

**BEYOND PATENTS:
MITIGATING THE IMPACT OF THE HEALTH CARE CRISIS ON DRUG DEVELOPMENT**

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Pharmaceuticals have provided the most compelling case for patents. The special status of drug patents is being eroded, however, by spiraling health care costs, which put downward pressures on patent premiums, and scientific developments, which stand to erode patent incentives by fragmenting drug markets. Notwithstanding stratospheric premiums for certain specialized drugs, changes to patent doctrines alone cannot counteract these inexorable changes. As is already evident in countries outside the United States, the capacity of governments to bargain for lower drug prices limits patent premiums and thus incentives. Similarly, insofar as the markets for individual drugs decline in size, aggregate market potential and patent returns will also drop. These shifts in market conditions and scientific advances call for a reexamination of the role that patents play in promoting biomedical innovation and consideration of alternative, or complementary, policies. This Article will examine these trends and propose policy responses, drawing on experience with niche statutes, such as the Orphan Drug Act, that combine several policy instruments (e.g., direct R&D subsidies/tax incentives, expedited regulatory review, extended market or data exclusivity).