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CREATES Act unfairly tips the scales to generics

The act's one-sided provisions and its disproportionate remedies cannot pass constitutional muster, argues John Cox of Barnes & Thornburg.

The Hatch-Waxman Act sought to balance pharmaceutical innovation and access to affordable generic drugs.

Congress enacted the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act in 2019 to adjust that balance by preventing an anti-competitive tactic known as sample blockades by innovator drug companies, such as delaying or refusing samples to generic drug companies seeking to include comparative testing in their abbreviated new drug application (ANDA), 505(b)(2) application, or biosimilar application.

But almost no information about how the CREATES Act is being used—such as (i) the number of requests made (a) citing the CREATES Act, (b) per product, (c) per requester per product; (ii) the quantities requested per product; (iii) the time between receipt of the request and receipt of product; (iv) the quantities received relative to the quantities requested; (v) the substance of communication between the requester and innovator—is available.

And only two cases have been filed citing the CREATES Act; neither passed the pleadings stage. (See ***Eisai v Newlife Medicals (USA)***, Case No. 24-cv-00124-GBW (D Del, filed Jan 21, 2024); ***Teva Pharms Dev v Amicus Therapeutics US***, Case No. 21-cv-03105-TJS (ED Pa, filed July 13, 2021).

This could mean that the CREATES Act has worked and simply eliminated sample blockades once and for all. Or the threat of available remedies has proven heavier than the burden of providing product in response to a request, regardless of whether or not the request—or requester—satisfies the CREATES Act. (see articles here, here, and here).

What is clear, however, is that the CREATES Act is fatally one-sided.

The CREATES Act arguably gives generic drug companies unilateral decision-making power to use it, including the threat of severe enforcement provisions, with seemingly little available to innovators in defence.

The result is that generics wield a sword to which the only shield could be expensive litigation—leading to an uncertain outcome potentially involving forfeiture of revenue—even when the innovator responds in good faith. This article attempts to add weight, including additional defences, to the other side of the balance.

One commentator observed that “[t]he process the act created is quick, the requirements are straightforward, and the bill imposes substantial penalties if a branded company acts in bad faith.”

And the generic drug industry has reported that sample blockades have entirely or almost entirely disappeared, crediting the “mere existence” of the CREATES Act for altering corporate behaviour. In that sense, it has succeeded in its primary goal of preventing bad acts.

But it is incorrect to suggest that the CREATES Act only penalises innovators acting in bad faith or “ensures that the generic companies receive what they need but no more”.

Beyond rare supply-related situations, the CREATES Act provides the innovator with only the ill-defined “legitimate business reason” defence, which is not self-fulfilling for the innovator (unlike the provisions benefitting the requester) and may be confirmed only well into litigation.

That defence appears limited to only a portion of the remedies listed in favour of the generics. A fulsome discussion of the defences not listed in the CREATES Act—particularly unconstitutionality both on its face and as applied by the generics industry—is beyond the scope of this article.

It is worth noting some of the more troubling provisions of the CREATES Act are live targets for such defences, starting with Section (a)(10).

Self-selecting eligible product developer definition

Section (a)(10) defines an eligible product developer (EPD) as “a person that seeks to develop a product for approval pursuant to an application for approval under [an ANDA or 505(b)(2) application] or for licensing pursuant to [a biosimilar or interchangeable biological product application].”

Requesters can self-identify as an EPD; the CREATES Act does not give the innovator any means to determine the legitimacy of the entity demanding the product.

For example, contract manufacturers seeking to supply an ANDA filer—whether or not a contract exists—could request product, citing the CREATES Act. If that manufacturer satisfies only the logistical requirements of the request, the CREATES Act seemingly provides standing to the manufacturer to seek the draconian remedies therein.

The same could be true if the innovator denies the request because the requester 1) is not licensed to handle pharmaceuticals, 2) refuses to satisfy the Uniform Commercial Code in contracting the sale, or 3) seeks to impose unreasonable or unfeasible terms upon the sale and delivery of the product.

The CREATES Act seemingly requires the innovator to provide product or defend itself in litigation before the requester even proves it can legally receive pharmaceuticals, let alone qualifies as an EPD.

And while cases under the CREATES Act are few and short-lived, one innovator attempted to preempt suit under the act by seeking declaratory judgment, stating the innovator had no obligations under the act and the requester was not an EPD (***See Eisai v Newlife*** at D.I. 1).

That case was voluntarily dismissed before a responsive pleading and after the parties conferred about the request for product (***See id.*** at D.I. 13 and 15).

No express limits on requests

Another unfair advantage occurs because the CREATES Act fails to place explicit limits on the amount of product the requester can demand. Instead, under interpretations by the generics industry, the innovator could be subject to liability and severe penalties if it fails to provide "sufficient quantities," which the CREATES Act defines as "an amount of a covered product that the [EPD determines] allows the [EPD] to [] conduct testing to support an application [such as an ANDA or 505(b)(2) and] fulfill any regulatory requirements relating to such an application for approval or licensing" (21 U.S.C. § 355-2(a)(10).

The generics industry has already looked to use this provision by claiming that the CREATES Act authorises multiple requests for different amounts, leading to self-approval of a tactic to redefine "sufficient quantities" at will.

And even if only one request is allowed, Congress justified providing the requester with the power to determine sufficient quantities by reasoning that, without it, there is "room for disagreements between the licence holder and the [EPD] as to the quantity of covered product needed by the [EPD] to develop their product and submit an application." (HHS/FDA Comments on HR 695/S.340, CREATES Act of 2019, at 2).

Under that reasoning, a requester could repeatedly demand excessive, varying amounts that the innovator seemingly must sell at wholesale price. Instead of striking a balance, Congress eliminated it.

Ripe for litigation at the generics' discretion

Under the CREATES Act, an innovator can counter-offer to sell sufficient quantities at commercially reasonable market-based terms, but the requester can refuse that counter-offer for any reason with no oversight, seemingly subjecting the innovator to litigation at the requester's discretion. Coupled with failure to comply with the arbitrary time demands in the act, an innovator may be subject to litigation—and potentially devastating remedies—even when it acts in good faith in response to an unscrupulous requester.

Even more troubling provisions can be found in Section (b)(4), which lists available remedies should an EPD prevail in litigation. Indeed, some in the generics industry have interpreted the CREATES Act to provide the requester attorneys' fees and costs even when the innovator acts in good faith. Under such an interpretation, an innovator who offers to sell the quantity actually needed to support a generic filing—and even provides product but misses one of the arbitrary deadlines in the CREATES Act—could be liable for not only fees and costs, but revenues from the

product with no consideration of the logistics of the sale. The severity of such a penalty and the absurdity of such an outcome cannot be overstated.

The one-sided provisions of the CREATES Act and its disproportionate remedies cannot pass constitutional muster. And while one commentator acknowledged the possibility that innovators would challenge its constitutionality, that acknowledgement is just part of a sales pitch to the generics industry arguing that, with the CREATES Act behind them, "generics companies will need access to capital for litigation." (***See*** "Pharma brand sued under the CREATES Act: Implications for generic drug developers").

While Congress passed it to remedy or even prevent anti-competitive behaviour, and it should prove useful in situations where the innovator is truly a bad actor, those in and around the generics industry see the CREATES Act as sanctioning something more than a way to secure product to support a generic application.

On one side of the balance, there are those focused solely on capital and arguing that the CREATES Act provides the means. On the other side, the limited defence of legitimate business reasons and threat of constitutional counterclaims in the face of abusive litigation tactics must suffice until the CREATES Act is struck down.

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