines, particularly given the requirement under Rule 55(5) for a reasoned order within one month of the hearing.

Post-grant opposition proceedings under Section 25(2) and Rules 56–62 require an Opposition Board to examine the matter and submit recommendations before the Controller's final decision. However, the law does not prescribe clear deadlines for constituting the Board, scheduling hearings after its recommendations, or issuing the final order. This lack of deadlines, particularly in the examination of patent applications in the field of pharmaceuticals patents directly impacts public health and market entry for generic alternatives.[54]

Therefore, the procedural delays and administrative inaction in resolving opposition proceedings, whether pre-grant or post-grant, have far-reaching substantive consequences.

Recommendations:

1. We recommend that the 2026 Draft Guidelines explicitly direct Controllers to issue a written, reasoned order addressing all technical grounds raised once opposition proceedings conclude- applying this requirement uniformly to both

[51] Indian Patent Application No. 1220/MUMNP/2009.
[52] Indian Patent Application No. 963/DEL/2002.
[53] Indian Patent Application No. 1602/DEL/1998.
[54] Prathibha Sivasubramanian, 'Delay Enables Monopoly: How Inaction in the Opposition Proceedings at the Patent Office Undermines Access to Medicines' (*SpicyIP,* 30 March 2026) https://spicyip.com/2026/03/delay-enables-monopoly-how-inaction-in-the-opposition-proceedings-at-the-patent-office-undermines-access-to-medicines.html.

pre-grant oppositions (under Rule 55(5)) and post-grant oppositions (under Rule 62).

2. We recommend that the 2026 Draft Guidelines should explicitly set uniform administrative standards to ensure that once a pre-grant opposition clears the first-stage filter, it is resolved expeditiously within statutory timelines rather than being subjected to prolonged procedural delays.
3. We recommend that in the absence of statutory deadlines for post-grant oppositions under Rules 56–62, the 2026 Draft Guidelines must explicitly direct Controllers to resolve proceedings within a reasonable timeframe and issue written, reasoned orders post-hearing.