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BPaL Patent Rejection in India

Boost for Affordable TB Treatment

BPaL Patent Rejection in India – Latest News

The Indian Patent Office has rejected a patent application for BPaL — a combination of three tuberculosis drugs (bedaquiline, pretomanid and linezolid) — filed by the US-based TB Alliance.

Experts have welcomed this as a major step towards making drug-resistant TB treatment more affordable in India, which bears nearly a quarter of the world's TB burden, with an incidence rate of 187 cases per 100,000 people (2024).

What Is BPaL?

BPaL is a six-month, all-oral treatment regimen recommended by the WHO for eligible drug-resistant TB patients.

It combines three drugs: bedaquiline, pretomanid and linezolid.

A related regimen, BPaLM, adds a fourth drug, moxifloxacin, recording an 89% success rate — far higher than the 52–75% success of older regimens.

Over 15,000 patients have already started BPaLM treatment under India's National TB Programme.

Unlike older regimens requiring many months of antibiotics and painful injections, BPaL offers a shorter, oral course — reducing physical, financial and emotional burden.

Why Was the Patent Rejected?

The rejection followed two pre-grant oppositions filed in 2020 — formal legal challenges allowing individuals or organisations to contest a patent before it is granted.

With this ruling, every bedaquiline-related patent application challenged in India has now been refused — including the salt form (2023), paediatric formulation (2024), long-acting injectable, and now BPaL.

Experts call this a win against "evergreening" — the practice of seeking additional patents on minor modifications of existing drugs to extend exclusivity and delay generic competition.

What Does This Mean for Patients?

No single company can now claim exclusive rights over the BPaL combination in India.

Any TB drug manufacturer can produce it for India's national programme and for export.

This removes a legal barrier to competition — but does not automatically lower prices or guarantee universal availability.

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Actual impact depends on the number of quality-assured suppliers, government procurement and uninterrupted supply chains.

Who Benefits Most?

Patients with multidrug-resistant or rifampicin-resistant TB (MDR/RR-TB), especially those facing financial hardship, treatment delays or poor access to treatment centres.

Will Treatment Become Cheaper?

Patients under India's public health system already receive TB medicines free of cost — so the immediate financial benefit accrues to the government, which procures these drugs.

A precedent exists: after the 2023 rejection of the bedaquiline salt patent, a six-month BPaLM course cost dropped from $588 (2022) to $284.

Lower procurement costs mean the same budget could treat more patients, and greater competition could ensure more reliable supply.

However, patients still face out-of-pocket costs for travel, additional tests, nutrition and lost income — lower drug prices alone will not eliminate these burdens.

Important Distinctions to Note

Patent approval is not the same as drug regulatory approval: a patent decides exclusivity rights; India's CDSCO (Central Drugs Standard Control Organisation) separately decides if a drug can be marketed.

CDSCO has already approved bedaquiline and pretomanid for use under the National TB Elimination Programme (NTEP); linezolid and moxifloxacin are older, already-used antibiotics.

WHO prequalification (assessing quality, safety and efficacy) also does not substitute for Indian regulatory marketing permission.

Rejection of the patent is not automatic permission for unrestricted commercial sale.

Quality Concerns

Generic medicines must contain the same active pharmaceutical ingredients and meet regulatory standards.

Experts stress that quality checks must continue even as more manufacturers enter the market.

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Conclusion

India's rejection of the BPaL patent marks a significant victory against pharmaceutical "evergreening" and reinforces India's role as the "pharmacy of the developing world."

While it opens the door to generic competition and potential cost savings for the government's TB programme, real impact for patients will depend on scaling up access, ensuring reliable supply chains and maintaining drug quality — essential steps if India is to meaningfully advance its fight against drug-resistant tuberculosis.

