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FROM THE ANALYST'S COUCH

Authorized generics

Gregory Glass

The past 18 months has presented the generics and brand pharmaceutical industries with a dilemma unique to the US market: whether a partnership to launch and market a generic version of the brand's product, a so-called 'authorized generic', is within their core brand and company strategies. The past 2 years have seen some brand companies, such as GlaxoSmithKline, Bristol-Myers Squibb and Janssen, contract with generics companies, such as Par, Sandoz and Watson, to sell authorized versions of their blockbuster products after the product's patent expires (TABLE 1).

However, some other companies, notably Novartis, AstraZeneca, Merck, Teva and Mylan, have so far been reluctant to enter into such an arrangement, because it represents a cooperative effort between bitter market rivals and a deviation from core business and product strategies. In addition, there was some concern within the market that these contractual arrangements might violate the Hatch–Waxman Act or even US antitrust laws. However, recent agency opinion and a court ruling have allayed these fears, marking an open pathway for brands and generics to enter into these partnerships. We can expect them to become part of the natural course of life-cycle management in the future.

Launching a generic drug

When a generic company wants to enter the market with a generic product that can be substituted at the pharmacy, it files an Abbreviated New Drug Application (ANDA) with the US FDA. In the ANDA, the generic applicant certifies against the patents of the brand product. If the applicant makes a certification commonly referred to as a 'Paragraph IV' certification, it in effect challenges the patents of the brand and asks the FDA for approval of the product before the patents challenged expire.

If the generic company is successful in its Paragraph IV challenge, the statute awards the first applicant an exclusivity period of 180 days. In other words, if the generic company is able to invalidate the brand product's patent(s), or shows a court that it does not infringe the patent, it is allowed 6 months of time on the market as the only generic; and by pricing its generic product only 15–20% below the brand price, it can take up to 80% of the brand's market share within about 2 months. In those 6 months, the generic company can reap substantial benefits through its generic monopoly status and price (which will decline quickly with the presence of other generic products) and through its first-mover advantage in the generic market, which will help to maintain significant market share when the 180 days expires and other generic products enter the market.

How the authorized generic works

The authorized generic has the effect of reducing the financial reward of the first ANDA generic. In this scenario, the brand company does not stand by and watch its share erode after the first ANDA generic, with exclusivity, enters the market. Instead, the brand company contracts with another generic company, different than the first ANDA generic, to launch and market its own generic product. In other words, the brand company will continue to manufacture its product as a brand, but it will also re-label its product as a 'generic' and allow its generic partner to sell it and compete with the first ANDA generic at a lower generic price.

The benefit of the arrangement

Three parties benefit from the authorized generics arrangement. First, the brand company can earn additional revenue for negligible transaction costs. In the partnership, the brand company will typically take between 80–90% of the profit of the authorized generic product. For a blockbuster, that can mean an additional US$88 million in revenue that would otherwise be lost to the first ANDA generic (BOX 1). Second, the generic company selling the authorized generic benefits by immediately entering a particular generic market and taking some of the revenues without any risk of drug development. Third, payors (that is, those who pay for the prescription, whether it be a patient or insurer) benefit from having another lower-priced product on the market. Of course, two generics on the market will mean more competitive pricing for the generic.

Extra pressure on the generics industry

Of course, the first ANDA generic is the one clear loser of the authorized generic arrangement. Arguably, the authorized generic is clearly not in the spirit of the Hatch–Waxman Act, the law that created the Paragraph IV reward system by giving market exclusivity to the first successful generic challenger to a patent. Instead of enjoying the reward by having a 6-month generic monopoly, the first ANDA generic has found itself in recent months competing against an authorized generic product.

Two generic companies in particular, along with the US generic trade association, have tried to put an end to authorized generics arrangements. First, Teva and Mylan filed Citizens Petitions with the US FDA asking it to disapprove of the authorized generics. The FDA declined to do so in June 2004. These generic companies also filed lawsuits against the FDA, and in June 2005 the Appeals Court for the District of Columbia in *Teva versus Crawford*, ruled against Teva, concluding that nothing in the Hatch–Waxman Act prevented the authorized generic partnership.

Clearly, such a ruling is a bit of a blow to the generics industry. By allowing authorized generics, the value of filing the first ANDA, and successfully challenging the brand's patents, has declined by half and can be in the order of hundreds of millions of dollars for a large product. In addition, any sense of civility in the generics market has clearly disappeared. If a generic company finds itself behind in product development, or even as a second or third ANDA filer, it can jump the queue and partner with a brand company. Of course, turnabout is now fair play, and that same generic can find itself in the same situation on a product it had been first to file.

Implications for investors

Investors should be aware that authorized generics are likely here to stay. The *Teva versus Crawford* decision validates the arrangements, and it leaves the last resort to Congress or the US Federal Trade Commission (FTC) as a means to eliminate the authorized generic. Congress and the FTC have provided only little indication that they will act. For example, some in Congress have proposed to include the authorized generic arrangement into the 'best price' calculation for Medicaid expenditures[2]. Even if this effort is successful, it will likely have little impact as most authorized generic arrangements will have financial merit though it would depend on pricing dynamics for the particular drug. The FTC has taken a spectator approach, indicating that the additional competition in the generics market benefits consumers. However, several senators have requested the FTC to investigate the impact of authorized generics to the generic market in the long run[3].

AUTHORIZED GENERICS | MARKET INDICATORS

With the potential loss of revenue for generics companies (see BOX 1), investors should then keep a keen eye on the impact to generics companies, particularly those whose strategies supported marketing exclusive generic products. In addition, some brand companies can increase quarterly earnings by as much as 5% during the time of an exclusive generic. Expect many brand companies to embrace the authorized generic, and in particular, the arrangement can be a needed benefit to small- and mid-cap brand companies.

Usually, the brand company waits for the launch of a generic and launches the authorized generic on day 1, 2 or 3 of the launch. Any sooner means unnecessary losses, especially if the first ANDA generic decides not to launch; later than 3 days or so will mean the authorized generic won't really gain any significant share.

As it is politically difficult to argue that there should be fewer generics on the market, the likelihood of either Congress or the FTC acting to eliminate the authorized generic is very small, and so far neither have made any indication that they will.

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1. Court of Appeals for the District of Columbia, Case Number 05-5004 (June 3, 2005). http://pacer.cadc.uscourts.gov/docs/common/opinions/200506/05-5004a.pdf
2. Chairman's Mark of the Deficit Reduction Omnibus Reconciliation Act of 2005 [online], <http://finance.senate.gov/sitepages/leg/102505chmkmod.pdf> (2005).
3. Press release. Grassley, Senators Request study of impact of 'authorized' generics [online], http://grassley.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=4903&Month=5&Year=2005 (12 May 2005).

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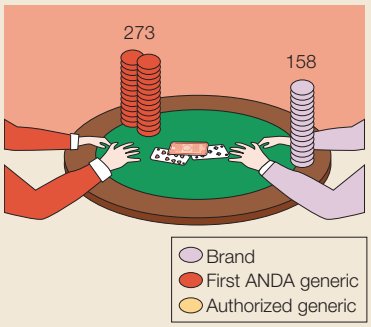
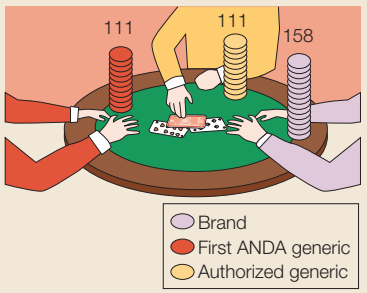
Box 1 | **The generic market: the first 6 months**

Graph 1 considers the financial ramifications of an authorized generic. Let's assume a brand product with 6-month revenues of US$500 million (M), based on 5M prescriptions priced at $100 per prescription. If there is only one generic (the 'first Abbreviated New Drug Application (ANDA) generic') priced slightly lower than the brand (say $80), we would expect that it would take about 30% share at the start of the first month on the market, 60% at the start of the second month, and about 80% at the start of the third month and the remainder of the time period (see top pie chart for revenues at the end of the 6 months after generic entry).



However, now let's introduce the authorized generic. With two generic products, we would expect the generic price to be lower to, say, $65 per prescription. The rates of market share erosion of the brand would be unchanged (the lower price will make little, if any, difference), and let's assume that the first ANDA generic and the authorized generic take 50% each of the generic market (see middle pie chart for revenues at the end of the 6 months after generic entry).



Savings for the payor under this arrangement would be the difference between the aggregate totals of each scenario. In this situation, the payor savings would be US$51M ([$158M + $273M] – [$158M + $111M + $111M] = $51M). Take home pay: remember that the brand will take a majority of revenues of the authorized generic. Let's assume it takes 80% of the revenues. Revenues are shown in the bottom pie chart (brand company: $247M (a gain of $88M) [($158M + 0.8 × $111M) – $158M = $88M]; first ANDA generic company: $111M (a loss of $162M) [$273M – $111 = $162M]; authorized generic company: $22M (a gain of $22M).

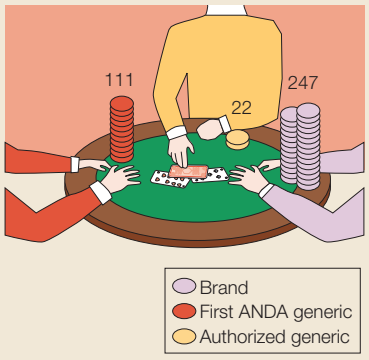


Table 1 | **Examples of authorized generics arrangements since they started**

Product	Brand company	Authorized generic	ANDA exclusive generic	Date launched	Indication
Paxil (paroxetine)	GlaxoSmithKline	Par	Apotex	September 2003	Depression, anxiety
Monopril (fosinopril)	Bristol Myers	Sandoz	Teva	December 2003	Hypertension
Glucophage XR (metformin)	Bristol Myers	Par	Ivax	January 2004	Diabetes
Wellbutrin SR (bupropion)	GlaxoSmithKline	Watson	Eon/Impax	January 2004	Depression
Macrobid (nitrofurantion)	Procter & Gamble	Watson	Mylan	March 2004	Antibacterial
Rebetol (ribavirin)	Schering Plough	Warrick	Sandoz, Three Rivers	April 2004	Hepatitis
Neurontin (gabapentin)	Pfizer	Greenstone	Teva/Alpharma	October 2004	Epilepsy
Duragesic (fentanyl)	Janssen	Sandoz	Mylan	January 2005	Pain management
Ultracet (Tramadol, Acetaminophen)	Ortho McNeil	Ivax	Kali Labs	April 2005	Pain control
Oxycontin ER (oxycodone ER)	Purdue	Ivax	Endo	June 2005	Pain management

The data is broken down by product, brand company, the ANDA Exclusive Generic (the one that had been awarded the 180 days exclusivity) and the launch date of the authorized generic product which typically coincides with the launch of the ANDA Exclusive Generic. ANDA, Abbreviated New Drug Application.