

March 29, 2026

The Economics of Skinny Labels **A Balanced Assessment of the Economic** **Considerations and Potential Consequences** **of Hikma v. Amarin**

Author: Kristina Acri

The Economics of Skinny Labels

A Balanced Assessment of the Economic Considerations and Potential Consequences of *Hikma v. Amarin*

Dr. Kristina M.L. Acri, née Lybecker
March 29, 2026

Background

On Friday, January 16th, 2026, the Supreme Court granted the petition for certiorari in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, (No. 24-889). The case challenges a June 2024 Court of Appeals for the Federal Circuit decision (104 F.4th 1370) and creates a high-stakes policy moment for innovators, generic manufacturers, and patients navigating the complex framework surrounding induced patent infringement in the context of “carve outs” or “skinny labeling” under 21 U.S.C. § 355(j)(2)(A)(viii) (popularly known as “section viii”). In its Supreme Court petition, Hikma Pharmaceuticals argued that “no skinny label is safe” under the Federal Circuit’s ruling, reasoning that branded drugmakers will always charge that a generic company’s marketing materials induce doctors to prescribe them for infringing uses. After years of uncertainty created by earlier Federal Circuit decisions¹, the Court is now poised to revisit the contentious issues surrounding induced patent infringement liability in the context of skinny labels, and how generic firms may label and describe their products without risking entering into inducement territory.

The Hatch-Waxman Act of 1984 (P.L. 98-417) was intended as a “grand bargain”, balancing public health interests by incentivizing pharmaceutical innovation while also enabling generic competition. In general, for a brand-name drug the first patent to expire covers the drug’s compound patent. Given that innovators will file a new patent application covering the new molecule or compound shortly after discovery, and before the proposed methods-of-use are clinically studied, the new molecule or compound patent (henceforth, “compound” patent) frequently expires years before the “use” patents. So-called “skinny labels” expedite market entry by generics upon expiry of the first patent, the “compound” patent. Importantly, this may happen when there is more than one approved indication. Congress sought to ensure that one patented use will not foreclose marketing a generic drug for other unpatented ones. Generic manufacturers relying on section viii statements are said to “carve out” the patented uses, resulting in a skinny label for the generic drug. The skinny-label pathway allows for generic production even while the brand-name manufacturer still has methods of use under patent protection.² This assessment fundamentally seeks to address which liability rule best preserves both incentives that encourage follow-on innovation and the timely entry of generic versions.

A recent Congressional Research Service [Report](#) concisely describes the skinny label provision which enables limited entry by generic manufacturers who can seek approval from the U.S. Food and Drug Administration (FDA) for the subset of approved uses of the drug no longer protected by patents. With the creation of the section viii pathway, Congress sought to balance competing interests. As described by the [Solicitor General](#), this was done by “(a) allowing a generic drug to enter the market even while one or more patents claiming methods of using the relevant chemical compound remain in effect; (b) carving out still-patented methods of use to ensure that the generic label itself does not encourage infringement; and (c) leaving in place, and fully applicable to generic drugs, the Patent Act provisions that prohibit both direct infringement of method-of-use patents and active inducement of such infringement.” This facilitates generic manufacturers bringing lower-cost generic drugs to market by using carved-out

labels, describing their drugs as the generic version of the corresponding brand-name drugs. While at the same time, it discourages them from affirmatively encouraging patent infringement.

Core to *this* case are method-of-use patents over a specific use of a brand-name drug, but not the active ingredient itself. The *Hikma* case centers on whether a generic manufacturer's "skinny label" combined with public statements constitutes inducement of infringement. Describing induced infringement, the CRS report notes, "Because the brand-name drug is still protected by one or more patents, patients and doctors may use a skinny-label generic in an infringing manner (i.e., for still-patented uses). If a generic manufacturer takes active steps to encourage the "carved out" patented uses, they may be held liable for inducing patent infringement. Recent judicial decisions on patent infringement liability for skinny-label drugmakers have increased concerns by some stakeholders about whether the skinny-label provisions remain effective in facilitating partial generic competition."

Both innovative pharmaceutical firms and generic manufacturers need guidance as to where the guard rails are for inducement of infringement, in the context of all of the following: generic labels themselves, public statements, and marketing materials. Generic manufacturers and their advocates have argued that skinny labels are in jeopardy, and this is a matter of life or death for section viii. However, the Hatch-Waxman Act seeks balance between generic manufacturers and innovative firms alike. Therefore, the analysis should evaluate both the risk of under-protecting new-use innovation and the risk of over-detering lawful generic entry.

For generic firms, the skinny labeling provisions of the bargain facilitate FDA approval and patient access to lower-cost medications. The protection that the skinny label pathway provides for the carved out patented indications is an important incentive for innovator firms to invest in new-use research. This is threatened by substitution for patented uses and off-label prescribing which provide a windfall to generic manufacturers that undermines the Hatch-Waxman compromise. From the innovator perspective, experience demonstrates that the provision enables generics to encourage substitution of their drugs for *all* uses of a drug, including *patented* indications. As such, that balance hinges on generic firms' communications about their skinny-label products that avoid induced infringement liability.

The significance of the case for the pharmaceutical industry centers on its potential to redefine the scope of liability for generic manufacturers under the Hatch-Waxman Act's skinny label provision. The Supreme Court will review the following two questions:

1. "When a generic drug label fully carves out a patented use, are allegations that the generic drugmaker calls its product a 'generic version' and cites public information about the branded drug (e.g., sales) enough to plead induced infringement of the patented use?"
2. "Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?"

The Supreme Court's decision, whatever it may be, will alter the strategies of both brand-name and generic drug manufacturers, impacting how risky it is to market a skinny label product, and the value brand-name firms place on method-of-use patents.

Economic Considerations

The Supreme Court’s decision will have implications for generic availability, biopharmaceutical research investments, launch planning, labeling strategy, marketing strategy, drug pricing, and litigation risk for both innovative products as well as the versions using skinny label carveouts. This review considers a range of possible economic consequences, examining the claims made by scholars, as well as advocates and critics of both the innovative industry and generic manufacturers. These are considered through the lens of three counterfactuals: broader liability, narrower liability, and a statutory safe harbor. Finally, the economic considerations evaluate the welfare consequences for consumers, innovators, generic producers, and society.

Balance between Innovation and Access

The balance in the Hatch-Waxman Act both incentivizes pharmaceutical innovation while also enabling generic competition. For generic manufacturers, strategic considerations include assessing market demand, measuring competitor saturation, ensuring sufficient manufacturing capabilities, and timing launches with patent expirations to maximize profitability. Generic firms must also navigate patent challenges (Paragraph IV), in order to – if done successfully – secure a 180-day exclusivity. Finally, they must weigh the profitability of the market against the risks of litigation exposure and the tactics frequently employed to deter or delay the launch of a generic version.

For innovator firms the incentives for innovation are critical because of the significant costs – time and funding – of drug development. Table 1, below, compares the positions of innovative to generic companies. Market exclusivity is one important mechanism for appropriating returns to drug development. Patents and regulatory exclusivities serve as barriers to entry, providing an exclusive market position during the term of protection. The attendant profits operate as the incentive to invest in research and development, and society accepts the short-term pricing consequences of exclusivity because the research is beneficial and society values the disclosure of the information in the patent. Ultimately, this helps to facilitate generic entry and broader advancement of scientific evidence to support additional research. Table 1 contrasts the time and expense of developing innovative drugs and the generic versions. The differences in resources – time and funding – point to the importance of the grand bargain, facilitating innovation and, in time, encouraging generic competition. Importantly, these figures reflect the differences in the development processes for new drugs, not post-approval innovation.

Table 1: Drug Development Process and Comparisons³

| Drug Development Phases | Innovative Companies | Generic Companies |
|--|--|---|
| Research and Development | 2-6.5 years (early-stage development) | 6 months – 1 year (secure active ingredient and formulation) |
| Tests and Trials | 7 years | 3-6 months |
| Time from Laboratory to Market | 11-14 years | 2.25-6.5 years |
| Estimated Total Costs | \$161 million - \$4.46 billion in 2019 U.S. dollars | \$2-10 million |
| Time to recover costs and build funding for new R&D | 6-9 years (Effective Patent Life) | No time limit |

Source: Acri, Kristina M.L. “Regulatory Exclusivities in the Biopharmaceutical Ecosystem,” forthcoming in *Bringing Medicines to Life: How Intellectual Property Enables Innovation in the Life Sciences*, eds. Jonathan M. Barnett and Bowman Heiden, Cambridge University Press, forthcoming 2026. Please reference the cited chapter for citations and documentation of all cited figures.

Beyond providing incentives to innovate, U.S. law is also designed to ensure prompt approval of lower-cost generic drugs. As envisioned by Congress, the section viii pathway reflects Hatch-Waxman’s goal of allowing generics labeled only for non-infringing uses to “quickly come to market.” As a result of faster market competition, skinny labels can result in significant cost savings. A 2024 [report](#) notes that generic and biosimilar drugs constitute 90% of all prescriptions dispensed in the United States while accounting for just 13% of prescription-drug spending. According to the [Association for Affordable Medicines](#), Congress’s solution was elegant and effective. Generic versions could come to market with skinny labels, so that patients would no longer have to pay branded-drug prices for off-patent indications. As evidence of the pathway’s functioning, they note that in nearly 50% of cases where a drug is no longer patented and some (but not all) of its uses are patented, a generic version of the drug is brought to market with a skinny label. Specifically, recent studies establish this in the context of both generic drugs and biosimilars. In a 2021 [study](#) of the brand-name drugs that first became available as generics between 2015 and 2019 and that were susceptible to skinny labeling, 43% had generic formulations with skinny labels.⁴ These results were echoed in a later [study](#) of the period 2021 to 2023, which also found 43% of brand-name drugs experienced skinny labeling generic competition.⁵

New-use Research and Continuing Innovation

Innovation continues after the drug’s FDA approval and after the new medicine launches. Just as patents and regulatory exclusivities incentivize breakthrough biopharmaceutical treatments and cures, they also provide incentives for continuing innovation, including for new-use research, as well as post-approval innovation. For years after the initial approval of a product, innovators will continue conducting research on their product, exploring ways to improve the product or treat other indications. Scholars have long established that small innovations result in great gains in efficiency across products and technologies.⁶ New-use research provides both follow-on medicines as well as the development of additional ways to utilize existing therapies, and supplemental indications.

There is an economic argument to be made here as well. Research and development of new medicines is expensive and time-consuming, and firms may decide to use the revenue from the initial approval to fund further research and development. This process, reasonably, may happen one at a time. In fact, this is the natural path of drug development from an economic perspective. Innovative firms will rationally weigh their options and pursue (1) the applications with the greatest unmet need and (2) the one most likely to be approved. This is both optimal in terms of firm profit and also socially responsible, as it maximizes social welfare.

As a society, we should seek to capture as much benefit as possible from investments in biopharmaceutical research and development. Once a treatment or cure has been established as safe and effective, society should capitalize on that and explore every possible use for every possible condition. After determining the safety and efficacy of a product, society should want – insist upon – explorations of other uses. “De-risked” compounds have lower development costs and shorter development timelines. Instead of risking human health in testing new compounds, it is wise to reduce research and development time, limit costs, and minimize clinical trials by investigating additional uses for existing compounds.

Public Health Value of New-use Research

Since first-in-class drugs are rarely optimal, continuing innovations may become best-in-class and first-line therapies. A study by Cohen and Kaitin (2008) finds that 63% of the drugs on the World Health Organization's Essential Drug Lists are follow-on drugs within a class.⁷ The scientific and financial resources required for these advances are an investment worth making and an important precedent for global health. As described in a 2006 *Pharmacoeconomics* article, "The importance of subsequent uses may be illustrated by the fact that in some therapeutic classes most of the actual use derives from indications approved later in time."⁸ The authors note that in some classes, 70–80 percent of total patient use was attributable to indications developed and approved after the drug first came to market.

From a public health perspective, these drugs ensure a variety of treatment options are available within a therapeutic class, which provides physicians with the ability to treat the individual needs of diverse patients with precision. For patients, the benefits are tremendous, since these improvements have the potential to: increase the number of available dosing options, uncover new physiological interactions of known medicines, allow for reformulations to encourage children's compliance, increase the shelf-life or heat-stability of a given medicine to secure effectiveness in diverse environments, eliminate treatment-limiting drug reactions or side effects, enhance patient administration and improve patient compliance. According to Wertheimer, Levy and O'Connor (2001), drugs within a single therapeutic class differ in their therapeutic profile, metabolism, adverse effects, dosing schedules, delivery systems, and other features.⁹ These differences increase a patient's probability of finding a treatment that is both effective and tolerated. Investments in new-use research bring this variety of treatments to life. Companies also routinely evaluate their products to treat new conditions. This continued research requires investments of time, talent and financial resources, and companies will not invest without adequate reason to do so.

Carveouts and skinny labels encourage that investment. It is a system that works for both branded innovators and generic firms. However, key to these benefits is that this encouragement of investment does not happen if the generic is inducing infringement. The effectiveness of the skinny label is evident in its prevalence. According to an [amicus brief](#) filed by the Association for Accessible Medicines, approximately half of the generic versions of drugs covered by method-of-use patents are brought to market using skinny labels. Moreover, generic manufacturer's use of section viii carveouts is increasingly common. This is not surprising given that many drugs, especially biologics, are approved for numerous indications. Consider, for example, that Merck's KEYTRUDA® has been approved for more than 40 [indications](#) across 18 types of [cancer](#). Again, multiple indications are optimal relative to many novel compounds that would each require clinical testing and would each have their own timelines for generic challengers.

Market-based Reward

The exclusive rights provided by patents are intended to be a market-based reward, where the more valuable an invention is, the greater market share the resulting product captures.¹⁰ While patents may live up to this promise for active ingredients and initial uses, in the case of new uses they do not. In practice, skinny labels undermine the reward because, once launched, the drugs are generally utilized for patent-protected uses regardless of the protection. The existing incentives – patents and exclusivity already enacted by Congress and applicable to new uses – are undermined. Although Congress meant for new uses to be excludable, currently they are not, and generic versions are utilized for original and new indications alike.¹¹ As described by [Lietzan](#), this is the challenge of incentivizing new-use innovation within a healthcare system (the entities that govern approval, prescribing, dispensing, and paying for medicines) that effectively ignores new-use patents and exclusivity. Eisenberg termed this the "new-use

problem.”¹² As envisioned, the existing system would incentivize innovation, including new-use innovation. Unfortunately, the existing system fails on this count.

In contrast, critics argue ([here](#) and [here](#)) that the existing structure invites abuse by innovators, claiming that the incentives for patent holders will be to aggregate large numbers of new-use patents to foreclose competition. They further argue that the Federal Circuit’s inducement rule, particularly in light of the potential injunctive relief available, potentially makes even the narrowest new-use patent equally effective for interfering with equivalent product sales by generic firms. The validity of the claim is questionable since the “narrowest new-use” will be carved out, and the generic version can be prescribed for all other uses to all other patients. This debate is revisited below in the discussion of new-use research’s impact on broad versus narrow populations.

Price Competition and Access

Generic drug approvals play a pivotal role in fostering market competition, which drives down prescription drug costs and reduces the economic burden for both patients and the healthcare system. Generic drugs provide significant value by offering the same quality, safety, strength, and active ingredients as brand-name drugs at 80% to 85% lower costs on average. They currently account for 91% of prescriptions filled in the U.S.¹³ By providing lower-cost alternatives, generics improve medication adherence for patients. In their most recent [report](#), the U.S. FDA estimated the cost savings from the 773 generic drug applications fully approved in 2023. This work is the latest rendition of an annual study examining the relationship between generic competition and drug prices, which shows that the market entry of just a few generic competitors yields generic prices below the brand price. Another government [study](#) establishes that prices decline by 20% in markets with about three competitors, and continue to decline by 70% to 80% relative to the pre-generic entry price in markets of ten or more competitors, three years after the first generic entry.¹⁴ In sum, generic medicines are important in creating market competition, lowering prices, and improving adherence for patients.

While the availability of generic drugs creates market competition and brings down prices for patients, so do new-use innovations and post-approval innovations. Specifically, continuing innovation also drives price competition. It also ensures that an increasing number of drugs and a variety of formulations are available. Evidence [shows](#) the existence of price competition in different therapeutic areas as a result of having various treatments available that would be substitutable in a majority of patients. In a study of pharmaceutical innovation, DiMasi examined 20 new entrants to existing classes (1995-1999), finding that 80% were launched at a discount relative to the price leader and 65% were launched at a discount relative to the average price for the class. The study shows that all but one of the follow-on drugs were discounted and sold at prices up to 70% lower than the pioneer drug.¹⁵ Further, in an evaluation of the impact of new therapeutic competition on net prices between 2011 and 2019, Dickson, Gabriel, and Hernandez (2023) find that the introduction of new therapies was associated with a 4.2% decrease in annual net price growth.¹⁶

Substitution Laws and Off-label Prescribing

While skinny labels are designed to carve out on-patent uses, operationally this is complicated by automatic substitution laws at the state level and off-label prescribing by physicians. Generic companies claim that the carve-outs ensure they are only marketing the generic drugs for non-patented uses, and as such, they are “not affecting the brand manufacturers’ exclusivity” or infringing patents. Alternatively, brand manufacturers point out that these generics are prescribed off-label for patented indications, even if those indications are not listed on the skinny label. Even if automatic substitution can occur for protected uses, the value of the patent is still critical for innovators. In an effort to save their patient’s money,

doctors may prescribe the generic for patented uses. In addition, the FDA's therapeutic equivalence decisions facilitate or trigger substitution under state pharmacy law. Under automatic substitution laws, the generic drug may be dispensed whenever the innovator's drug is prescribed, including for new uses under patent protection or regulatory exclusivity. It is, however, important to clarify that market leakage through substitution or off-label prescribing does not automatically establish intentional encouragement by the generic manufacturer to utilize the drug for the patent-protected indications.

As detailed by [Lietzan](#), "although the precise wording varies, in every state the law authorizes (and in some cases, it requires) a pharmacist to substitute a therapeutically equivalent generic drug when filling a prescription for a brand product. State medical practice laws do not require a physician to specify the patient's condition or the intended use of a medicine on the prescription form." In addition, payers generally mandate this substitution, without regard to the patient's condition or the scope of the dispensed drug's approval. In this way, even new-use prescriptions are shifted to the generic product. Despite the fact that federal law intends drug manufacturers to have exclusive sales for the new uses, partial labeling to respect protected uses is functionally irrelevant.

Broad versus Narrow Populations

Cumulative innovation moves medical progress from narrow indications to a broader spectrum of treatments. New uses may be discovered at any point in time, years, decades or even centuries after the original product was developed. However, there is some debate as to whether this should be thought of as (1) innovations that treat smaller and smaller subpopulations or (2) innovative efforts that result in treatments for a broader swath of the population. In reality, it probably varies, depending on the drug in question. Importantly, the debate could be resolved by establishing a metric to distinguish clinically meaningful new-use innovation from strategic fragmentation. For example, therapeutic significance, patient benefit, and non-obviousness could be measures employed for this purpose.

Critics [argue](#) that a savvy manufacturer could manipulate this system to repeatedly obtain new-use patents sequentially, thereby precluding competitors from communicating product equivalence forever. They clearly point out that this would contravene the most fundamental tenet that patent rights are granted only for limited times. Admittedly, if patent inducement liability is based on equivalence statements (discussed in more length below), it would be possible to control competitors' behavior indefinitely. This would in effect dismantle the patent bargain and the underlying innovation incentives that the patent system is supposed to serve. The argument critics rely on unfolds as follows: Given that the use of a drug for a broad indication will generally not invalidate a later patent on a more specific indication, innovators have an incentive to subdivide an existing use into ever smaller subcategories. This subgroup-division strategy would thus be used to generate a chain of new-use patents ultimately covering minuscule subpopulations. Importantly, this criticism rests on the assumption that carve-outs no longer function as they should and skinny labels are worthless.

In contrast, the [argument](#) is also made that following approval, the innovator company's understanding of the medicine's safety and effectiveness for the labeled uses becomes more refined, as the medicine is used by a broader population over a longer period of time than could be studied before approval. Post-approval innovations may also result in greater tolerance, increased safety, reduced contraindications, and more therapeutic options. These innovations result in greater compliance due to reduced toxicity, fewer negative side effects, and more convenient dosing (extended release). Over time, such innovation allows treatment advances to reach broader populations (children, those with complicating diseases, geriatric patients, those with a variety of genetic makeups, patients of different races) and have greater reach (medicines for delivery in countries without refrigeration, or those needing longer shelf-lives).¹⁷ Without incentivizing further innovations, medical advances would be limited to the initial population. Ultimately,

a broader population is reached as advances are better tailored to different segments of diverse populations.

Uncertainty

The economy does not like uncertainty. Uncertainty not only retards consumer spending and hinders business investment, it can also pull down economic growth.¹⁸ The uncertainty surrounding skinny labels plays out on a microeconomic scale, but with consequences that are no less severe. First, consider the impact on generic manufacturers. For those who believe that recent court decisions have narrowed the skinny-label provisions, the concern is that generic drug manufacturers may face the risk of extraordinary liability, making the skinny-label pathway all but unusable. Given the potential for ruinous lost-profits damages, no generic manufacturer could risk using a skinny label.

Uncertainty may also discourage generic entry. Given that brand-name drugs are more expensive than generics, an infringement finding can be particularly costly. In the case of an infringement finding requiring a generic manufacturer to compensate a patent owner for lost profits, the generic firm could face liability greater than its profits. Fundamentally, this risk of liability may result in generic manufacturers abandoning the skinny label pathway and delaying generic entry.

Uncertainty also increases the risk of litigation. A 2019 study estimates that the average cost of defending a patent-infringement lawsuit is around \$3.5 million.¹⁹ The risk and associated costs of litigation change the calculus of bringing a generic product to market. Litigation costs can quickly consume any profits available to a generic manufacturer, potentially discouraging entry in the first place. Hikma Pharmaceuticals filed a reply brief in which it argued that “[t]he decision . . . urgently warrants review because it exposes every generic drugmaker marketing the ‘generic version’ of a branded drug to potentially catastrophic damages, even if the generic omits all patented uses from its label.”

Consider too the impact on branded innovator firms. Without additional guidance and guardrails as to what constitutes induced infringement, innovator firms are left without assurances that their investments can be protected and without confidence that they will earn a return in the market. Under such uncertainty, it is difficult to justify investing hundreds of millions of dollars. New-use research withers and medical progress stalls.

Finally, uncertainty harms patients. One of the more subtle issues in this case concerns the use of “equivalence statements” by generic firms. Are they able to describe their products as equivalent to the brand-name medicine, and if so, in what language? Equivalency statements protect consumers from confusion. For consumers, equivalence statements provide confidence because they are a concise way to convey a tremendous amount of information about a product. In this way, they are tremendously valuable. As described in a brief to the Supreme Court, where a product expected to be equivalent lacks any such claim, the potential implication is that the two products are not the same.

Equivalence Statement

The *Hikma* case brings the uncertainty surrounding equivalence statements to the fore. On the one hand, FDA-required drug information is intended to inform and guide the safe and effective use of prescription drugs. Alternatively, recent court decisions embrace a legal theory Sherkow and Gugliuzza refer to as “infringement by label,” treating statements in drug labels as evidence of patent infringement by generic manufacturers. The authors argue that the Supreme Court could use this case as an opportunity to clarify that FDA-required labeling language, along with a generics manufacturer’s straightforward statements about therapeutic equivalence, cannot alone prove patent infringement. To be explicit, the limiting

principle should be: truthful equivalence claims are necessary and economically important, but liability may be justified when communications materially steer prescribers to a patented use.

The uncertainty surrounding equivalence statements plays out in several ways. Scholars [note](#) that “[a]cross a wide range of industries, statements of product equivalence promote efficient competition, streamline regulatory processes, avoid undue legal gamesmanship, and avoid consumer confusion.” Equivalence statements signal that goods are perfect substitutes, which facilitates maximum price competition. In markets characterized by imperfect substitutes, product differentiation allows producers to raise price above marginal cost without losing all sales, such that the equilibrium price will be higher than under a competitive market with equivalent products.²⁰ Product equivalence enhances the efficiency of a market, enabling the production of equivalent products by multiple producers. This, in turn, reins in monopoly power, lowering prices and reducing deadweight loss.

In the context of pharmaceutical markets, equivalency statements also serve an important legal purpose. State drug substitution laws allow pharmacies to dispense generic equivalents. That is, products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.²¹ Without a statement of equivalence, a generic product would have to be explicitly identified on the prescription in order to be dispensed.

In a regulated market, such as pharmaceutical products, equivalence statements serve to lower regulatory compliance costs and reduce administrative waste. Generic drugs must demonstrate several levels of equivalence to the reference product in order to be granted FDA approval. As described by [Vivian](#), “The FDA classifies as therapeutically equivalent products that are approved as safe and effective; are pharmaceutical equivalents (i.e., contain identical amounts of the same active drug ingredient in the same dosage form and route of administration and meet compendial or other applicable standards of strength, quality, purity, and identity); are bioequivalent (i.e., do not present a known or potential bioequivalence problem and meet an acceptable in vitro, or in some cases in vivo, or both, standard—or, if they do present such a known or potential problem, are shown to meet an appropriate bioequivalence standard); are adequately labeled; and are manufactured in compliance with current Good Manufacturing Practice (GMP) regulations.” The generic drug must be “bioequivalent,” and labeling of the generic must be “the same”. Product equivalence expedites regulatory review and avoids unnecessary, duplicative expenses for both the government and regulated entities.²² Equivalence statements enhance the efficiency of both firms and regulators, reducing costs and eliminating waste.

Policy Implications

Bipartisan Bill introduced to provide a safe harbor

The issues at the center of the *Hikma v. Amarin* case are also the focus of a recent bipartisan bill. The origins of the bill may be traced to the Federal Circuit’s 2021 opinion in *GSK v. Teva* and the debate it generated. The opinion did not eviscerate the generic industry’s ability to utilize the skinny label carveout, as is asserted by critics ([here](#) and [here](#)). In reality, generic manufacturers have prevailed in recent cases when relying on carve-outs, see, for example, *H. Lundbeck A/S v. Lupin Ltd.* Moreover, the opinion reconfirmed that generic manufacturers are obligated to ensure that their representations – including the labeling – do not induce infringement of the innovator’s patented, approved indications. Some policymakers see this differently. Drawing the conclusion that GSK *did* put the skinny label pathway in “jeopardy” opens the door to advocating for a safe harbor in which any information in FDA-

approved prescribing information could not be the basis for induced infringement. Indeed, the protections of a safe harbor have made their way into a bipartisan bill.

Senators John Hickenlooper, Tom Cotton, Peter Welch, and Susan Collins introduced the bipartisan *Skinny Labels, Big Savings Act*, in January of 2025. The companion bill was introduced in the U.S. House in December 2025 by Representatives Ben Cline and Zoe Lofgren. The proposed legislation is described [here](#) as intended to “provide for a safe harbor from infringement of a method-of-use patent relating to drugs or biological products”. According to the [press release](#) issued by Rep. Ben Cline, “The Skinny Labels Big Savings Act ensures that generic manufacturers who obtain FDA approval for skinny label uses are not held liable for method-of-use patent infringement when operating in accordance with federal law. It also provides clarity that drugmakers can describe their generics as FDA-approved therapeutic equivalents, provided that description aligns with FDA regulations. Importantly, the bill reinforces that the use of skinny labels does not weaken legitimate patent rights, but rather supports a system that was designed to bring savings to patients, insurers, and taxpayers alike.”

The proposed safe harbor would remedy many existing concerns and also resolve much of the uncertainty currently surrounding the use of skinny labels. First, the reform would establish clearer rules, providing guidance to generic entrants and clarifying the expectations of innovator firms. In addition, a safe harbor would reduce the discouragement of lawful generic entry, enabling generic versions to reach the market in a more timely manner. At the same time, the safe harbor would enhance the preservation of the carve-out pathway, providing innovators with greater confidence that their post-approval discoveries will be rewarded.

However, such a system, in which FDA approval of skinny labeling immunizes generic producers from any risk of patent infringement liability based on their labeling, would materially shift the allocation of litigation risk and compliance costs. It is essential to recognize that for both innovator firms and generic producers, the risk of infringing another’s patent is always present in marketing a pharmaceutical product. Accordingly, companies routinely conduct freedom-to-operate analyses and pursue licensing opportunities. Further, generic manufacturers have always borne the responsibility for making sure skinny labels sufficiently carve out patented indications. The FDA does not want this responsibility, having [stated](#) that a “fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents. The courts have the experience, expertise, and authority to address complex and important issues of patent law.”

The safe harbor reform is vulnerable to a number of criticisms. Such a policy would risk devaluing method-of-use patents thereby undermining an important avenue for getting the most possible benefit out of research and development expenditures. Fundamentally, it would weaken the incentives for post-approval investment, derailing the opportunity to explore new uses for medicines already established to be safe and effective.

The skinny label provisions are critical to the balance Hatch-Waxman sought between encouraging development of innovative indications and allowing generic entry for off-patent uses. The skinny label pathway, as confirmed by *GSK v. Teva*, simply provides that generic manufacturers may obtain approval of their drugs for *off-patent* uses, as long as labeling and promotional materials omit *patented* uses. Hatch-Waxman’s skinny-labeling provisions were never intended to give the generic industry *carte blanche* to promote their drugs’ use for patented indications. Nor did Congress intend to provide generic companies seeking to use skinny labeling with preferential treatment relative to firms in other industries for purposes of inducement.

Implications beyond the Biopharmaceutical Industry

It is important to recognize that this case will likely recalibrate the balance between protecting patent rights and encouraging competitive generic entry. Clarity from the justices on the ultimate framework regarding “active encouragement” as opposed to “promotion of a product” may impact more than pharmaceutical companies, with long-reaching consequences for other sectors. In particular, other patent-heavy industries where induced-infringement theories can also be applied may be subject to the consequences. Since statements of equivalence abound in industries as diverse as information technology, manufacturing, construction, and groceries, this decision could have expansive consequences. Uncertainty imposes a cost, and uncertainty about patent inducement is no exception. Free markets depend on open entry of substitutable, equivalent products, such that the Supreme Court’s decision could have significant implications for facilitating or stifling competition across a wide range of industries.

Conclusion

In anticipation of the Supreme Court’s decision, it is important to think through not only the legal implications of this case but also the economic consequences. Without knowing whether the decision favors patent-holding innovators or generic manufacturers, it is worthwhile to think through the practical implications in the interim.

For generic manufacturers utilizing section viii and the skinny label, continue to do the mundane, correct things, and create your labels as though a regulator is reading over your shoulder. Scrutinize your labels for any stray clinical references that could be misconstrued and present an accurate carve-out. Finally, present accurate “generic version” claims and ensure that they are accompanied by clear disclaimers that the approval is for fewer than all brand indications. For brand innovators, review generic promotions with a keen eye and calibrate litigation to true “active steps” and genuine “inducing acts.” The best outcome will be one that provides all parties with greater direction and clear guardrails, ensuring that patent infringement can be avoided and further litigation eschewed.

The question at the heart of the debate should be: which legal rule best preserves both timely generic entry and credible rewards for socially valuable new-use research? Fortunately, we know. The answer is: the one that minimizes both false positives that chill generic entry and false negatives that weaken incentives for socially valuable new-use research.

¹ This uncertainty surrounds whether and how a generic company may use a skinny label to fully carve out a patented use without liability of induced infringement. It stems from rulings in the GSK v. Teva and the Hikma v. Amarin cases.

² A 2024 [article](#) by Boumil and Beninger provides an excellent description of the role of skinny labels, as well as providing context through an examination of two recent cases: *Teva Pharmaceuticals USA, Inc. v GlaxoSmithKline LLC et al.* (2021) and *H. Luncbeck A/Set al. v Lupin et al.* (2023).

³ The sources of these numbers may be found in the Acri chapter, available at:
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5363518

⁴ Walsh, B.S., A. Sarpatwari, B.N. Rome, and A.S. Kesselheim. "Frequency of first generic drug approvals with 'skinny labels' in the United States," *JAMA Internal Medicine*, vol.181, no.7, 2021, pp.995-997.

⁵ Ziaks, Therese J., Chukwubuike M. Akanegbu, Alexander C. Egilman, and Aaron S. Kesselheim. "Frequency of first generic drugs approved through 'skinny labeling,' 2021 to 2023," *Journal of Managed Care & Specialty Pharmacy*, vol.31, no.4, April 2025, pp.343-350.

⁶ Copeland, Melvin T. "Progress of the Automatic Loom," *The Quarterly Journal of Economics*, vol.25, no.4, August 1911, pp.746-750.

⁷ Cohen, J., and K. Kaitin. "Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice," *American Journal of Therapeutics*, vol.15, 2008, pp.89-91.

⁸ Ernst R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals*, 24 *Pharmacoeconomics* (Supp. 2D) 69, 81 (2006).

⁹ Wertheimer, A., R. Levy, and T. O'Connor. "Too Many Drugs? The Clinical and Economic Value of Incremental Innovations," in *Investing in Health: The Social and Economic Benefits of Health Care Innovation*, 2001, volume 14, pp.77-188.

¹⁰ Hemel, Daniel J. and Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 *YALE L.J.* 544, 553 (2019).

¹¹ Lietzan, Erika. Paper Promises for Drug Innovation, 26 *George Mason Law Review* 168 (2018). Available at: <https://scholarship.law.missouri.edu/facpubs/960>

¹² Eisenberg, Rebecca S., *The Problem of New Uses*, 5 *YALE J. HEALTH POL'Y L. & ETHICS* 717, 720 (2005).

¹³ U.S. Food and Drug Administration. "Estimating Cost Savings from New Generic Drug Approvals in 2023," online report, November 2025. Available at: <https://www.fda.gov/media/189635/download?attachment>

¹⁴ Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *Effect of Entry on Generic Drug Prices: Medicare Data 2007-2022*. Issue Brief No. HP-2025-06, January 2025. Available at: <https://aspe.hhs.gov/sites/default/files/documents/510e964dc7b7f00763a7f8a1dbc5ac7b/aspe-ib-generic-drugs-competition.pdf>

¹⁵ DiMasi, Joseph A., "Price trends for prescription pharmaceuticals 1995-1999," a report prepared for the Conference on Pharmaceutical Pricing Practices, Utilization and Costs of the U.S. Department of Health and Human Services, 2000. Available at: <http://aspe.hhs.gov/health/reports/Drug-papers/dimassi/dimasi-final.htm>

¹⁶ Dickson, Sean, Nico Gabriel, and Inmaculada Hernandez. "Changes in Net Prices and Spending for Pharmaceuticals after the Introduction of new Therapeutic Competition, 2011-19," *Health Affairs*, vol.42, no.8, August 2023. Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00250>

¹⁷ Wertheimer, Albert I. and Thomas M. Santella, "Pharmacoevolution: the benefits of incremental innovation," *International Policy Network*, March 2005.

¹⁸ Caldara, Dario, Matteo Iacoviello, Patrick Molligo, Andrea Prestipino, and Andrea Raffo (2019). "Does Trade Policy Uncertainty Affect Global Economic Activity?," *FEDS Notes*. Washington: Board of Governors of the Federal Reserve System, September 4, 2019, <https://doi.org/10.17016/2380-7172.2445>.

¹⁹ Day, Gregory and Steven Udick, *Patent Law and the Emigration of Innovation*, 94 *Wash. L. Rev.* 119, 125 (2019).

²⁰ Viscusi, W. Kip, et al., *Economics of Regulation and Antitrust*, 87 (4th ed. 2005).

²¹ Vivian, Jesse C. "Generic-Substitution Laws," 33 *US PHARMACIST* 30 (2008). Available at: <https://www.uspharmacist.com/article/generic-substitution-laws>

²² Trebbi, Francesco and Miao Ben Zhang, *The Cost of Regulatory Compliance in the United States* 12 n.25 (Nat'l Bureau of Econ. Rsch., Working Paper 30691, Nov. 2022).