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Pharma 2: Injunctions: Innovator vs. innovator

The business model of the biopharmaceutical industry depends on the ability to sell innovative products exclusively for period of time in order to recoup the substantial research investment. Generally, regulatory approval for a generic version is based on the innovator's safety and efficacy data. Thus, the cost of bringing a generic product to market is considerably lower.

The advent of complex bioproducts has changed this equation. The US case *Amgen v Sanofi* involves two innovator companies in a patent infringement dispute over a new class of cholesterol lowering agents. The court at first instance enjoined Sanofi from selling its competing anti-cholesterol agent after Amgen's patents were found valid and infringed. Both innovator products are the result of billions of dollars of research.

This finding shocked the biopharmaceutical industry. Medical professionals filed amicus briefs in Sanofi's appeal, indicating that trials of the Sanofi drug are on the verge of finding the superior product. The Court of Appeals stayed the pending appeal, noting several factors, including Sanofi's likelihood of succeeding on the merits, and the possibility of irreparable harm.

This panel will debate the relief that is appropriate in cases when innovators compete in the same field and infringement is found.