

New Delhi
24th March 2026

To

Shri Amardeep Singh Bhatia
The Secretary, DPIIT
Department for Promotion of Industry and Internal Trade (DPIIT),
Room No.: 223, Vanijya Bhawan, New Delhi – 110001
Email: secy-ipp@nic.in

Subject: Concerns regarding delays and non-compliance with statutory timelines in opposition proceedings

Dear Sir,

We, Third World Network (TWN), write to express our deep concern regarding systemic and recurring delays in the disposal of pre-grant and post-grant opposition proceedings before the Indian Patent Office. These delays are not merely administrative or procedural irregularities—they have serious legal and constitutional consequences, directly affecting public health, access to life-saving medicines, and the fundamental right to life guaranteed under Article 21 of the Constitution of India.

TWN has undertaken a comprehensive review of opposition matters concerning critical pharmaceutical products and found multiple instances of non-compliance with the Patents Act, 1970 and the Patents Rules, 2003. In numerous pre-grant opposition matters, no orders have been issued even after the completion of hearings. In several other matters, no notice of opposition has been issued or hearings fixed despite pleadings being complete. In post-grant opposition cases, Opposition Boards have not been constituted despite statutory requirements and despite parties having completed all pleadings.

Our review reveals that several patent applications (**Table 1**) for essential and life-saving drugs remain indefinitely pending without final decisions, including applications for Remdesivir (IN 201727012821 [IN 332280]), Molnupiravir (IN 201717025098), and Lumacaftor (3158/KOLNP/2012) . This delay constitutes a clear violation of Rule 55 (5) of the Patents Rules, which mandates that decisions in pre-grant oppositions be issued ordinarily within one month from the conclusion of proceedings in pre-grant opposition.

Table 1: Oppositions in which hearing have been concluded but orders have not been issued.

Sl.No.	Drug Name	Nature of Opposition	Application No.	Date of conclusion of hearing
1.	Remdesivir	Post-grant	IN 201727012821 [IN332280]	7/10/2024
2.	Molnupiravir	Pre-grant	IN201717025098	November- December, 2024
3.	Lumacaftor	Pre-grant	3158/KOLNP/2012	19/04/2022
4.	TBI-223	Pre-grant	IN201817004931	17/02/2025

Similarly, there are pre-grant opposition proceedings involving Lenacapavir, AT527, and Glecaprevir

Pibrentasvir where the Patent Office has failed to issue notice or fix hearings even after the expiry of reasonable period of time (**Table 2**).

Table 2: Oppositions – where early hearing/ issuance of notice requests have been filed

Sl.No.	Drug Name	Application No.
1.	Lenacapavir	IN202018020805
2.	Molnupiravir	202017019418
3.	AT527	IN201717035303
4.	Glecaprevir + Pibrentasvir	IN201817002543

Further, post-grant opposition matters such as those concerning Cabotegravir, Baricitinib, and Ledipasvir in which Opposition Boards have not been constituted (**Table 3**). This is in clear conflict with Section 25(4) and Rule 56 of the Patents Act and Rules, which requires timely constitution of Opposition Boards in post-grant opposition proceedings. These provisions are not optional—they are binding statutory obligations designed to protect the public interest.

Table 3: Post-Grant Oppositions – where requests to constitute opposition board to conduct hearing have been filed

Sl.No.	Drug Name	Application No.
1.	Baricitinib	5348/DELNP/2014
2.	Ledipasvir	9313/DELNP/2011
3.	Remdesivir	1328/CHENP/2013

We further note with concern that despite repeated requests from the opponents in several of these matters—including requests for early hearings, letters to issue notice to applicants, letters urging issuance of orders post-hearing, and representations for the constitution of Opposition Boards to expedite proceedings—there has been no response from the Patent Office. It bears recalling that India overhauled the pre-grant opposition framework in 2024 - purportedly on the premise that opposition proceedings were delaying the grant and prosecution of patent applications. Yet, in practice, the experience has too often been the opposite: despite repeated representations and requests from opponents for timely disposal, matters have languished without reasoned action from the Patent Office. Such prolonged inaction undermines the credibility of the legal framework and erodes public confidence in the integrity of the opposition process.

The right to life under Article 21 of the Constitution has been expansively interpreted by the Hon'ble Supreme Court to include the right to health, the right to access affordable treatment, and the right to timely access to essential medicines. Failure to provide a timely decision in opposition proceedings effectively blocks or delays the entry of generic medicines into the market. This prolongs monopoly conditions and keeps prices of life-saving medicines unaffordable, exorbitantly high, directly impacting patients right to health, and the ability of the state governments to discharge the constitutional

obligations to provide healthcare. Such inaction is not merely a bureaucratic delay—it constitutes an infringement of the right to life and health of millions of people.

When statutory timelines are ignored, the effectiveness of the opposition system is eroded, uncertainty is created in the pharmaceutical market, and applicants are allowed to enjoy de facto exclusivity even before a patent is granted. This undermines India's position as a global supplier of affordable generic medicines and directly burdens patients, public health programs, and the national exchequer. Such delays are particularly alarming in the context of drugs used for life-threatening conditions such as HIV, hepatitis, COVID-19, and other serious illnesses where treatment costs can determine whether patients live or die.

Against this background, we request you to:

- Direct the Controller General of the Patent to implement the rules related to patent opposition without any further delay to facilitate timely hearing of pre and post-grant opposition applications.
- Issue reasoned orders on all pre-grant opposition matters where hearings have concluded without further delay.
- Establish an internal monitoring mechanism to fix accountability, ensure compliance with statutory timelines going forward, and maintain updated and transparent status reporting of opposition proceedings, including the introduction of mandatory periodic public updates on the dedicated page of each application, with clearly defined timelines for the completion and communication of every procedural step.

Yours sincerely,



KM Gopakumar
Legal Adviser and Senior Researcher
Third World Network (TWN)

About Third World Network: Third World Network (TWN) is an international non-profit policy research and advocacy organization. It works globally on issues of development, trade, and public interest, with a strong focus on intellectual property and access to medicines. TWN actively monitors patent policies, supports the use of public health safeguards, and engages with governments, civil society, and international bodies to promote equitable access to affordable medicines.

CC to:

Smt. Himani Pande
Additional Secretary
Department for Promotion of Industry and Internal Trade (DPIIT),
Room No.: 237, Vanijya Bhawan, New Delhi – 110001
Email: ashp.dpiit@gov.in

Prof. (Dr) Unnat P. Pandit
Controller General of Patents, Designs & Trade Marks (CGPDTM)
Office of Controller General of Patents, Designs and Trade Marks,
Bouddhik Sampada Bhawan, Plot No. 32, Sector 14,
Dwarka, New Delhi-110078.
Email: cg.ipindia@nic.in, cgooffice.in@gov.in