The Unintended Economics of the BLOCKING Act

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EXECUTIVE SUMMARY

The Hatch-Waxman Act established two categories of clear and powerful incentives for pharmaceutical manufacturers: patent extensions and market exclusivity to encourage innovator drug manufacturers to invest in R&D for new drugs, and an important complementary incentive for generic drug manufacturers to challenge brand drug patents and bring lower-cost drugs to market.

Specifically, the first generic manufacturer who challenges a brand drug patent, in what is known as a Paragraph IV challenge, is eligible for 180 days of market exclusivity. This exclusivity effectively establishes a temporary market of limited competition, affording the generic firm the opportunity to earn a return on the cost (and risk) associated with challenging a brand drug's patents.

Recently, the House of Representatives and the Senate HELP Committee passed versions of a legislative proposal to allow the Food and Drug Administration (FDA) to more easily approve a subsequent applicant's abbreviated new drug application if the first applicant has not yet received final approval. Known as the BLOCKING Act, this legislation may result in some generics coming to market sooner, as intended, but it would also have the unintended effect of weakening the incentive for generic manufacturers to invest in efforts to bring other generics to market as early as they otherwise would.

This report investigates the economic and budgetary effects of these unintended consequences, which the FDA ignored in its analysis of the policy. A proper understanding of the economic consequences of the bill would acknowledge that it will, on balance, delay average generic entry and increase pharmaceutical spending. Our analysis of these consequences relies on data from the FDA's memorandum on this issue and the agency's records on Paragraph IV certifications. We find that, on average, a single case of the BLOCKING Act discouraging a Paragraph IV challenge will lead to a four-year delay in generic entry and $1.7 billion in lost savings nationally.

The BLOCKING Act's delay of one generic drug =

$1.7 billion in lost savings

Introduction

In 1984, the Hatch-Waxman Act established new incentives for the pharmaceutical industry, innovator and generic companies alike. Innovator companies receive strong protections from the Food and Drug Administration (FDA) in the form of extensions to certain patents and limits on when generic applications can be submitted and approved.

These policies ensure that brand drug companies can recoup the substantial R&D costs associated with bringing a new drug to market. On the generic side, Hatch-Waxman provides that the first generic applicant with a substantially complete abbreviated new drug application (ANDA) with a Paragraph IV certification is eligible for 180 days of market exclusivity. This exclusivity period affords the first generic the opportunity to earn, for a limited time, economic rents. (Though in many cases, an authorized generic is sold during the 180-day exclusivity period, and more than one generic firm can share exclusivity.) After the 180-day period, other generic manufacturers may be approved and enter the market.

In February 2018, the Trump Administration's FY19 budget proposed a legislative reform aimed at increasing generic drug competition by "ensur[ing] that first-to-file generic applications who have been awarded a 180-day exclusivity period do not unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period." In plain English, the FDA appears concerned about the risk of first-to-file generic drug manufacturers "parking" their 180-day exclusivity and delaying the entry of subsequent generics.

The Administration's proposal, which was also included in its FY20 budget, was developed into formal legislation and introduced by Representatives Kurt Schrader (D-OR) and Buddy Carter (R-GA) as HR 938, Bringing Low-cost Options and Competition while Keeping Incentives for Generics Act of 2019, commonly referred to as the BLOCKING Act. The bill purports to address the policy concern raised by the Administration by allowing the FDA to finally approve a subsequent applicant's ANDA if certain pre-conditions are met, including that the first applicant has not been finally approved within 30 months of submission.

Intentional and knowing delay of generic entry by a generic drug manufacturer should be concerning to policymakers. Such actions would be counter to the intent of the Hatch-Waxman Act and would result in an unduly long period of brand drug market exclusivity and unnecessarily high drug costs. But the BLOCKING Act as drafted would go beyond addressing perceived problems and would impede generic competition by weakening the incentive inherent in the 180-day exclusivity statute. This report explains how this is so and presents an analysis of the cost of the unintended consequences of the bill.

The BLOCKING Act would impede generic competition by weakening the incentive inherent in the 180-day exclusivity statute.

Why the BLOCKING Act Is Misguided

There are at least two reasons why the BLOCKING Act is a misguided attempt at promoting generic competition. First, the existing statute significantly mitigates the risk that a generic manufacturer could "park" its 180-day exclusivity. The "failure to market forfeiture provisions" [FD&C Act Section 505(j)(5)(D)(I)(I)] establish a two-part test under which 1) a prescribed period of time passes, and 2) a final patent judgement occurs, a court agrees to a settlement order finding the patent is invalid or not infringed, or the patent in question is withdrawn by the innovator company. Should a first applicant fail this two-part test, the applicant forfeits exclusivity if it does not launch within 75 days. To our knowledge, there has been no formal explanation by the FDA regarding why 505(j)(5)(D)(I)(I) is inadequate. A first applicant would also forfeit its exclusivity if it does not have tentative approval within 30 months of submission [FD&C Act Section 505(j)(5)(D)(I)(IV)]. This prevents first applicants with ANDAs of poor quality or deficient facilities from tying up subsequent applications.

Second, the BLOCKING Act establishes broad authority for the FDA and potentially permits the FDA to trigger exclusivity for reasons that are outside the control of the first applicant. In other words, the first applicant can lose some or all of its 180 days of exclusivity through no fault of its own. This creates unintended consequences by weakening the incentive that the 180-day exclusivity period creates for generic manufacturers to challenge brand drug patents.

Well-intentioned ANDA applicants may, as the result of actions beyond their control, lose the opportunity to be rewarded for their risk taking.

Unintended Consequences of the BLOCKING Act

The 180-day exclusivity period was intended to reward the ANDA applicant who incurred the cost and risk of mounting a challenge to a brand drug's patent. Patent challenges also serve to police misuse of the patent system. In an empirical analysis of Paragraph IV challenges, Columbia University researchers point to "the social value of generic patent challenges":

> Our results suggest that patent challenges target drugs whose portfolios include weak late-expiring patents. Under the assumption that weaker patents are less likely to be related to socially valuable research and development, challenges might be an important means to curtail patents that have high social costs (by sustaining high prices) but bring little innovative benefit. (*Hemphill and Sampat, 2011*)

It is widely recognized that an attempt to launch a generic before the expiration of a brand drug's patents is costly, time consuming, and risky. Therefore, if the 180 days of exclusivity for the first generic is more uncertain, it reduces the incentive for generic manufacturers to take this risk because the opportunity to recoup those costs and earn an economic profit may not materialize. This is precisely what the BLOCKING Act would do. Specifically, it would create the risk that well-intentioned ANDA applicants may, as the result of actions beyond their control, lose the opportunity to be rewarded for their risk taking. As drafted, the BLOCKING Act could deprive first applicants of some or all of their exclusivity period through no fault of their own — if there is, for example, a post-filing rule change at the FDA, a citizen petition, a delay at the FDA, or a failure to inspect or reinspect facilities in a timely fashion, to name a few.

Paragraph IV challenges are already uncertain. A review of Paragraph IV case outcomes in district courts from 2009 through 2012 finds that generic companies won only 46 percent of the time (31 out of 68 cases that did not settle) (*Glass, 2013*). Without confidence that an investment risk could be rewarded with a temporary period of generic exclusivity, generic manufacturers' incentives to undertake this risk are reduced. This should not be interpreted to mean that no further Paragraph IV challenges will occur. Rather, those marginal cases where expected costs and expected returns are already close to offsetting will be abandoned.

This has significant implications for pharmaceutical competition and the generic savings to which the U.S. health system has become accustomed, as Paragraph IV challenges have become much more common in recent years. Among new molecular entities experiencing first generic entry, 9 percent had a Paragraph IV challenge in 1995; by 2014, 76 percent had a Paragraph IV challenge (*Grabowski et al., 2016*).

Estimates of the Budgetary Impact of the BLOCKING Act

Both the Executive and Legislative branches have produced multiple estimates of the budgetary impact of the policy underlying the BLOCKING Act. The most detailed of these estimates was developed by the FDA as a memorandum in March 2019 (*FDA, 2019*).

FDA ESTIMATE

In its memorandum, the FDA presents two estimates of potential savings from the Administration's proposal. It is important to note that both of the FDA's estimates assume that a subsequent applicant would enter the market promptly, but the BLOCKING Act does not require a subsequent applicant to launch upon receipt of final approval.

In the first estimate, the FDA calculates "forgone savings" as a result of the lack of statutory authority in past years. The FDA estimates that there were approximately 30 instances in 2012–2017 (5 per year) when a first applicant's eligibility for 180-day exclusivity purportedly blocked a subsequent applicant's approval. Calculating the average generic entry delay (12 months) and the average generic savings per month ($29.5 million), the FDA estimates lost savings of $1.8 billion per year (5 delays/year * 12 months/delay * $29.5 million/month).

In an alternative analysis that relies on a more robust sample of generic savings by month from all initial generic approvals from 2014 through 2016, the FDA determines average realized cumulative savings per month for generics that first entered the market during this period. In this analysis, average lost savings attributable to a 12-month delay total $299.8 million per instance. Given the FDA's assumption that there are five such cases annually, this yields an estimate of forgone savings of $1.5 billion per year (5 delays/year * $299.8 million/delay).

Because the FDA analysis relates to national drug spending, not federal spending like traditional federal budget scores, it is worth noting that federal drug spending is approximately 40 percent of national spending. Therefore, by the FDA's methodology, lost federal savings may be between $600 million ($1.5 billion * 40%) and $720 million ($1.8 billion * 40%).

OTHER ESTIMATES

The Administration has provided two official budget scores of this policy proposal. In the FY19 budget analysis, the Department of Health and Human Services (HHS) estimated Medicare budget savings of $1.8 billion over 10 years (HHS, 2018). In the FY20 budget analysis, HHS reduced the Medicare savings estimate to $960 million over 10 years while expanding the scope of the analysis to include federal spending on Medicaid of $200 million (*HHS, 2019*).

The Congressional Budget Office (CBO) has provided two estimates of the proposal. HR 938, as adopted by the House Energy and Commerce Committee, was estimated to reduce federal spending by $374 million in direct spending over 10 years and increase federal revenues by $68 million (*CBO, 2019a*). A similar provision

included in the S. 1895, the Senate HELP Committee's Lower Healthcare Costs Act, is estimated to reduce direct spending by $356 million and increase revenues by $68 million over 10 years (*CBO, 2019b*).

Neither the estimates from HHS nor the estimates from CBO include any details regarding the assumptions underlying their scores. In all cases, estimated savings are dramatically lower than the FDA's estimate, but the root of the differences is not explained other than the aforementioned fact that the FDA's scope is national savings while the budget scores relate only to federal spending. (A lesser difference is that the FDA's analysis scales prices to the January 2018 Consumer Price Index while the CBO and HHS estimates assume projected nominal prices in the future.)

Analysis of the Unintended Consequences of the BLOCKING Act

To demonstrate the impact of the unintended consequences of the BLOCKING Act, we estimate the expected lost savings from the chilling effect the policy would have on Paragraph IV challenges. For this exercise, we rely heavily on the FDA's own analysis (*FDA, 2019*).

To crystalize the economic impact of weakening the incentive effect of 180-day exclusivity, we estimate the lost generic savings associated with just one occurrence of generic manufacturers choosing to wait until brand drug patent expiration instead of pursuing a Paragraph IV challenge.

To estimate the average delay associated with the decision not to pursue a Paragraph IV challenge, we reviewed the FDA's published list of Paragraph IV patent certifications as of November 19, 2019. There are 48 certifications on this list for which the FDA has noted both the date of first commercial marketing by the first applicant and the expiration date of the last qualifying brand drug patent. The average time between the market entry of the first applicant and the expiration of the last relevant brand drug patent is 62 months (5 years, 2 months). The median duration is 50 months (4 years, 2 months). See **Table 1** for a summary of results. We make the conservative assumption in our model that the expected delay in generic entry will be four years.

Next, we estimate the expected lost generic savings by delaying generic entry for four years. Our estimate relies on the analysis in FDA (*2019*) of monthly generic savings for an 18-month period. The FDA estimates are based on IQVIA sales data for 80 drugs for which there was an initial generic entry between 2014 and 2016 and adequate sales data. (As noted above, in this analysis, the FDA determines that the 12-month delay that the BLOCKING Act purportedly would avoid represents $299.8 million of savings per drug.)

TABLE 1. SUMMARY OF PARAGRAPH IV PATENT CERTIFICATIONS DATA

	TIME BETWEEN GENERIC MARKET ENTRY AND BRAND PATENT EXPIRATION
Observations	48
Average	5 years, 2 months
Median	4 years, 2 months
Minimum	0 months
Maximum	16 years, 2 months

Source: *FDA, Paragraph IV Patent Certifications as of November 19, 2019.*

Based on the 18 months of savings data provided by the FDA, we estimate a logarithmic model to predict expected monthly savings beyond the 18-month period. **Chart 1** below illustrates the average monthly savings as estimated by the FDA (solid line) and shows the fitted logarithmic estimate (dotted line). For any duration, the aggregate lost savings is the sum of monthly savings estimates.

Using this model, we estimate that a four-year delay in one generic entry would result in $1.677 billion in lost national healthcare savings. In other words, our analysis finds that lost savings from one generic arising from the BLOCKING Act could easily exceed the estimated gains that the FDA claims would arise from accelerating entry for five generics.

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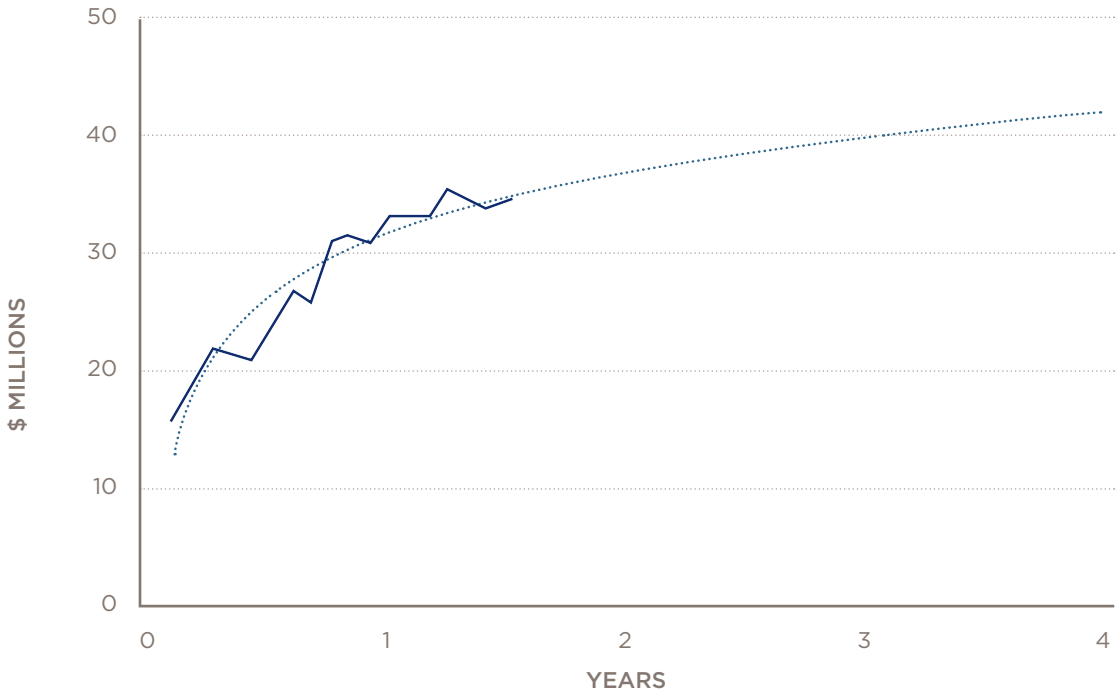
CHART 1. SAVINGS FROM GENERIC ENTRY: A LOGARITHMIC FORECAST



Note: *Values reported represent the average monthly savings associated with generic entry based on FDA (2019) and author's calculations. The estimated model is y = 7.6152* ln(x) + 12.613 and the* R^2 *is 0.92.*

CONCLUSION

The critical shortcoming of the BLOCKING Act is reducing the incentive for generic firms to challenge brand drug patents. In so doing, it would cause delays in generic entry and significant missed savings opportunities. We conclude that, on average, delaying one generic entry by four years — the median point at which a first applicant currently enters the market before brand patent expiration — would cause $1.7 billion in additional brand drug spending.

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