

Chapter 7

Regulatory and Strategic Challenges of Patent Evergreening in the MedTech Industry: An Analysis of Competition Law Implications

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ABSTRACT

Patent evergreening is a strategy used by pharmaceutical companies to extend their market exclusivity through minor modifications of existing drugs, often without significant therapeutic advancements. This practice raises concerns about access to affordable medicines, particularly in developing countries like India, where high drug prices impact public health. A comparative analysis with the European Union (EU) reveals that while India relies on patent law restrictions, the EU employs competition law under Article 102 of the Treaty on the Functioning of the European

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Union (TFEU) to regulate evergreening. Cases such as AstraZeneca v. European Commission demonstrate the EU's effects-based approach to curbing anti-competitive patent strategies. This study highlights the gaps in India's regulatory framework, emphasizing the need for greater coordination between the Indian Patent Office (IPO) and the Competition Commission of India (CCI), and adopting an effects-based approach are crucial to preventing evergreening while ensuring both innovation and consumer welfare.

1. INTRODUCTION TO PATENT EVERGREENING IN HEALTHCARE

Patent evergreening refers to the practice of extending the monopoly of a patented product through minor modifications, often without significant technological advancements. This strategy, widely observed in the pharmaceutical industry, involves obtaining secondary patents on variations such as altered dosages, extended-release formulations, or new combinations. While these secondary patents may technically meet the standards of novelty and inventiveness, they often offer minimal therapeutic benefits, raising concerns about their impact on competition and public health (De & Samuel, 2020).

The MedTech industry, much like pharmaceuticals, is a patent-driven industry. Companies rely on intellectual property (IP) protection to safeguard their investments in medical devices, diagnostics, and treatment technologies. Unlike pharmaceuticals, where evergreening is primarily associated with extending drug monopolies, MedTech firms employ strategic patenting practices that can have similar effects—delaying market entry for competitors and inflating healthcare costs. These strategies include patent thickets, software-based exclusivities, and restrictive licensing agreements that limit generic or biosimilar alternatives. While these practices may not fit the traditional definition of evergreening, they raise significant competition law concerns by restricting innovation diffusion and maintaining monopolistic control.

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