Can Public Health Override a Pharmaceutical Patent? The BPaL Patent Dispute in India

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Pharmaceutical innovation and access to medicines are closely connected aspects of public health. While patent protection can encourage investment in research and the development of new treatments, questions may arise when patent applications concern combinations or formulations of existing medicines. How does the law assess such applications while accounting for both the requirements of patentability and broader public-health considerations?

India's BPaL patent dispute provides an opportunity to examine this relationship. The dispute concerns a treatment regimen for drug-resistant tuberculosis and a patent application covering a combination of three medicines. It also highlights the role of India's patent opposition framework in examining pharmaceutical inventions against the statutory requirements for patent protection.

What Is BPaL and Why Does It Matter?

BPaL combines three medicines: bedaquiline, pretomanid and linezolid. It is a six-month, all-oral treatment regimen recommended for eligible patients with certain forms of drug-resistant tuberculosis.

The regimen represents an important development in TB treatment. Earlier treatment approaches could involve considerably longer courses, multiple medicines and injectable drugs. A shorter oral regimen can reduce the treatment burden for patients.

The Global Alliance for TB Drug Development (TB Alliance), which developed pretomanid, filed an Indian patent application in April 2018. The application concerned a combination product involving these medicines and their use in a treatment regimen.

The controversy was not about whether BPaL offered therapeutic value. It concerned whether the particular combination and formulation described in the patent application satisfied India's legal requirements for patent protection.

Patent Application Challenged: The Story Behind

Two pre-grant oppositions were filed in July 2020.

The first was brought by Eldred Tellis of Sankalp Rehabilitation Trust and Ganesh Acharya, with

support from the Lawyers Collective and Médecins Sans Frontières' Access Campaign. The second was filed by the Delhi Network of Positive People (DNP+), with support from the Third World Network.

The opponents challenged the application on several statutory grounds. These included lack of novelty, lack of inventive step, non-patentability under Sections 3(d), 3(e) and 3(i), and insufficient disclosure of the invention.

Their central contention was that combining known medicines into a particular formulation or treatment regimen did not, by itself, establish a patentable invention. They also questioned whether the claimed combination demonstrated the necessary technical and therapeutic advantages.

The opposition is processed under Section 25(1) of the Patents Act, 1970 that says any person to oppose a patent application before its grant on specified statutory grounds.

Why the Indian Patent Office Rejected the Application

On 27 October 2026, the Indian Patent Office rejected the application under Section 15 of the Patents Act.

The decision followed consideration of the objections raised by the opponents. The reported grounds included lack of novelty, lack of inventive step, exclusions under the Act and insufficient disclosure.

Three provisions are particularly relevant.

Section 3(d) restricts patents for certain new forms or uses of known substances unless the statutory requirements concerning enhanced efficacy are satisfied.

Section 3(e) excludes a mere admixture resulting only in the aggregation of the properties of its components.

Section 3(i) excludes methods of medical treatment of human beings from patentability.

These provisions serve different purposes. They do not automatically prohibit pharmaceutical combinations or new formulations. Their application depends on the claims, the disclosed invention and the evidence before the Patent Office.

The rejection is therefore important for what it demonstrates: a combination involving known medicines must independently satisfy the requirements of patent law. Its medical importance alone cannot establish patentability.

Does Public Health Override Patent Rights?

The BPaL dispute should not be understood as establishing that public health automatically overrides pharmaceutical patents.

Indian law provides several mechanisms to balance patent protection with public interest. Pre-grant opposition under Section 25 allows patent applications to be scrutinised before rights are granted. Section 84 separately provides for compulsory licensing under specified circumstances, including where reasonable public requirements are not satisfied, the patented invention is not available at a reasonably affordable price, or it is not worked in India.

These are distinct legal mechanisms. A pre-grant opposition challenges whether an application deserves a patent in the first place. Compulsory licensing concerns the use of an invention after a patent has been granted, subject to statutory conditions.

The distinction matters. Public-health considerations do not replace the legal test for patentability. They operate within a statutory framework that recognises both innovation incentives and access concerns.

What Does the Decision Mean for Patients?

The rejection removes the possibility of exclusive rights being granted through this particular Indian patent application. It may create greater room for generic competition around the claimed BPaL combination.

However, patent rejection does not automatically reduce medicine prices or guarantee immediate availability. Drug regulatory approvals, manufacturing capacity, quality standards, procurement arrangements and supply chains continue to determine whether patients can access treatment.

The development is nevertheless significant. It demonstrates how patent examination and opposition proceedings can influence the commercial landscape surrounding essential medicines.

The Balance Between Innovation and Access

Pharmaceutical patents provide statutory protection for inventions that satisfy the requirements of the Patents Act, 1970. In the pharmaceutical sector, these requirements may involve questions of novelty, inventive step, disclosure and the patentability of new formulations or combinations of known substances.

The BPaL dispute brings these questions into focus. It concerns the application of patent law to a combination of existing medicines and the objections raised during the pre-grant opposition process. The proceedings also illustrate how Sections 3(d), 3(e) and 3(i) may be considered when assessing pharmaceutical patent applications.

The dispute highlights the relationship between patentability, pharmaceutical research and access to medicines within India's statutory framework. The outcome of such proceedings can have implications for patent applicants, generic manufacturers and the wider healthcare sector.

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