

Novartis Position on Application and Scope of the Exemption from Patent Infringement for Certain Activities Related to Regulatory Approval (a.k.a. “Bolar” Exemption)

Patents and the limited term of exclusivity that they provide enable innovators like Novartis to assume the costs and take the risks inherent in pharmaceutical R&D, to invest in clinical studies to demonstrate the safety and efficacy of new medicines, and to deliver these medicines to patients in a way that optimizes physician and patient knowledge, helping to ensure proper use and optimize health outcomes. At the same time, we believe that, as a mechanism aimed at bringing the fruits of innovation to the public, patents should be used responsibly, and, once the patent term expires, should not unduly delay the use by others of the inventions that they protect, particularly in our field where patents pave the way for generic medicines at the end of patent term.

Unfortunately, though fully justified on the basis of patient safety, the process of securing regulatory approval to market a medicine takes time, not only for an innovative drug, which must demonstrate safety and efficacy through the conduct and results of extensive original clinical trials, but also for a generic product, which in most markets must demonstrate "bioequivalence" by comparative studies to the patented medicine that the drug seeks to copy. Because these comparative studies and related activities use the patented medicine without the innovator's consent, they would normally constitute a form of patent infringement, despite being mandated by regulators. Thus, in the absence of a recognized exception, such work could only begin after patent expiry, leading to undue delays in the launch of generic medicines. For this reason, Novartis supports a formal exemption from patent infringement for activities like these which are undertaken as part of the regulatory review process. Many countries across the world, through legislation or the development of case law, have introduced precisely such an exemption, which is commonly known as the "Bolar" (or sometimes "Safe Harbor") exemption.

Even where a Bolar exemption is well-defined, however, questions remain regarding its scope, and more generally regarding the types of activities and products that should benefit from the exemption.

Novartis Position

- **Territorial Scope:** Novartis favors the application of Bolar exemptions without limitation of territorial scope, meaning that exempted activities should be covered by a local exemption regardless of where regulatory approval is ultimately sought.

- **Application to Innovators as Well as Generics:** In the interest of bringing all new medicines to patients without unreasonable delays due to patent protection, Novartis supports the application of the exemption to all qualifying activities, regardless of whether those activities relate to approval of a generic medicine or a new innovative medicine.
- **Limitation to Pre-Approval Activities:** As the aim of Bolar exemptions is to avoid delays in the approval of generic or alternative medicines once the relevant patents covering the reference medicine expire, Novartis believes that the exemption should be limited to those eligible activities that occur prior to regulatory approval. Activities that occur after a competing medicine is approved but while relevant patents that cover those activities are still in force do not implicate this purpose, but instead interfere with core patent rights and undermine the innovation incentives that patents were designed to provide.
- **Stockpiling and Clinical Trials to Investigate Market Potential:** With respect to the types of activities that should be covered, it is our view that commercial activities not directly connected to obtaining regulatory approval, such as stockpiling or clinical trials to investigate market potential, should not be covered by the exemption.
- **Application to Third Parties:** A third party that assists a primary party in carrying out preparatory work for regulatory approval (e.g. by contract manufacturing), should benefit from the Bolar exemption, provided that such third-party activities are clearly directed and limited to assisting the primary party in seeking regulatory approval.
- **Application to Diagnostic Tests:** With respect to patented diagnostic tests, it is our view that such tests should be covered under the exemption if they are used in order to obtain marketing approval of a competing or further developed test, either alone or in connection with a companion drug treatment. Use of such tests solely as tools in the research and development process (i.e. for the commercial purposes for which those tests were designed) should not, in our view, be covered by the exemption.
- **Application to Medical Devices:** Last, we favor application of the Bolar exemption to medical devices since, like medicines, devices are subject to regulatory delays caused by marketing approval, and facilitating better medical devices is an important public health goal.

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