WHITE PAPER
THE FIVE MYTHS OF GENERIC COMPETITION.

A PHARMA MATTERS REPORT.

MARCH 2009

A unique, wide-ranging survey of originator pharmaceutical companies by Thomson Reuters found that commercial professionals either consider there is nothing they can do to prevent sales erosion by generic drugs, or assume that the problem is being dealt with by somebody else in their organization. In this white paper, Thomson Reuters exposes these and other myths about generic competition, and shows what originators can do to predict its likely timing, source, and intensity.

HEALTHCARE AND SCIENCE

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INTRODUCTION

Today's generic drugs industry is sophisticated, globally-focused, competitive and fueled by extremely good intelligence. Executives in originator companies regularly cite generic competition as the most important strategic challenge to their business.

You might naturally expect generic intelligence to be firmly on the agenda of each and every brand team's lifecycle plan. However, a unique, wide-ranging survey of executives and managers in key commercial functions of originator pharmaceutical companies by Thomson Reuters found that this is typically not the case.

The study discovered that:

- monitoring and analysis of generic competition within brand and lifecycle management is often an ad-hoc process, with poor communication and coordination across teams
- many companies operate under an assumption that generics are inevitable, and employ standard information techniques that come too late in a product's lifecycle to be effective
- short planning horizons and rapid career trajectories may hamper proper understanding of generic competition among senior management
- many brand teams lack the time, resources or incentives to conduct adequate analysis of generic competition
- little is likely to change until senior management empowers brand teams, holds them accountable for understanding the impact and timing of generic competition, and places it firmly on their agenda

In coming to these conclusions, Thomson Reuters found five common misapprehensions under which executives tend to operate and suggests some solutions to each one, including:

- gaining a better understanding of the decision-making and targeting processes employed by generic companies
- focusing analysis on early warning intelligence
- understanding that originator companies should be concerned about generic competition at the point of launch or approval, if not before
- ensuring that senior management places generic competition firmly on the agendas of brand teams and their lifecycle plans, and provides them with the resources, tools and incentives to follow through their generic monitoring responsibilities

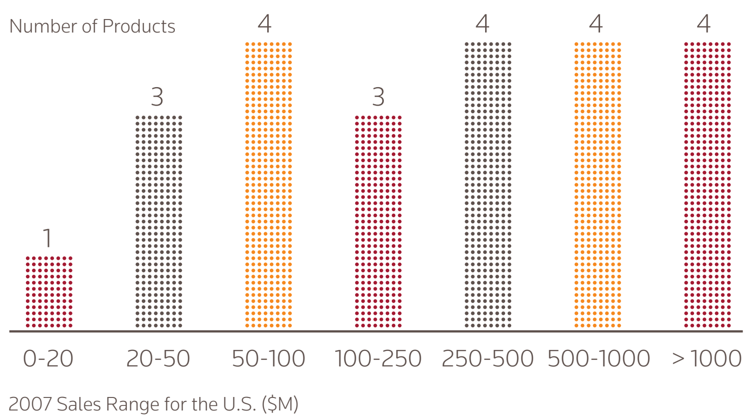
MYTH 1: THE PRIMARY INTEREST OF GENERIC COMPANIES IS IN PRODUCTS WITH SALES IN EXCESS OF $500 MILLION

According to the Thomson Reuters research, most executives in originator pharmaceutical companies believe that the sales cut-off for generic companies targeting drugs for future development and launch is around US $500 million per annum. Any market smaller than that simply isn't worth their while.

Fact: The true picture is quite different. Competition and specialization in the generic industry is resulting in products with US $20 million or even less per annum in sales being considered as potential generic opportunities.

This means that originators cannot afford to ignore possible generic competition, even if they're not in the blockbuster league. And yet a corporate culture that focuses purely on supporting and defending the big brands risks leaking significant revenue elsewhere. *"The big brands get all the attention,"* one product director commented. *"If you aren't selling billions a year, you get no help from anyone."*

2007 US SALES OF BRANDED PRODUCTS WHICH SAW GENERIC COMPETITION IN THE UNITED STATES IN 2008



Source: Thomson Reuters API Intelligence and IMS Health

Eight products had US sales greater than $500M while 15 had sales less than $500M.

The smallest product was $9M and there were three additional products with sales ranging from $20-$50M. There were as many products with modest sales (less than $50M) as blockbusters (>$1B) that saw generics last year. In both cases it was four, with the range from $9M in the lower end to over $3B on the higher end.

MYTH 2: PATENT CHALLENGES, ANDAS AND DRUG MASTER FILES ARE THE FIRST SIGNS OF GENERIC ACTIVITY

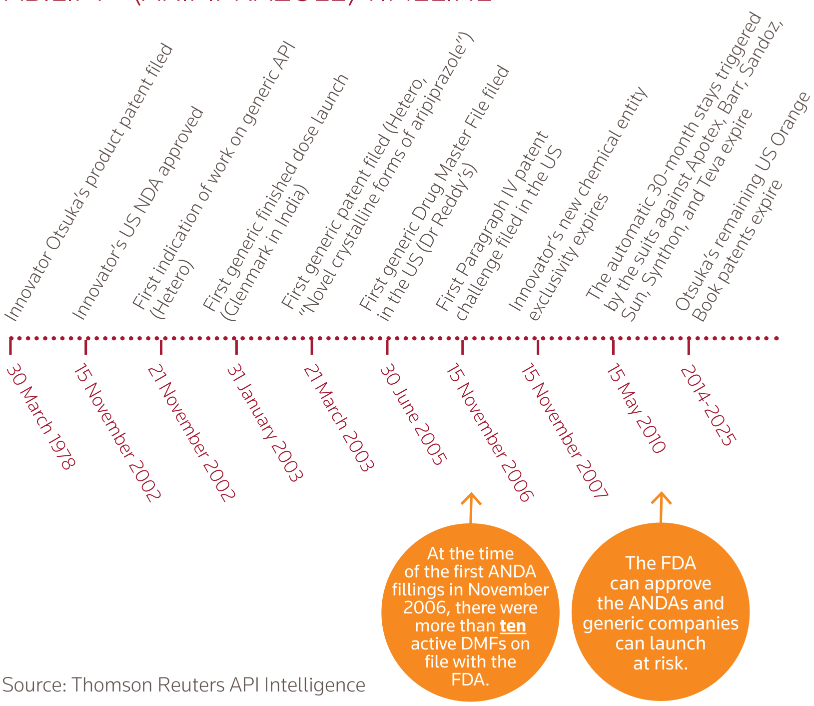
Thomson Reuters found that most generic competitive intelligence programs concentrate on monitoring for developments in regulatory activities such as patent challenges, Abbreviated New Drug Application (ANDA) approvals and Drug Master File (DMF) filings. Executives believed that these are the first clear indicators that generic companies are showing an interest in their products.

Fact: Far from being the harbingers of generic competition, these activities come towards the end of developing a generic product. The earliest and most reliable signal of future generic competition is the activity of companies manufacturing generic active pharmaceutical ingredients (APIs).

Without a source of quality generic API, a generic finished product can never be a reality in regulated markets and so a reliable source is one of the very first items that generic companies look for as they target future opportunities. ANDA filings and DMFs happen years later, and in the case of the latter, may never appear if they are filed as part of the generic company's dossier.

Indeed, accurate intelligence on API manufacturing may increase an originator's ability to detect developing generic competition by several years, as seen in the aripiprazole timeline below. This is the case for all pharmaceuticals, whether they are a small molecule or one manufactured through a biological process, and regardless of their sales potential.

GENERIC COMPETITION TIMELINE: ABILIFY® (ARIPIPRAZOLE) TIMELINE



Source: Thomson Reuters API Intelligence

BIOTECH

The one sector of the industry that has so far remained largely immune from generic competition is biotech, meaning that biotech companies have had little incentive to develop the intelligence sources and early warning processes to identify potential generic competition common to the rest of the industry. But there are strong indications that this situation is about to change.

Not all biotech products are technically challenging to produce, and even for some of the more challenging products, generic companies with the required skills are already in a position to target them. As regulatory pathways for bio-similar products open in major markets, the level of competition is bound to increase markedly.

Regardless of how and when bio-similar regulatory pathways develop, tracking generic API development must be at the heart of the competitive intelligence processes for biotech companies. Large or small molecule, the availability of generic API will remain the central component behind the timing, source and intensity of generic competition.

At the very least, a sound strategy for monitoring potential generic competition should cover:

- generic API manufacturing intelligence worldwide
- patenting activity by generic companies and API manufacturers worldwide
- patent challenges and ANDA and DMF filings (and similar documents in other countries)
- minor market launches of generics
- general (public) news sources
- consultants, PR agencies, advisory boards and external law firms
- the FDA website
- company websites
- industry contacts and colleagues
- tradeshows

Since we are also beginning to see therapeutic substitution in the marketplace, it is also important for an originator to apply these intelligence programs to the products of their rivals.

MYTH 3: THE RIGHT TIME TO START GENERIC COMPETITIVE INTELLIGENCE ACTIVITIES IS 2 YEARS BEFORE PATENT EXPIRY

When Thomson Reuters analyzed the responses gained from their research, they found that the typical horizon for originators to start worrying about generic competition is 2 years before the product's patent or market exclusivities expire. Approximately half of the respondents believed that there is no value in performing regular generic competitive intelligence activities earlier than two years before loss of patent protection.

Fact: This myth appears to stem from the impression that 2 years is the time horizon to which generic companies operate. In fact, most generic companies work to similar development timelines as originators—typically around 8–10 years. The product targeting process is actively examining drugs for future development as soon as they've been approved or launched, some even while they're in phase III clinical development. It all depends on the anticipated commercial potential of the compound, the readiness of a reliable source of the generic API, patent protection and exclusivities.

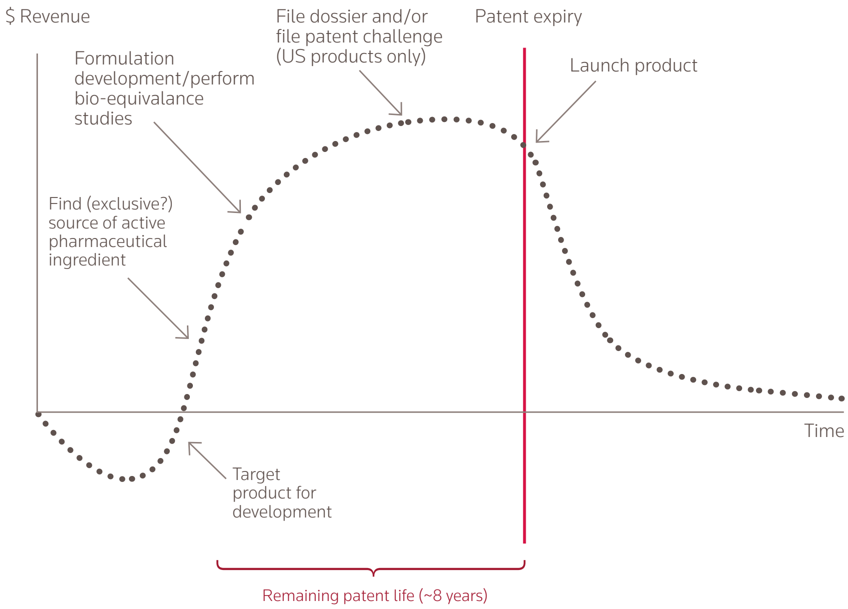
Indeed, at 2 years before patent expiry, most generic companies have long since started focusing their attention elsewhere. They're ready to begin production and distribution the moment the originator's time is up. Therefore, it is critical that generic intelligence becomes an integral element of an originator's lifecycle management plan from the moment the product is launched, if not before.

"The really smart team is thinking about it as they are going into phase III," a vice president of marketing explained, *"because they are thinking about back-up compounds. They may change clinical trial strategies, because a back-up compound may have patent protection longer. The smart team starts really early on in the process, but it doesn't usually happen that way."*

According to this respondent, the business impact of not conducting competitive intelligence on the generic competition is 'opportunity cost': *"If you don't have a generic strategy in place, the opportunity cost to the company can be huge. The longer you wait, the longer it takes to get your new idea into play."*

"We should be using [competitive intelligence] to track the level of exposure to generics 6–8 years prior to patent loss," another respondent commented. *"We should be doing the same for each of our product's competitors."* The information is there. You need to find it, analyze it, and act on it.

HOW GENERICS VIEW THE DRUG DEVELOPMENT LIFE CYCLE



Source: Thomson Reuters API Intelligence

THE EUROPEAN COMMISSION REPORT

The Pharmaceutical Sector Inquiry Preliminary Report from the European Commission, presented on 31 January 2009, found that originators do protect their product portfolios very aggressively immediately ahead of the anticipated launch of a generic alternative.

The findings of the Thomson Reuters survey support the Preliminary Report by making clear the need for early generic intelligence among originator companies. With longer preparation times, originators may be able to devise strategies to deal with the loss of revenues from patent expiry that would not be perceived negatively by both regulators and the public alike.

MYTH 4: GENERIC COMPETITION IS INEVITABLE—THERE IS NOTHING THAT CAN BE DONE

Thomson Reuters discovered that many executives operate in the belief that their drug is certain to be targeted. One senior product manager commented, *"There is a feeling [in my corporation] that nothing much can be done about the expiration of the patent, and we just pray that something doesn't happen prior to the date."*

Another said, *"For my brand, the things that impact brand protection strategies are going to be what the brand means to the company at this particular time. The competitive intelligence on generic activity is less important. You could have a plan to compete against the one generic who has the 180-days exclusivity, but if the whole market is genericized, then it will not matter. Physicians don't fight for branded drugs."*

Fact: Patent expiration and loss of exclusivity are inevitable but generic competition is not. Generic companies need to consider a number of factors before including or excluding a drug from their development portfolio.

For many companies, the availability of reliable, quality supplies of the generic API is the key determinant as to whether, where and when an opportunity can be pursued. The number of manufacturers competing for supply to generics, their current capabilities and historical track-record for working in key markets like the US, Europe and Japan can also have a huge bearing on the intensity of generic competition. What's more, there are many examples where well-managed patent strategy and technical complexity have not made generics inevitable.

Having answers to these questions on hand, and at the right time, can be worth millions of dollars to an originator when considering the timing of major lifecycle investments.

In tandem with thorough competitive intelligence, lifecycle management is the most effective tool an originator can use to grow and defend their brand. At the least, every originator needs to consider the standard strategies of brand protection:

- line extensions, such as new indications and new formulations
- enhanced accessibility and pricing parity, such as consumer co-pay programs, vouchers and coupons
- new products to replace the ageing product
- careful manufacturing and production management, covering the entire supply chain
- better marketing messaging and tactics
- clear, robust patent strategies in the legal department

It is certainly not the case that prior to the generic approval, the only recourse the originator has is the last item on this list.

MYTH 5: SOMEBODY IN THE COMPANY IS ON TOP OF GENERIC COMPETITION ISSUES

When Thomson Reuters questioned respondents from all parts of originator companies, regardless of the size of the company, one theme emerged repeatedly. Monitoring, analyzing and reporting on developments concerning generic competition would benefit from improved attention, priority, and resources from senior management.

Respondents admitted that in many cases there's neither the time nor adequate priority to get the job done, or they hoped that someone else in their organization was doing it for them. Our respondents knew that generic competition should be firmly on the brand team's agenda, but more often than not it was missing or didn't get done.

Fact: Most brand team lifecycle management plans operate with little or no input on generic competition, or input only towards the end of the lifecycle which, as we've demonstrated, is often too late to have any meaningful value.

Most of the marketing managers surveyed indicated that they lack the resources to spend time working on generic competition. As a senior product manager commented, *"I don't have enough time to get my work done for this promotional cycle. How can I worry about something that is six years away?"*

Moreover, Thomson Reuters found that brand protection and generic defense is often an ad hoc and disorganized process. Most respondents monitor generic activity only for their own brand, with only about a third monitoring generic activity on competitors' products. On average seven drugs are monitored by a brand team, but no senior management level respondent was aware of this number for the team(s) in their care.

None of the companies approached allocated specific resources in the product budget for generic defense, even in the face of industry compression and downsizing when it is most needed.

Where there is more than one person or function working on lifecycle management, brand protection or generic defense issues, particularly for multiple brands, they often fail to coordinate their actions—or even communicate effectively with each other. One vice president of marketing explained that when he took over the role, he found *"three groups working on different approaches, all in isolation, and two were counterproductive to the other"*.

The study found that solving the problem of generic competition also lacks adequate incentives. A product marketing director told Thomson Reuters, *"We pay our product managers to build their brands so they're attractive to generics."* That's fine in the short term, while the product is well within patent, but by the time it's reaching expiry that same product manager has probably moved on.

Pharmaceutical industry career paths and compensation systems for product management are focused on no more than a two-year horizon. A potential consequence is that the only product managers truly concerned about generic competition are those whose product has less than two years of patent life remaining.

Incentives are based on current product performance. Nowhere did Thomson Reuters find incentives for future strategies and good planning. Tasks with long time-frames and uncertain outcomes are simply not personally attractive to managers—or even their superiors. *"If I am looking to optimize my budget,"* one senior director commented, *"am I going to gain more revenue by purchasing [competitive intelligence], or by doing an ad?"* The company needs to create and enforce incentive systems aligned with its high-level strategic goals, promoting the correct type of behavior all down the chain.

Indeed, the Thomson Reuters research found, time and again, that brand management needs to come from above—to be driven by senior management. *"If the President or the CEO makes this an important issue, all of a sudden the people sit up and take notice,"* one vice president of marketing explained. *"Monies start to appear, and things get done."*

But every member of the team has an input. *"Our company leadership decides,"* said a product director. *"If we took ideas to them prospectively, I assume they would listen."* The brand team should be responsible for the issue, but only senior management has the level of experience, responsibility and authority to make brand protection a significant area of effort.

Clearly, out of all the different strategies in this white paper, good internal communication and a concerted, organized plan of action, with clear responsibilities throughout the management chain, are the most important. Without them, none of the other strategies have a chance of succeeding—and potential profits and funding for new research will continue to be lost unnecessarily.

NOTE

The findings in this white paper are based on independent research among professionals in pharmaceutical and biotech companies in the US, conducted by The Key Group (keygroupresearch.com) on behalf of Thomson Reuters in May and June 2008. A total of 27 executives, directors and managers from big pharmaceutical and small and mid-sized innovator companies were selected from a database provided by The Key Group, and from past and current customers of Thomson Reuters. Respondents were recruited by telephone and email, and interviewed by telephone. Throughout, Thomson Reuters was identified as the sponsor of the study.

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