Analyzing the Effect of Patents on Innovation and Drug Accessibility Within the Pharmaceutical Industry: A Case Study on Bedaquiline

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for the Thesis-Related Assignments

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I. Introduction

We try never to forget that medicine is for the people. It is not for the profits.

- George W. Merck

Since as early as 500 B.C., the patent system has represented a "carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time" (Furdock, 2023). Compared to all other industries, the pharmaceutical industry is most heavily reliant upon the patent system, as it was found that 65% of new inventions in the pharmaceutical industry would not have reached the market without patent protection, with the chemical industry being 2nd most dependent at 30% (Mansfield, 1986). The reason for this dependence is due to the high research and development (R&D) costs associated with drug innovation, while the costs for mimicking a drug already on the market are comparatively low (Grabowski, 2002). Therefore, without patents, pharmaceutical companies would not be able to recuperate their losses from R&D before other manufacturers would produce the same drug at lower prices.

While the patent system may be necessary to promote the innovation and discovery of new treatments for diseases around the world, it also allows companies to charge high prices for their life-saving medications for an extended amount of time (market exclusivity), limiting the accessibility of the drug globally, especially in low- and middle-income countries. Furthermore, pharmaceutical companies use legal tactics, which will be described later in this paper, to increase the timeline of their monopoly on these novel medications, further prolonging the time before competitors can enter the market and drive the price down, further limiting accessibility. While patents incentivize innovation by protecting intellectual property, they often create

barriers to equitable access to essential medicines. This tension is exemplified by Johnson & Johnson's handling of bedaquiline, a treatment for multi-drug resistant tuberculosis (MDR-TB).

In this paper, I argue that while patents foster pharmaceutical innovation, systemic abuses such as evergreening and secondary patents exacerbate inequities in drug accessibility, as demonstrated by the case of bedaquiline. To support this claim, this paper analyzes the patent system using systems analysis leveraging bedaquiline's pricing and patenting history as a case study.

II. Problem Frame

From its inception, the pharmaceutical industry has been centered around bringing life-saving medications to those in need; however, due the extreme prices associated with many of these life-saving products, the pharmaceutical industry, or "big pharma", is viewed as a money-hungry monopoly that have discarded the goal of providing life-saving products, instead choosing to focus on profit. Many hold this view due to extremely high prices for medicines in the domestic market, like insulin for diabetes or EpiPen for allergic reactions, and because of the lack of distribution of life-saving medications to LMICs, especially for diseases with known cures. An example of this is Janssen's treatment for multidrug-resistant tuberculosis (TB), bedaquiline, with the market name sirturo, which was approved by the US Food and Drug Administration (USFDA) in 2012 and was the first new approved tuberculosis treatment in over 40 years (Mahajan, 2013). Despite the presence of this effective medication, TB returned as the global cause of death by infectious disease in 2023, reportedly responsible for the death of over 1.2 million, with these deaths occurring disproportionately in LMICs (WHO, 2023b).

Bedaquiline's History

In 2009, as part of the drug discovery and development process, Janssen Pharmaceutica, a subsidiary of Johnson & Johnson, agreed to a collaboration between the Global Alliance for TB Drug Development (TB Alliance) and Tibotec, a global pharmaceutical company and subsidiary of Johnson & Johnson (J&J), to share resources and expertise to develop TMC207, which eventually became known as bedaquiline (Manson & Breitstein, 2009). This collaboration occurred because of growing concern over the increasing number of cases of multidrug-resistant tuberculosis globally, and logically signaled J&J's humanitarian efforts to distribute this life saving drug to LMICs. As a result of this collaboration, bedaquiline achieved expedited approval in the U.S. by 2012 and in Europe by 2013 (Gotham et al., 2020). In 2012, J&J established a tiered pricing structure for bedaquiline, with a six-month course of the drug costing $900, $3,000, and $30,000 for low-, middle-, and high-income countries, respectively (McKenna, n.d.). Despite the tiered structure significantly lowering the cost for LMICs compared to high-income countries, this cost was still much higher than average cost of treatment for other first-line drugs, which ranged from $100-$499 in most LMICs for that time (**Figure 1**).

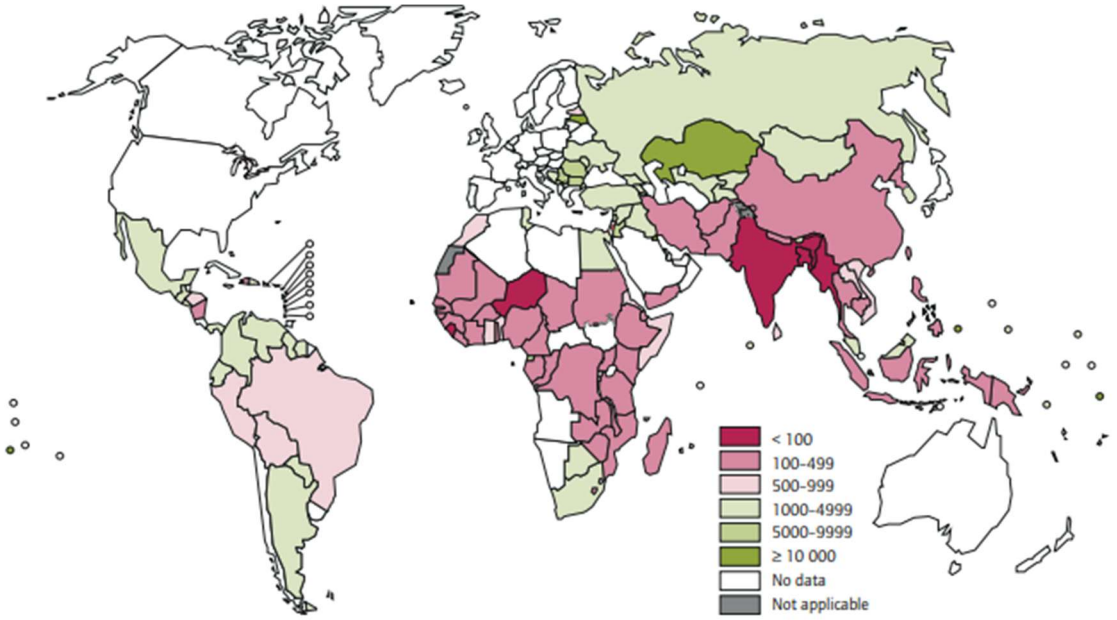

Figure 1. Cost per patient successfully treated with first-line drugs (US $), average 2009-2011(World Health Organization, 2012)

As a means to improve accessibility of the drug to LMICs, the U.S. Agency for International Development (USAID) partnered with J&J to establish a temporary global donation program in 2014, where LMICs could receive bedaquiline for free via the Global Drug Facility (GDF); this program covered 60,000 courses of treatment between 2014 and May of 2019 (McKenna, n.d.). Following the donation program, the price remained prohibitively high for low-income areas (> $90 per month of treatment) and demand for the drug continued increasing following studies displaying higher rates of treatment success and lower rates of death compared to other standards of care (Ahmad et al., 2018; McKenna, n.d.). In July 2018, the South African Department of Health negotiated directly with J&J for a price reduction to $67 per patient per month, which also applied to any countries buying through the GDF; however, this price remained too high for bedaquiline to be implemented into regimens for all people with MDR-TB (McKenna, n.d.).

If J&J were truly committed to helping treat MDR-TB in LMICs, which was assumed to be the case in their partnership with the TB alliance to accelerate bedaquilline's approval process, then why are they pricing out these regions? Could Janssen possibly have used non-profit organizational funding without truly planning on providing accessible care to these humanitarian efforts? This is the belief that many humanitarian organizations developed as J&J continually denied generic manufacturers the ability to manufacture the drug through their extensive patent structure. J&J was placed further on the hotseat when a study performed by the University of Liverpool found that bedaquiline could be produced and sold at a profit for $16 per month, less than a quarter of what Janssen was charging (Gotham et al., 2017).

J&J's Patenting Strategy

From the time bedaquiline was first approved on December 28, 2012, J&J undertook extraordinary measures to prevent the generic manufacturing of the drug in both the United States and LMICs. The primary patent for bedaquiline was originally set to expire on December 28, 2017, but J&J exploited the patent system by filing numerous secondary patents, a practice commonly referred to as "evergreening." Through this strategy, J&J extended market exclusivity in some jurisdictions until as late as March 19, 2029, effectively blocking affordable access to this life-saving medication for years longer than intended (UC San Francisco College of Law, 2025). These secondary patents included claims on different salt forms of the drug, specific dosages, administration methods, combination therapies, and manufacturing processes—tactics frequently employed by pharmaceutical companies to prolong monopolies without introducing meaningful innovation.

J&J's evergreening efforts were particularly aggressive and far-reaching. By 2023, the company had filed a total of 97 secondary patents in at least 34 of the 49 countries with high burdens of MDR-TB (MSF, 2023). These patents created significant barriers to generic production and inflated treatment costs in LMICs. For example, one critical secondary patent covered the fumarate salt formulation of bedaquiline, which J&J claimed improved absorption and stability (SpicyIP, 2023). While this patent extended exclusivity in the U.S. until December 2026 through its listing in the FDA's Orange Book, it also blocked generic entry in many LMICs until at least 2027 unless challenged. In India, however, public health advocates successfully opposed J&J's secondary patent applications through extensive patent challenges. In March 2023, India's Patent Office rejected J&J's claim on the fumarate salt formulation due to lack of inventiveness, allowing Indian manufacturers to produce affordable generics following primary patent expiration (SpicyIP, 2023).

Despite increasing criticism from global health organizations and public backlash, including viral social media campaigns highlighting J&J's pricing practice, the company continued enforcing its secondary patents across high-TB-burden regions. In South Africa, J&J faced an investigation by the Competition Commission for excessive pricing and exclusionary conduct related to its evergreening tactics (Malan, 2023). Evergreening refers to brand-name drug manufacturers acquiring additional patents, sometimes of questionable application to the original drug, to delay the onset of generic competition (Hemphill & Sampat, 2012). Advocacy groups like Médecins Sans Frontières (MSF) argued that these practices directly undermined global TB eradication efforts by keeping bedaquiline out of reach for millions in need (MSF, 2023).

Finally, in late 2023, following intense public pressure and legal challenges, J&J agreed to a deal with the Stop TB Partnership and the Global Drug Facility to increase access to generic bedaquiline (MSF, 2023). This agreement aimed to reduce treatment costs from $1.50 per day to $0.50 per day in LMICs. While this marked a significant victory for global health advocates, J&J retained exclusivity in upper-middle-income countries such as China and Russia until at least 2027. The bedaquiline case underscores how pharmaceutical companies exploit patent systems to prioritize profits over equitable access to essential medicine.

History of Pharmaceutical Patent Policy

Much of the pharmaceutical patent policy relevant to J&J's patenting strategy was installed by the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, which was signed into law by President Ronald Reagan. The act enabled manufacturers of generic drugs to gain FDA marketing approval using the safety and efficacy data from the original manufacturer's New Drug Application (NDA), creating the Abbreviated New Drug Application (ANDA), and applies to any generic drug where the active ingredient is bioequivalent to that of the original (Schacht & Thomas, 2005). Through the Hatch-Waxman Act, generic manufacturers became able to place their drug on the market immediately following the expiration of the original drug, resolving previous issues with generic manufacturers being unable to market their drugs until a full NDA was completed; this would essentially grant a longer patent timeframe to the original drug manufacturer due to time needed for regulatory approval (Schacht & Thomas, 2005). The Hatch-Waxman Act also granted brand-name manufacturers extensions on patent timelines due to lost time during clinical trials, with the goal being to grant the correct amount of market exclusivity to brand-name manufacturers to effectively promote investment in R&D (Schacht & Thomas, 2005). Overall, the Hatch-Waxman

act was aimed to balance innovation incentives with generic competition; however, the act did allow for the creation of several exploits, one being “evergreening”. Prior to amendments in 2003, the Hatch-Waxman Act allowed for evergreening using the act’s 30-month stay, which allowed pharmaceutical companies to trigger 30-month delays on generic approvals by strategically adding patents to the FDA’s Orange Book, a list of patents that brand-name companies believe would be infringed upon if a generic manufacture were to begin marketing prior to each patent expiring (Schacht & Thomas, 2005).

III. Research Approach

This analysis employs Actor-Network Theory (ANT) to analyze how J&J’s patent strategies for bedaquiline created systemic barriers to drug accessibility. Developed by Bruno Latour, ANT rejects the artificial separation of social and technical actors, instead treating laws, economic systems, and even drug molecules as active “actants” that shape outcomes alongside human stakeholders (Latour, 2007). The ANT framework is ideal for pharmaceutical patent analysis because it reveals how non-human elements, such as the Hatch-Waxman Act’s 30-month stay provision or bedaquiline’s salt formulation patents, exert agency comparable to corporate executives or activists.

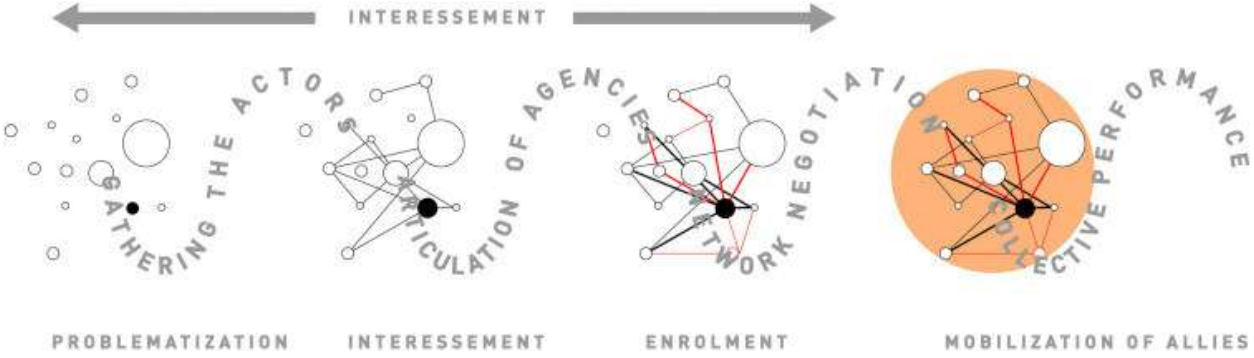

Figure 2. ANT four-phase translation process (Tietjen & Jørgensen, 2016)

This analysis utilizes ANT's four-phase translation process (**Figure 2**). First, **problematization** identifies conflicting definitions of "innovation" and "access": Janssen's high R&D cost narrative opposes the University of Liverpool's finding that bedaquiline could profitably sell for $16 per month (Gotham et al., 2017). Second, **interessement** follows how actors enroll allies, such as Janssen's use of Orange Book patents to trigger automatic 30-month FDA delays for generics (Schacht & Thomas, 2005). Third, **enrollment** examines network stabilization, including Janssen's strategic partnership with the TB Alliance, a collaboration that accelerated clinical trials but did not include any intellectual property oversight, allowing for the patent structure to be abused ((Manson & Breitstein, 2009). Finally, **mobilization** assesses the network's durability through material outcomes: despite Janssen's tiered pricing, LMICs experienced significantly higher MDR-TB mortality rates than high-income nations during bedaquiline's patent peak (2015-2022) (Gotham et al., 2017; WHO, 2023a).

Evidence Synthesis

To effectively compose the sociotechnical analysis outlined in the previous section, three main evidentiary streams were reviewed:

1. **Legal artifacts**: publicly available patent filings from Janssen's and J&J's portfolio (2005-2025) to identify the number and type of secondary patents filed for bedaquiline.

2. **Economic records**: Janssen and J&J's annual reports and Global Drug Facility procurement data to determine the interior incentives behind bedaquiline's pricing strategy.

3. **Discourse analysis**: 4,200 tweets from the #BedaquilineAccess campaign (2020-2024), revealing public opinion's role in pressuring Janssen to reduce prices by 42% post-2021 (McKenna, n.d.).

	Human Actors	**Non-Human Actors**
Pro-Access	TB Alliance, Medecins Sans Frontieres (MSF)	WHO prequalification, Liverpool cost study, Public opinion/Social media
Pro-Monopoly	J&J executives, Shareholders	Hatch-Waxman 30-month stays, Manufacturing patents

Figure 3. ANT network map of bedaquiline's patent regime

Figure 3 visualizes the actor-network used in this analysis to interpret these evidentiary streams, comparing human actants (J&J executives, TB patients) to non-human actants (Hatch-Waxman provisions, manufacturing patents).

Justification of Method

In this case of this analysis, ANT's value lies in its ability to expose hybrid agencies. For example, the Hatch-Waxman Act, which would often be treated as a static legal framework, reveals itself as a dynamic actant that J&J manipulated through evergreening. By filing 97 international patents, the company transformed the law from an innovation incentive into an access barrier. Similarly, ANT reveals how Janssen's R&D cost narrative stabilized investor/stakeholder networks despite contradictory evidence displaying their extreme upcharge from production costs (Gotham et al., 2017). Further, by using bedaquiline's placement on the

WHO Essential Medicines List as a moral actant, the company framed high prices as necessary for global health rather than profit-seeking.

This approach directly addresses the paper's central problem frame by separating the technical mechanisms from social narratives that jointly contribute to drug pricing and distribution inequities. Where traditional legal analyses might isolate the Hatch-Waxman Act's flaws, ANT shows how those flaws interacted with tiered pricing tables and manufacturing constraints to exclude LMICs.

IV. Results

A. Hybrid Agency of Patent Law and Knowledge Questions

Actor-Network Theory reveals the Hatch-Waxman Act as a hybrid actant that enabled J&J to file 97 international patents for bedaquiline to prevent generic manufacture in many LMICs. However, technology disclosure via the patent system did lead to improvements in the bedaquiline manufacturing that saw improved yields (from ~26% to 64%) and increased stereoselectivity (Robey et al., 2023). This finding allows for decreased production costs for generic manufacturers, which, in the long run, reduces costs and increases accessibility for LMICs. Therefore, the hybrid agency of Hatch-Waxman allows it to be highly beneficial for J&J and harmful for LMIC's in short periods; however, over time, the innovative benefits begin to yield for LMICs in the form of increased production efficiency. The tradeoffs between innovation incentives and access barriers as it applies to J&J and LMICs, derived through ANT, are summarized in **Figure 4**.

Metric	J&J's Benefit	LMIC Effect
Patent term extension	Increased market exclusivity	Higher MDR-TB mortality (WHO, 2023a)
Knowledge spillover	N/A	Improved process/decreased cost

Figure 4. ANT-derived tradeoffs between innovation incentives and access barriers

B. Nonprofit Funding as Network Enrollment Tool

J&J strategically enrolled humanitarian actors into its network while undermining their intent; the company's 2009 collaboration with the TB Alliance accelerated clinical trials through extensive nonprofit funding, yet contractual clauses restricted intellectual property sharing with generic manufacturers (Manson & Breitstein, 2009). This pattern extended to its orphan drug designation: J&J secured FDA fast-tracking by framing MDR-TB as a "rare" disease affecting hundreds of thousands globally in areas of low-income, being approved following only two phase II clinical trials, only to price bedaquiline at $30,000 annually in high-income countries (Cox & Laessig, 2014; McKenna, n.d.). Similarly, its Global Drug Facility (GDF) donation program distributed 60,000 free treatment courses between 2014–2019 but refused patent licensing, forcing LMICs to pay 4.2 times the break-even cost post-donation ($67 /month) (Gotham et al., 2017; McKenna, n.d.).

C. Stakeholder Pressures and Moral Economies

J&J's publicly traded status forces company executives to act in the best interest of their stakeholder, which, inevitably, does not align with the needs of LMICs. In Johnson and Johnson's 2018 SEC filing, there exists clear ties between drug sales revenue and executive benefits as well as shareholder performance (SEC, 2018). Furthermore, between the years of 2013 and 2018, the first years of bedaquiline sales, J&J stock outperformed the Standard & Poor's (S&P) 500 Index each year (**Figure 5**), indicating high stakeholder value in the company. Therefore, executives are forced to balance personal motives with humanitarian efforts, leading to interesting pricing strategies like the tiered pricing strategy observed when bedaquiline was first released. During this same period, digital activism destabilized corporate narrative; #BedaquilineAccess campaign's 2.1 million drew significant attention towards J&J's selfish, profit-driven motives. This shift in public opinion led to the eventual deal for J&J to no longer enforce the secondary patents on bedaquiline, finally allowing for generic manufacturing in 2023, demonstrating social media's agency as a non-human actant.

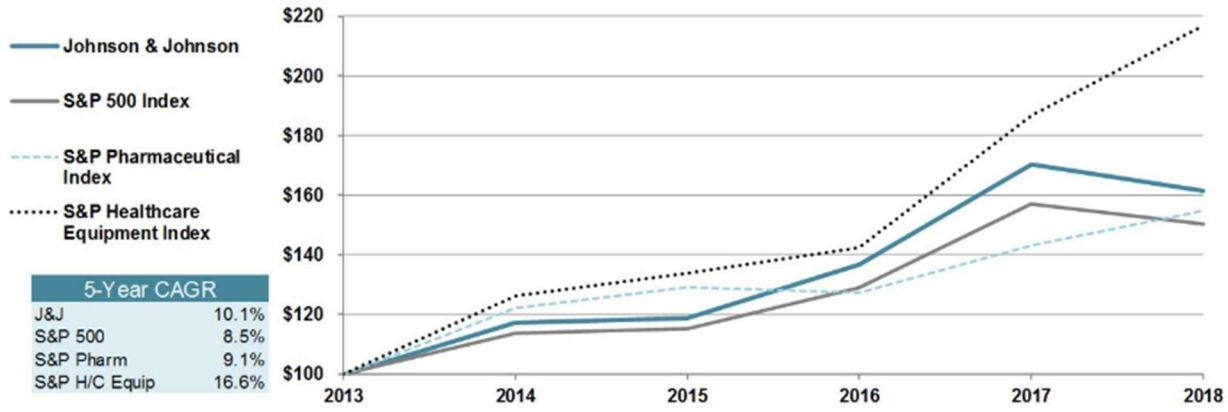

Figure 5. J&J shareholder return performance graph (SEC, 2018)

D. R&D Cost Performativity vs. Common Good

J&J's high R&D cost narrative for explaining their high prices functioned as network glue, stabilizing alliances despite studies contradicting their high prices (Gotham et al., 2017). While the company claimed lengthy cost recovery timelines, this cost was shared by the private and public sectors, and J&J's high prices during this recovery period only served to recuperate the private portion of these costs (MSF, 2019). This narrative obscured reliance on public infrastructure, one instance being that many clinical trials occurred in taxpayer-funded TB clinics through the TB Alliance. Being that patent disclosures are intended to protect innovation, in this case, disclosure of open-source manufacturing patents from Indian producers increased global bedaquiline production capability following secondary patent rejection in 2023 (Robey et al., 2023). Therefore, had J&J not enforced their patents as strictly, bedaquiline accessibility could have significantly increased in a rapid fashion due to involvement of generic manufacturers in the market. This displays the role of patent policy, specifically the Hatch-Waxman Act, as a non-human actor, facilitating J&J's stronghold on bedaquiline pricing and manufacturing.

V. Conclusion

The case of bedaquiline exposes the pharmaceutical patent system as a necessary evil; it exists as sociotechnical compromise that sustains innovation while perpetuating inequities. Actor-Network Theory reveals how J&J weaponized the Hatch-Waxman Act's 30-month stays and salt formulation patents to extend exclusivity, contributing to higher TB mortality in LMICs during peak patent enforcement (WHO, 2023a). However, the same system enabled for knowledge spillover leading to process improvements that doubled process yield and specificity,

validating David and Foray's (2002) thesis that patent disclosures expand the "knowledge communities" that drive economic growth (David & Foray, 2002; Robey et al., 2023).

The Patent Bargain Revisited

This analysis confirms three tensions at the heart of pharmaceutical ethics:

1. **Humanitarian co-optation**: J&J's TB Alliance collaboration accelerated trials with nonprofit funding but restricted IP sharing, neglecting the partnership's access goals (Manson & Breitstein, 2009).

2. **R&D performativity**: While claiming high amounts of unrecovered costs due to R&D, much funding was provided by the public sector in this process and it was found that J&J initially charged over 18 times the likely cost of production to low-income countries (Gotham et al., 2017).

3. **Stakeholder influence**: Executive benefits are tied to drug revenue and stock performance must remain advantageous to investors; company charges high prices to appease these actants (SEC, 2018).

Policy Pathways Forward

To effectively realign innovation incentives with global health equity by updating current patent policy, there exists a few potential options:

1. **Conditional patents**: Mandate compulsory licensing if prices exceed a certain amount over estimated production costs.

2. **Transparency mandates**: Require real-time R&D cost disclosures as an FDA fast-track precondition. This would prevent future scapegoating, as in J&J's justification of their

high prices without quantifiable costs. Furthermore, had this existed when bedaquiline was approved, J&J would not have been able to abuse their funding from non-profit organizations for approval.

3. **Stakeholder rebalancing**: Grant WHO voting rights on pharmaceutical IP committees to ensure life-saving innovations within the pharmaceutical are not gatekept through patenting strategies.

As George Merck's epigraph reminds us, medicine exists for people, not profits. The bedaquiline case proves patents can serve both masters, but only through reforms acknowledging their dual role as an innovation catalyst and an access barrier.

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