Centre for CIPROM intellectual property management

# NEWSLETTER

Volume No.9 | Issue No. 8

AUGUST 2025

Intellectual Property advocacy in the fields of:

- IP Infrastructure
- IP Policy
- Patent Law
- Copyright
- IP Valuation
- Technology Transfer
- Licensing
- Collaborations
- M & A
- Innovation Research
- Data Management
- Balance for Rights & Obligations

## EDITORIAL

### 1. NEED FOR UPDATE ON REGULATIONS BY NBA

International trade is in turbulence lately, due to politically and economically disturbed times globally. India is trying to achieve optimum results through FTAs (Free Trade Agreements) and trade negotiations with developed countries on a fast-track. Indigenous research and innovation are now facing hurdles and blockades. National Biodiversity Authority (NBA) needs to open up to the community to apprise the user community about the latest Act (2023) and Rules (2024) and the revised (2025) ABS Guidelines. New Forms 6, 7, 8, 9 and others have been introduced for seeking approval (replacing the earlier Form III). Details are available on nbaindia.org website.

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### 2. INDIA NEEDS TO ENHANCE R&D OUTPUTS FOR GREATER NATIONAL WEALTH CREATION

India needs to increasingly invest on innovative research outcomes to support the national efforts and to move up the ladder of economic prosperity. National wealth creation through intangible asset generation and build-up is the most essential activity being need of the hour. It is essential to scale up not only academic research but also generate commercializable innovations to take them to marketplace, nationally and internationally. A recent successful innovation at Digital University, Kerala, supported by funding for academic research, led to the IP generated by startup. “Kairali AI Chip”.

The chip leverages unique features to deliver capabilities such as speed, power efficiency and scalability. It is touted to contribute its edge intelligence (or edge AI) in a wide array of areas including agriculture, aerospace, mobile phone and

automobile industries, drones and security.

The integrated circuit has been designed by a team led by Dean (Academics) Alex P. James at the AI Chip Centre that functions at the Degital University Kerala.

A controversy developed thereafter. The Save University Campaign Committee (SUCC) came up with an allegation of misuse of funds by diverting for the "AI Kairali chip". Such allegations are baseless and misleading. Related reports are attached.

Saturday, July 26, 2025
Kochi

# AI Chip developers hit back at charges, cite Centre's support

Makers of Digital University Kerala's invention – Kairali AI Chip – maintain that their invention is an academic research initiative and not a commercial product. Forum alleges misuse of funds

Sarath Babu George
THIRUVANANTHAPURAM

Countering allegations surrounding Digital University Kerala's invention, Kairali AI Chip, its makers have maintained that their invention is an academic research initiative, and not a commercial product.

They also emphasised the ground-breaking nature of its achievement of designing a functional AI test chip at a State-funded institution with limited infrastructure and funding.

The Save University Campaign Committee (SUCC) had raised concerns regarding Kairali Chip by alleging a lack of transparency in its development and misuse of public funds. The organisation also claimed that the chip's design was not disclosed, lacked patents and had not been commercially validated.

Developers of Kerala's first silicon-proven AI chip say that the project is a ground-breaking one

It had also questioned why the chip development was not officially communicated to the Central government, particularly at a time when the Centre has invested heavily in India's semiconductor ecosystem.

The developers of Kerala's first silicon-proven AI chip, have stated that the project's first prototype was developed by teams of Master's and PhD students, and was validated through multiple reviews under the Ministry of Electronics and Information Technology's (MeitY) Chip to Startup (C2S) programme.

Highlighting the prohibitive costs of chip development, ranging from $1 million to over $200 million, the makers pointed out that the test chip was realised with limited resources using programmes such as Efabless platform and open-source tools, using a 130nm fabrication process.

Under C2S initiative, the research team led by Professor Alex James was able to carry out modular tapeouts, publish research and provide real-world chip design training to students.

The university also received support through the GF-Synopsys Pilot Program, giving students hands-on experience in designing chips ready for commercial fabrication.The Kerala government has also recognised the work of Prof. James by awarding him the Kairali Researcher Award which further supported research into bio-inspired AI.

"This project too was research-driven, and tackled more experimental architecture and spiking neural models. In addition, the university also received selective access to ReRAM design files from TSMC, a global semiconductor leader, which is currently given only to a very limited set of researchers around the world," the developers added.

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## PUBLICATION OF NEW GUIDELINES FOR EXAMINATION OF COMPUTER RELATED INVENTIONS (CRIS) – 2025

The Office of the Controller General of Patents, Designs, and Trade Marks (CGPDTM), under the Department for Promotion of Industry and Internal Trade, has issued the revised Guidelines for Examination of Computer Related Inventions (CRIs) – 2025.

This update marks a significant improvement over the 2018 version, aiming to bring clarity and consistency to the examination process of CRIs.

Key additions include:

- Annexure I – Examples that illustrate how to apply the guidelines.
- Annexure II – Relevant case laws pertaining to CRIs.

In keeping with a transparent and collaborative policy approach, the guidelines also include:

- Feedback received on Draft Version 1.0.
- Details of stakeholder consultations held in Mumbai, Delhi, Kolkata, and Chennai.
- Comments and suggestions submitted on Draft Version 2.0.

Further suggestions or examples for implementation can be submitted to cgoffice.in@gov.in

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## Public Notice: PAE 2026 and TAE 2026 Notification Published

The Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM) has released the official notification for the **Patent Agent Examination (PAE) 2026** and

the **Trademark Agent Examination (TAE) 2026**.

The public notice can be accessed at the following link:

- **PAE & TAE 2026 Public Notice**

**Registration Process:**

Applicants are required to complete an online registration to apply for the examinations. Registration can be done through the following link:

- **Registration Portal**

Candidates are advised to carefully review the eligibility criteria, important dates, and examination guidelines mentioned in the notification before proceeding with the registration.

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## CASE SUMMARY

## TITLE: E.R. SQUIBB & SONS LLC & ORS. V. ZYDUS LIFESCIENCES LTD.

Citation: CS (COMM) 376/2024, Delhi High Court

Coram: Hon'ble Ms. Justice Mini Pushkarna

Date of Order: 18 July 2025

Plaintiffs: E.R. Squibb & Sons LLC and affiliates

Defendant: Zydus Lifesciences Ltd.

**Subject Matter**

Interim injunction sought by the plaintiffs in a quia timet action for alleged infringement of Indian Patent No. IN 340060, covering the monoclonal antibody Nivolumab (marketed as Opdyta® in India).

**Key Issues**

- Whether the defendant's biosimilar product ZRC-3276 infringes the suit patent.
- Whether the plaintiffs established a credible apprehension of imminent infringement.
- Whether activities such as stockpiling or preparations for launch are protected under Section 107A (Bolar Exemption).
- Whether the validity of the suit patent could be questioned at the interim stage.

**Court's Findings**

- Prima Facie Infringement: The Court found that ZRC-3276 references Nivolumab as the comparator, and its amino acid sequences fall within the scope of the patented CDRs, indicating likely infringement.
- Biosimilarity as Infringement: The Court accepted that biosimilarity, where structural elements overlap, may establish infringement, even absent direct product-to-claim mapping.
- No Protection under Section 107A: Preparations for commercial launch, including stockpiling, were held outside the scope of Section 107A of the Patents Act, 1970.

- **Patent Validity:** The Court ruled that the defendant had failed to raise a credible challenge to patent validity at the interim stage. Prior art cited by the defendant, including D1–D3 and EP '878, did not disclose the specific six CDRs claimed in the suit patent.

- Opposition Proceedings Irrelevant at This Stage: The post-grant opposition and the Opposition Board Recommendation (OBR) were deemed non-binding and pending further adjudication.

### Order

The Court restrained the defendant from manufacturing, importing, marketing, or stockpiling its biosimilar ZRC-3276 until the expiry of the suit patent on 2 May 2026, or until further orders. The defendant was also directed to file an affidavit disclosing quantities of Nivolumab manufactured or imported.

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## INDIA-UK COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA): IMPACT ON INDIAN PATENT LAW

On July 24, the final text of the India–United Kingdom Comprehensive Economic and Trade Agreement (CETA) was signed and published, just two months after its initial appearance in the media. The agreement has been described as "historic" and "landmark," largely due to the anticipated economic benefits, including significant tariff reductions for Indian exports—99% of which are to be granted duty-free access to the UK market. Additionally, Indian professionals stand to benefit from improved provisions concerning employment visas and exemption from dual social security contributions. However, these gains are accompanied by obligations for India to revise certain domestic regulatory safeguards, such as those involving patent working requirements and access to specific government procurement contracts.

Among the most comprehensive sections of the Agreement is the Intellectual Property (IP) chapter, extending across 52 pages. It covers a broad array of topics including geographical indications (GIs), trademarks, copyrights, industrial designs, patents, and trade secrets. This analysis focuses on the provisions concerning patents and their potential consequences for India's IP framework.

### Divergence from the Draft Proposals

The final version of the IP chapter diverges significantly from the draft that was unofficially circulated in 2022. That earlier version drew considerable concern for proposing several TRIPS-plus measures, such as: removing Section 3(d) of the Indian Patents Act (which limits patentability of incremental pharmaceutical innovations); eliminating the pre-grant opposition mechanism; introducing patent term extensions; waiving the requirement to submit

working statements; and mandating protection for undisclosed test data during marketing approval processes.

Fortunately, many of these problematic provisions have been omitted or substantially revised. For example, the proposed elimination of Section 3(d) has not been included in the final text. Similarly, obligations to extend patent terms or protect proprietary data submitted for marketing approvals have been excluded. These omissions are crucial in maintaining access to affordable generic medicines and in preventing evergreening practices by pharmaceutical firms.

## Remaining Concerns: Dilution of Safeguards

Despite these positive revisions, the agreement retains provisions that may weaken key public interest safeguards in Indian patent law. Notably, the agreement reflects several commitments found in the India-EFTA Trade and Economic Partnership Agreement (TEPA), which has already influenced recent amendments to the Patent Rules in 2024. These include changes to the working requirement for patents, now reduced to a formal submission every three years. The revised requirement also replaces substantive disclosure—such as production data and commercialization details—with a simplified compliance declaration. This diminishes the usefulness of working statements in contexts such as compulsory licensing and preliminary injunction disputes.

The significance of such disclosures was recently demonstrated in Conqueror Innovations v. Xiaomi, where non-working of a patent was a key factor in denying interim relief. The revised rules would likely have undermined such a legal argument.

## Reforms to the Pre-Grant Opposition Framework

Another area of concern involves the pre-grant opposition mechanism. Although the final Agreement retains the right to challenge patents prior to grant, it mandates that such proceedings be resolved within a "reasonable" time. A footnote suggests that one method of achieving this could be by establishing an expedited procedure to dismiss "unfounded" oppositions—a recommendation that mirrors proposals in the TEPA. This aligns with the 2024 Patent Rules, which introduced a preliminary screening layer and significantly increased the cost of filing such oppositions. These changes are likely to deter public interest challenges and reduce scrutiny of patent applications.

The Agreement further states that such compliance will be deemed sufficient if reforms were enacted between September 23, 2023, and the agreement's enforcement date—timing that directly overlaps with India's 2024 amendments, thereby validating concerns over the influence of trade

negotiations on domestic IP regulation.

### Modifications to Foreign Filing Disclosure Rules

In its earlier iteration, the Agreement aimed to make the non-disclosure of foreign patent filings irrelevant in revocation or refusal decisions. While the final text softens this stance, it still adopts language from the TEPA. It now specifies that non-compliance shall not in itself justify revocation or refusal—unless a competent authority finds deliberate concealment. This change weakens a longstanding transparency mechanism that enables comparative scrutiny of patent applications filed in multiple jurisdictions.

### Emphasis on Voluntary Licensing

The Agreement promotes voluntary licensing and technology transfer on mutually agreed terms as the preferred routes for expanding access to patented technologies, especially in healthcare. While it affirms the Doha Declaration and permits recourse to its flexibilities during public health emergencies, the Agreement's framing favors voluntary mechanisms over compulsory licensing. This is consistent with India's approach during the COVID-19 pandemic and further entrenches a policy direction that may limit options for safeguarding access to essential medicines.

### Patent Harmonization and Administrative Cooperation

Another dimension of the Agreement involves provisions for cooperation between the Indian and UK patent offices. These include commitments to share best practices, exchange quality assurance methodologies, and reduce procedural discrepancies in examination processes. While these measures may enhance administrative efficiency, they could also compromise India's regulatory autonomy in the name of harmonization.

### Potential for Broader Consequences

Although the final text avoids many of the most contentious provisions of the earlier draft, it nonetheless sets a precedent that may influence future negotiations with other developed economies such as the United States and the European Union. The overlap in provisions between the UK agreement and the EFTA TEPA suggests a coordinated strategy among trade partners to standardize IP norms through bilateral treaties. Without proactive assessment and negotiation safeguards, India may find itself locked into restrictive IP obligations that hinder public health and innovation policy.

To address this risk, it is essential that India undertake a forward-looking analysis of how such agreements may cumulatively affect its legal and economic landscape. Anticipating the domino effect of successive trade commitments will allow for both preventative measures in ongoing negotiations and contingency planning for future challenges.

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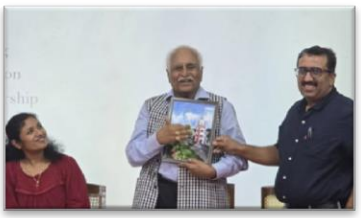
## EXPERT TALK: FROM IDEAS TO ASSETS - NAVIGATING INTELLECTUAL PROPERTY AND PATENTS

An insightful expert session titled "From Ideas to Assets" was held on July 29, 2025, at the Cardinal Padiyara Hall, St. Berchmans College. The talk was delivered by Dr. Gopakumar G. Nair, one of India's most respected Intellectual Property strategists, Designated Partner and Founder of GNANLex Associates LLP.

Dr. Nair, former Dean of the Institute of Intellectual Property Studies (IIPS), Hyderabad, and CEO of Patent Gurukul, offered a comprehensive overview of the role of patents and intellectual property in transforming innovation into valuable, legally protected assets. His session provided clarity on the often complex processes of IP registration and enforcement, making the subject accessible to students and aspiring entrepreneurs.



**Key Takeaways:**

- Simplified understanding of Patents and Intellectual Property Rights
- Practical steps from innovation to legal protection
- Real-world insights from an experienced practitioner in the field
- Interactive engagement with students and innovators

Organized by BCIE@SB in collaboration with the Institution's Innovation Council (IIC) and IQAC, the session successfully empowered participants with the knowledge and tools to navigate the intellectual property landscape.

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## Conference - "Innovation & Impact: Exploring Intellectual Property Rights and Research Grant Opportunities

**Topic:** The art of patent filing: understanding required forms and formats.


An online Conference on Innovation and Impact Exploring Intellectual Property Rights and Research Grant Opportunities was organized by Seva Mandal Education Society's Smt. Sunanda Pravin Gambhirchand College of nursing in collaboration with MES College of Nursing, Ratnagiri was conducted by Dr Srividya Ravi Consulting Patent Associate of Gnanlex associates LLP.