The Legal and Policy Folly of Price Controls on Drug Patents

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In early January 2025, the Biden Administration issued new licensing guidelines for patents owned by the National Institutes of Health (NIH). These guidelines mandate that licensees commit in advance to an "affordability" plan for any future therapeutic treatments. This was the result of a failed effort by the Biden Administration to adopt regulatory guidelines that authorized the NIH to use the Bayh-Dole "march in" power to grant licenses if "the price or other terms at which the product is currently offered to the public are not reasonable." The new NIH licensing guidelines suffer from similar but not identical problems as the unsuccessful effort to adopt march-in price controls under the Bayh-Dole Act. Legally, the Bayh-Dole Act does not authorize the NIH to impose price controls on patents through the march-in power, as made clear by the text, purpose, and interpretation of this statute by officials for over four decades. The new licensing guidelines are also folly as a matter of policy, as evidenced by the disastrous effects of price-control conditions imposed through NIH research grants in the 1990s. Drug pricing is a complex institutional, legal, and policy matter that cannot be reduced to a single cause like patents.