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NEWSLETTER

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Intellectual Property advocacy in the fields of:

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EDITORIAL

INDIA'S FTAS & INITIATIVES

India has recently embarked on finalizing many important and useful Free Trade Agreements.

India's FTA with New Zealand has officially come into force from October 20, 2026, granting 100% duty-free market-access to a wide range of tariff categories including pharmaceuticals.

India signed the CETA (Comprehensive Economic Trade Agreement) with UK on July 24th, 2025 which is already in operation for duty-free and preferential access on a broad spectrum of goods and services. India and Oman has also signed a CETA which is welcome move, beneficial to both countries.

India is also on the fast-track to conclude India-EU FTA which is due for official signing and declaration on December 16, 2026. India and EFTA (European Free Trade Association comprising of Switzerland, Norway, Iceland and Liechtenstein) has also signed TEPA (Trade and Economic Partnership Agreement), which is expected to bring in (US DOLLAR) 100 Billion investment-by Switzerland into India.

India and USA are also negotiating for a Bilateral Trade Agreement (BTA) as a precursor to a regular Free Trade Agreement (FTA), negotiations for which are in progress with a few "road blocks". It is hoped that the FTA negotiations will pick up after the mid-term elections in USA. In all these negotiations, it is heartening to note that India has strongly defended India's IP and patent law features, steadfastly with merits from industry associations like IDMA and IPA.

Draft Guidelines For Examination Of Patent Applications In The Field Of Biotechnology, 2026: Key Considerations For Patent Applicants

The Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM), under the Ministry of Commerce & Industry, Government of India, released the *Draft Guidelines for Examination of Patent Applications in the Field of Biotechnology, 2026* on 29 October 2026.

The draft guidelines address examination-related considerations specific to biotechnology inventions, an area where scientific complexity often presents distinctive challenges in determining patentability. They provide proposed guidance on the assessment of biological inventions under the Patents Act, 1970, covering aspects such as novelty, inventive step, industrial applicability, statutory exclusions, sufficiency of disclosure and requirements concerning biological materials.

The proposed guidance is particularly relevant to biotechnology innovators, pharmaceutical and life sciences companies, researchers and patent practitioners involved in preparing and prosecuting patent applications in this field.

The following are some of the key areas addressed in the draft guidelines.

1. Novelty and Assessment of Prior Art

The assessment of novelty requires consideration of both patent and non-patent literature. Particular attention is necessary when examining inventions involving biological sequences, where even minor variations may require a detailed comparison with existing disclosures.

The draft also highlights that introducing a new process does not necessarily result in a novel product. The claimed product must independently satisfy the applicable requirements of novelty.

2. Inventive Step and Technical Advancement

A modification to an already known biological sequence, protein or process does not automatically establish an inventive step. The assessment must consider whether the claimed modification contributes a meaningful technical advancement over the existing state of the art.

The nature of the modification, its technical significance and the supporting experimental evidence may therefore become important in determining whether the invention involves an inventive step.

3. Industrial Applicability

Biotechnology inventions must demonstrate a practical application capable of being identified and substantiated. A biological sequence or protein cannot satisfy the requirement of industrial applicability merely on the basis of a theoretical or speculative possibility of use.

The claimed function and proposed application should have a credible technical basis supported by the disclosure in the specification.

4. Statutory Exclusions under Section 3

The draft guidelines address the application of various exclusions under Section 3 of the Patents Act, 1970, to biotechnology-related inventions.

The areas covered include biological material occurring in nature, new forms of known substances, mere admixtures, methods of agriculture and treatment, plants and animals, computer programmes and algorithms, and traditional knowledge.

These exclusions require careful consideration when defining the scope of biotechnology claims, particularly where the claimed subject matter involves naturally occurring biological material or applications falling within excluded categories.

5. Efficacy, Enhanced Properties and Synergistic Effects

The discussion concerning Sections 3(d) and 3(e) is particularly relevant to pharmaceutical and biotechnology inventions.

Where Section 3(d) is applicable, the applicant may need to establish the requisite enhancement in efficacy over the known substance. Similarly, where a composition is examined under Section 3(e), evidence of a synergistic effect may be relevant to distinguish the claimed composition from a mere aggregation of the properties of its individual constituents.

Accordingly, appropriate experimental data and comparative evidence can play an important role in addressing these objections.

6. Sufficiency of Disclosure and Support for Claims

The specification must provide sufficient technical information to enable a person skilled in the relevant field to perform the invention. The disclosure should adequately support the scope of the claims and provide the necessary details

concerning the claimed biological material, its characteristics, functions and applications.

Claims extending beyond the information and technical support available in the specification may attract objections relating to sufficiency of disclosure and claim support.

7. Biological Material, Source Disclosure and Deposit Requirements

Biotechnology patent applications may involve biological materials that require specific disclosure and deposit-related considerations.

The draft addresses the importance of identifying the source and geographical origin of biological material, complying with applicable biodiversity requirements and meeting deposit requirements where the nature of the biological material necessitates such a deposit.

These aspects are important not only for examination of the patent application but also for ensuring compliance with the relevant legal framework governing access to biological resources.

Significance for Patent Practice

The draft guidelines highlight the scientific and legal scrutiny required in the examination of biotechnology patent applications. They bring together considerations relating to prior art, technical contribution, industrial applicability, statutory exclusions and the adequacy of disclosure.

For patent applicants and practitioners, these considerations are relevant at both the drafting and prosecution stages. The identification of the technical contribution, appropriate formulation of claims, availability of supporting experimental data and compliance with disclosure requirements can significantly influence the examination of a biotechnology patent application.

The broader message is that a scientific finding or modification involving biological material does not, by itself, establish patentability. The claimed invention must demonstrate compliance with the applicable requirements of patent law, supported by an adequate technical disclosure.

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DELHI HIGH COURT SETS ASIDE PATENT ABANDONMENT ORDER OVER FAILURE TO ESTABLISH EFFECTIVE COMMUNICATION OF FER

Tetra Technologies, Inc. v. Union of India & Ors. | Delhi High Court | 6 October 2026

The Delhi High Court has set aside the deemed abandonment of a patent application after finding that the Patent Office had not established that the First Examination Report (FER) was effectively communicated to the applicant. The Court held that where receipt of the FER itself is seriously in doubt, failure to respond within the prescribed period cannot, by itself, justify treating the application as abandoned under Section 21(1) of the Patents Act, 1970.

Background

Tetra Technologies, Inc. approached the Delhi High Court under Articles 226 and 227 of the Constitution of India, challenging the decision to treat its Indian Patent Application No. 202017019804 as abandoned.

The application, which entered the Indian national phase from an international application, was filed on 11 May 2020. The applicant had provided both a postal address in New Delhi and an email address for service. Following a request for examination, the Patent Office stated that the FER had been issued by email on 28 October 2021.

As no response was filed within the prescribed period, the application was treated as abandoned. Tetra Technologies, however, maintained that neither the applicant nor its patent agent had received the FER. The applicant discovered the abandonment through the Patent Office portal on 25 April 2023 and subsequently made repeated representations to the Patent Office. A petition seeking relief and re-issuance of the FER, filed on 5 March 2024, remained undecided.

Dispute Over Service of the FER

The Patent Office argued that its records showed the FER had been transmitted electronically to the email address provided in the application. It relied on Rule 6(3) of the Patents Rules, 2003, which permits electronic communication, and contended that the applicant had failed to comply with the prescribed timelines under Rule 24B.

The applicant disputed receipt and produced screenshots of the relevant email inbox covering the period in which the FER was allegedly sent. The Court noted that the applicant had furnished a postal address as well as an email address for service, and that the material produced by the Patent Office established dispatch but did not establish delivery.

The Court also considered that the email was a

system-generated intimation containing a link to the examination report and a disclaimer stating that the information was under testing and was not valid for legal proceedings under the Patents Act. In these circumstances, the Court found that the alleged electronic dispatch could not, on its own, justify the serious consequence of deemed abandonment.

Court's Analysis

The Court examined Section 21(1) of the Patents Act, which links the period for putting an application in order for grant to the forwarding of the first statement of objections by the Controller. It held that deemed abandonment must be considered in the context of effective communication of the examination report to the applicant.

While acknowledging that Rule 6 permits electronic transmission and recognises the date of dispatch as the date of communication, the Court also considered Rule 6(5), which contemplates the possibility of delay in a communication reaching its recipient. The statutory scheme, therefore, does not make dispatch conclusive proof of actual receipt in every circumstance.

The Court further referred to the principle discussed in Telefonaktiebolaget LM Ericsson (Publ) v. Union of India & Ors., under which abandonment requires consideration of the applicant's conduct and the circumstances surrounding non-compliance. It observed that this principle carried particular weight where receipt of the FER itself was seriously disputed.

The applicant had entered the national phase within time, requested examination and pursued the matter after discovering the abandonment. The Court considered this conduct inconsistent with an intention to abandon the application.

The Court also noted that the applicant's repeated representations had not resulted in a substantive decision on its grievance. It emphasised the importance of notice and a reasonable opportunity to respond, consistent with the principles of natural justice reflected in Section 80 of the Act and Rule 129 of the Rules.

Decision and Directions

The Court set aside the decision treating the application as deemed to have been abandoned and directed that it be restored to the Patent Office records.

The Patent Office was directed to furnish the FER dated 28 October 2021 to the applicant's patent agent, or another address notified by the applicant, through both postal and electronic service within one week of the judgment. The applicant was granted eight weeks from the date of the judgment to submit its response.

The Court directed that, upon filing the response within that period, the application should proceed to its logical conclusion in accordance with the Patents Act and the Rules. It expressly clarified that it had not examined the merits of the patent application.

Significance

The judgment reinforces the importance of effective communication in patent examination proceedings. Although the Patent Office may use electronic transmission to communicate examination reports, a record showing dispatch may not be sufficient where the evidence raises a serious doubt about whether the communication reached the applicant.

For patent applicants and practitioners, the decision highlights the importance of maintaining accurate service details, monitoring application status and preserving records of communications with the Patent Office. It also underscores that a failure to respond to an FER must be assessed in the context of the applicable statutory framework and the facts surrounding its communication.

The ruling does not dispense with the timelines prescribed under the Patents Act and Rules, nor does it establish that every allegation of non-receipt will justify revival. Its significance lies in the Court's conclusion that, on the particular facts, the application could not fairly be treated as abandoned without establishing effective communication of the FER.

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DELHI HIGH COURT REAFFIRMS THE NEED FOR PROCEDURAL FAIRNESS IN PATENT EXAMINATION

Glisten LLC v. The Assistant Controller of Patents & Designs | Delhi High Court | 1 October 2026

The Delhi High Court has set aside an order refusing a patent application after finding that the applicant had not been given a fair opportunity to address the grounds ultimately relied upon by the Controller. The decision highlights the importance of clear and effective communication of outstanding objections during patent examination

and reinforces the application of natural justice to proceedings before the Patent Office.

Background

In *Glisten LLC v. The Assistant Controller of Patents & Designs* (C.A. (COMM.IPD-PAT) 21/2026), the applicant challenged the refusal of Indian Patent Application No. 202017005875, titled "Gemstone Coating and Methods of Making and Using the Same". The application had been refused under Section 15 of the Patents Act, 1970, on the ground that claims 1–17 lacked an inventive step under Section 2(1)(ja).

The First Examination Report (FER) had raised an inventive-step objection against claims 1–18 in view of two prior-art documents, D1 and D2. However, the subsequent hearing notice confined the objection to claim 18, referring to the absence of working examples in the specification. At the hearing, the applicant abandoned claim 18 and submitted amended claims 1–17 along with written submissions.

Despite this, the Controller refused claims 1–17 on the basis that they were obvious in view of D1 and D2. The refusal also rejected the applicant's wear-test results as failing to demonstrate an unexpected technical effect. The applicant contended that these grounds had not been adequately communicated through the hearing notice and that it had therefore been denied a meaningful opportunity to respond.

Court's Analysis

The Court examined the relationship between Sections 14, 15 and 80 of the Patents Act. It observed that although Section 15 confers the power to refuse a patent application, that power must be exercised consistently with the examination and hearing process contemplated under the Act.

The Court clarified that the Controller is not required to grant a patent merely because a particular objection is absent from the hearing notice. However, where the Controller proposes to refuse an application on a ground that has not been communicated to the applicant, the applicant must first be informed of that ground and given a reasonable opportunity to address it.

In the present case, the hearing notice did not indicate that claims 1–17 continued to face an inventive-step objection based on D1 and D2. The applicant could reasonably have understood that its response to the earlier examination objections

had addressed the position concerning those claims. Further, the final refusal relied on the alleged insufficiency of the wear-test results to establish an unexpected technical effect, a point that the applicant had not been specifically called upon to address during the hearing process.

The Court also rejected the proposition that general written submissions defending the claims could substitute for proper notice of the grounds on which the application might be refused. Had the applicant been informed of the concerns regarding its test data, it might have addressed them through further submissions.

Importantly, the Court confined its decision to procedural fairness. It did not determine whether claims 1–17 ultimately satisfied the inventive-step requirement.

Decision and Significance

The Court allowed the appeal and set aside the impugned refusal order. The patent application was restored to the Controller's file for fresh consideration in accordance with the Patents Act and the Patents Rules, 2003. The rights and contentions of both parties were left open, and the Controller was directed to reconsider the application without being influenced by the Court's observations on the procedural issue.

The decision underscores that the hearing notice is an important part of the patent examination process. Applicants must be able to identify the objections that remain outstanding and prepare their responses accordingly. Where the Patent Office intends to rely on a ground that has not been communicated, procedural fairness requires that the applicant be given an opportunity to address it before a final adverse decision is made.

For patent practitioners, the ruling highlights the importance of comparing the objections in the FER with those carried forward into the hearing notice and the final refusal order. A material difference between the grounds communicated and those ultimately relied upon may provide a basis to challenge the refusal on procedural grounds. At the same time, the judgment does not prevent the Controller from considering a valid ground of refusal; it requires that the ground be communicated and that the applicant receive a fair opportunity to respond.

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CALCUTTA HIGH COURT GRANTS INTERIM RELIEF IN PROCESS PATENT AND TRADE SECRET DISPUTE

NOCIL Ltd. v. Finorchem Ltd. & Anr. | Calcutta

High Court (IPR Division) | 7 October 2026

The Calcutta High Court has granted interim relief in favour of NOCIL Ltd. in its dispute with Finorchem Ltd. concerning alleged infringement of a process patent and the use of confidential technical information. The order addresses the protection of patented manufacturing processes and commercially sensitive information, particularly where a former employee is alleged to have disclosed confidential material to a competing enterprise.

Background

The dispute concerns NOCIL's process for manufacturing 4-ADPA (4-aminodiphenylamine), an intermediate used in the production of rubber antioxidants. NOCIL asserted rights in Indian patents, including Patent Nos. 341922, 366559 and 389262, and alleged that Finorchem was developing or manufacturing 4-ADPA through a process substantially equivalent to its patented process.

NOCIL's case also involved allegations concerning confidential technical information. According to the case summary, a former NOCIL employee had joined Finorchem, and NOCIL alleged that its confidential information had been used or disclosed in connection with Finorchem's activities.

The proceedings raised two related issues: whether Finorchem's manufacturing process allegedly adopted protected features of NOCIL's process, and whether confidential information obtained through the former employment relationship had been misused.

Proceedings Before the Court

By an order dated 26 November 2025, the Court directed Finorchem to disclose the process it was using to manufacture 4-ADPA. Finorchem subsequently submitted different versions of its process and amended its patent application.

NOCIL challenged the validity of Finorchem's patent application, contending that the challenge was insufficient and that the matter required consideration in the context of the parties' competing patent claims. The case summary also records that the Court considered the significance of the existing patent rights and the alleged similarities between the processes.

A further issue concerned Finorchem's failure to pursue available mechanisms to challenge the

validity of NOCIL's patents, including pre-grant or post-grant opposition, revocation proceedings, or other remedies under the Patents Act, 1970. This formed part of the Court's consideration of the competing positions at the interim stage.

Court's Analysis

1. Protection of the patented process

The Court considered the alleged similarities between NOCIL's patented process and the process disclosed by Finorchem. The case summary indicates that the Court placed weight on the number of common process features and the material produced in the proceedings.

In considering interim protection, the Court observed that where the conditions for relief are met, including a prima facie case, the evidentiary burden may shift to the defendant to demonstrate that its process is materially different from the patented process. This aspect of the dispute highlights the importance of process disclosures and technical evidence in cases involving alleged infringement of process patents.

2. Patent validity and infringement remain distinct questions

The Court's interim assessment of the competing processes did not amount to a final determination of patent validity or infringement. The case summary records that the Court considered the validity challenge insufficient at that stage and found a prima facie basis for protection.

The ultimate determination of whether the relevant patent claims are valid and whether Finorchem's process infringes those claims remains open for consideration in the continuing proceedings.

3. Confidentiality and trade secret protection

The dispute also concerned the alleged misuse of NOCIL's confidential technical information, including information said to have been accessed through a former employee. The Court considered the confidentiality concerns alongside the patent dispute.

The case summary identifies the risk of irreparable injury to NOCIL and the balance of convenience as relevant considerations in granting interim relief. The order underscores the importance of protecting commercially sensitive information while the underlying allegations are adjudicated. However, the trade-secret and

confidentiality issues have not been finally determined.

Decision and Current Status

By its order dated 7 October 2026, the Calcutta High Court granted interim relief in terms of prayers (a) and (b) of NOCIL's notice of motion. The separate proceeding, GA-COM/1/2024, was disposed of in accordance with the order.

The principal suit, IP-COM/25/2024, continues. The Court has not finally determined the validity of NOCIL's patents, the question of infringement, or the trade-secret and confidentiality allegations.

Significance

The decision highlights the role of interim judicial protection in disputes involving patented manufacturing processes and confidential technical information. Such disputes may require the Court to consider technical disclosures, similarities between competing processes, the circumstances in which confidential information was accessed, and the risk of commercial harm before the final issues are tried.

For patent holders, the case illustrates the potential importance of maintaining evidence of proprietary process features and safeguards around confidential manufacturing information. For defendants, it highlights the importance of supporting claims of process differentiation with clear technical evidence.

The ruling should nevertheless be understood within its procedural limits. The interim relief protects NOCIL's position pending further adjudication; it does not constitute a final finding on patent validity, infringement, or misappropriation of trade secrets.

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INDIAN PATENT OFFICE REJECTS PATENT APPLICATION FOR DRUG-RESISTANT TB DRUG COMBINATION

Source: Eshan Kalyanikar, The Times of India, 29 October 2026

The rejection of a patent application relating to a combination treatment for drug-resistant tuberculosis (DR-TB) has brought renewed attention to the relationship between pharmaceutical patentability and access to essential medicines. As reported by *The Times of India* on 29 October 2026, the Indian Patent Office rejected an application filed by the TB Alliance concerning a treatment regimen combining three

existing drugs, following opposition by public health activists.

Background

The patent application concerned a combination of bedaquiline, pretomanid and linezolid, commonly referred to as the BPaL regimen, for treating drug-resistant tuberculosis. The proposed treatment has been associated with a shorter treatment duration, potentially reducing the course of therapy from approximately 18–20 months to six months.

According to the newspaper report, the TB Alliance, a global non-profit organisation, had sought patent protection for the specific combination and dosing formulation. The application was opposed by public health activists, including the Sankalp Rehabilitation Trust and the Delhi Network of Positive People. The opponents challenged the application on the basis that combining existing medicines did not, by itself, establish a patentable invention.

Grounds for Rejection

As reported by *The Times of India*, the Patent Office rejected the application on grounds relating to lack of novelty, lack of inventive step, non-patentability and insufficient disclosure under the Patents Act, 1970.

The dispute raises an important question in pharmaceutical patent examination: whether a claimed combination of known drugs demonstrates the technical features required for patent protection. The mere fact that medicines are administered together does not automatically establish patentability. The claimed subject matter must be assessed against the applicable statutory requirements and the relevant prior art.

The outcome is particularly significant because the application concerned a treatment regimen intended to address a serious public health challenge. However, the public health importance of a treatment and the patentability of the claimed invention remain distinct considerations under patent law.

Public Health Implications

The rejection has implications for the availability of affordable treatment options for patients with drug-resistant tuberculosis. Shorter treatment regimens can reduce the duration of therapy and may ease the burden on patients and healthcare systems.

The newspaper report also highlighted concerns about periodic shortages of essential tuberculosis medicines. It reported calls for sustained supplies through the national tuberculosis programme.

The patent decision should not, however, be understood as guaranteeing immediate price reductions or uninterrupted availability. Those outcomes also depend on manufacturing capacity, procurement arrangements, supply-chain management and public health policy.

Significance for Patent Practice

The reported decision illustrates the importance of examining pharmaceutical combination claims against the statutory requirements of novelty and inventive step, alongside other applicable exclusions and disclosure requirements. Where an application concerns existing active pharmaceutical ingredients, the claims and supporting disclosure must be assessed to determine whether the claimed combination satisfies the requirements for patent protection.

The matter also demonstrates the role that pre-grant opposition can play in bringing technical and public-interest concerns before the Patent Office. Such proceedings provide an avenue for challenging applications that opponents consider inconsistent with the requirements of the Patents Act.

Ultimately, the decision highlights the need to balance the patent system's objective of encouraging genuine pharmaceutical innovation with the importance of access to essential medicines. That balance must be pursued through the application of statutory patentability criteria and careful examination of the claims and supporting evidence.

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BIOSIMILARS OFFER NEW POSSIBILITIES FOR AFFORDABLE CANCER IMMUNOTHERAPY IN INDIA

Source: Malathy Iyer, The Times of India, 25 October 2026

The growing use of biosimilar medicines is creating new possibilities for improving access to cancer immunotherapy in India, where the high cost of treatment remains a significant barrier for many patients. A report by Malathy Iyer in *The Times of India* highlights how the availability of lower-cost alternatives to established immunotherapy drugs, alongside research into lower-dose treatment approaches, could help reduce the financial burden associated with cancer care.

Reducing the Cost of Immunotherapy

Cancer immunotherapy works by helping the body's immune system recognise and attack cancer cells. Although these treatments have become important options for several cancers, their high cost can limit access.

According to the newspaper report, clinicians have observed an increase in immunotherapy prescriptions following the introduction of more affordable versions of certain drugs. Nivolumab, an immunotherapy medicine used in the treatment of multiple cancers, is one example discussed in the report.

The article also highlights research at Tata Memorial Centre examining whether lower doses of immunotherapy medicines may be effective in certain treatment settings. If supported by appropriate clinical evidence, such approaches could offer another avenue for reducing treatment expenditure without compromising patient outcomes.

Biosimilars and the Patent Landscape

Biosimilars are biological medicines developed to be highly similar to an already authorised reference biologic, with no clinically meaningful differences in safety, purity and potency. They can introduce competition into markets where treatment options have traditionally been expensive.

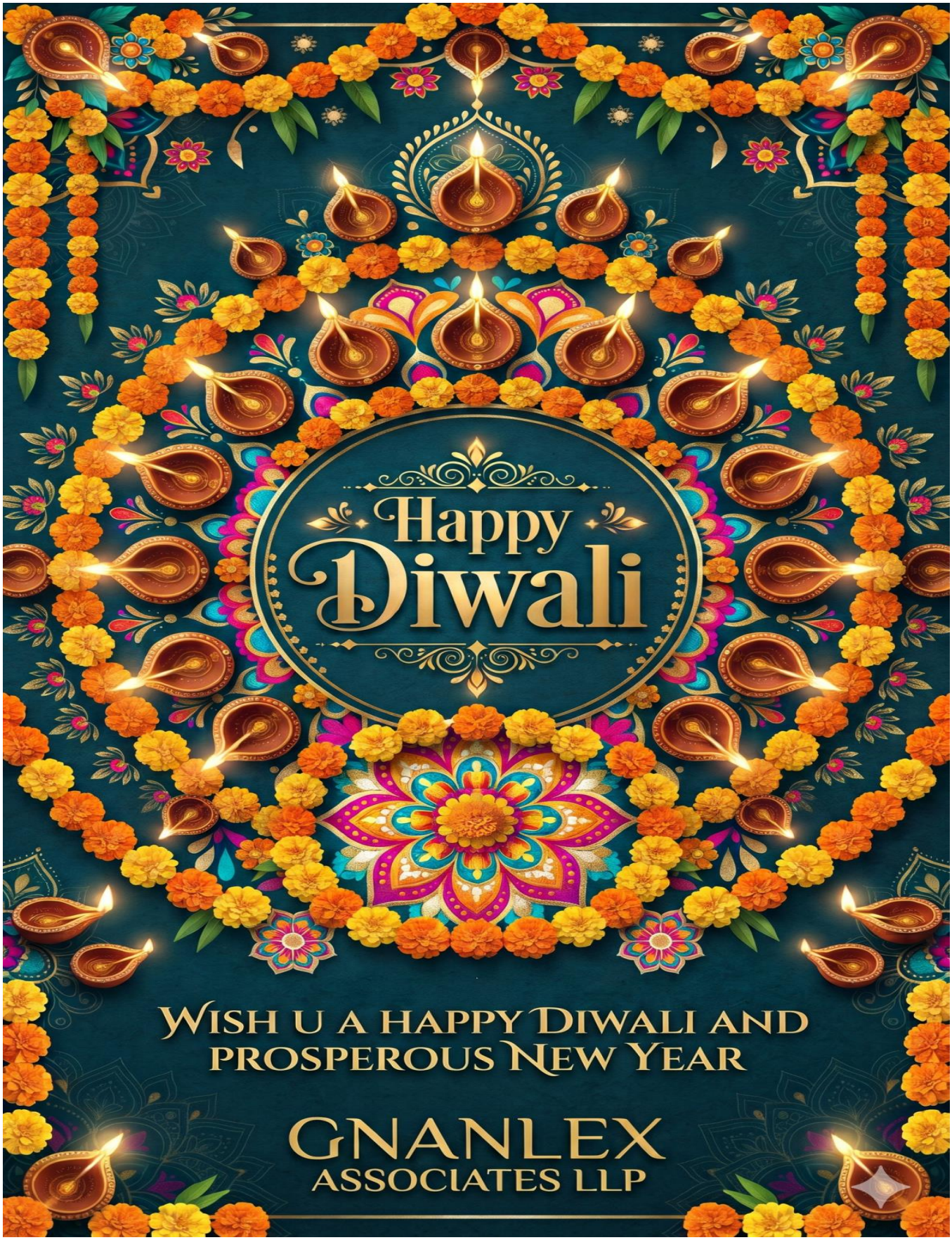
The report refers to developments concerning domestic manufacturers and biosimilar versions of immunotherapy medicines. It also notes that pembrolizumab, another important cancer immunotherapy drug, was expected to face patent expiry in 2028, potentially creating further opportunities for competition.

Patent expiry, however, does not automatically guarantee immediate market entry. Regulatory approval, manufacturing capabilities, applicable intellectual property rights and commercial considerations can all affect when a biosimilar becomes available and at what price.

Implications for Patients and Healthcare Providers

The availability of lower-cost alternatives could enable more patients to access treatments that might otherwise be financially out of reach. Greater competition may also encourage manufacturers to reconsider pricing and expand their presence in the Indian market.

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