

LIFE SCIENCES

Oncology product sales and patent expiration: A Policy Brief



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I. INTRODUCTION¹

It would be difficult to find any time since the 1960s when the cost of prescription drugs has not been controversial. However, over the past several months, the topic seems to have reached a new level of concern. No doubt this concern is heightened by certain high profile events that have drawn attention to the prices of certain new products and the actions of certain companies. Nevertheless, expressions of concern about prescription drug prices and prescription drug spending are widespread.

Among the product classes that have drawn attention is oncology. Certain policy makers and thought leaders have expressed concern about the growth in spending on cancer treatment and the ability of our health care system to sustain paying for such growth. Concerns tend to focus on what seem to be the most challenging of trends and rarely if ever consider the economic dynamics that play out in prescription drug markets.

One of the most well-established regularities in the economics of the U.S. pharmaceutical industry is the life cycle of new products. At least for oral medications, it is widely understood that a successful new product takes several years to develop and obtain marketing approval from the FDA. Following launch, depending on numerous factors, including the competition it faces in the market and other factors, such a product will grow in sales over a period of time until its patent or other forms of exclusivity expire. Upon the loss of exclusivity (LOE), novel prescription drugs typically experience a “patent cliff” as generic copies enter the market and rapidly erode sales.

These life cycle effects have been seen many times over, and their effects have left many brand name drugs little more than memories. Prozac, Zocor, Nexium, Lipitor, and many others have all gone through this cycle and now have sales totals that are only a shadow of their former levels. It is less understood that this phenomenon is not limited to famous brand names. Patent cliffs happen to all types of innovative drugs—even oncology medications.

The purpose of this brief is to provide illustrations of the life cycle in prescription oncology therapies to place concerns about sustainability into context. While the market for oncology products is complicated by changes in treatment standards and ongoing medical advances, and not every medication goes through the life cycle in the same way, the loss of sales that is common, or even typical, upon LOE is an important occurrence. It has had and will continue to have a substantial impact on the overall cost of cancer therapy in the United States.

In this brief, we offer four examples of oncology products that have experienced the patent cliff as products have lost market exclusivity. Two of these are oral products and two are injectable. They illustrate a commonly understood phenomenon: oral products tend to lose almost all sales upon loss of exclusivity, and while the drop is not as severe for injectable products, it is still quite large.

II. REVENUE LIFE CYCLE TRENDS

Using data from Quintiles IMS, we have evaluated life cycle trends in sales of several oncology therapies. Our data include gross revenues for oncology products sold in the United States from the fourth quarter of 2001 to the fourth quarter of 2015. It is important to emphasize that the data do not include discounts and rebates paid by branded manufacturers to pharmacy benefit managers and insurers. Discounts and rebates are substantial and have been increasing in recent years so their omission from the data suggests that the sales levels and growth rates we observe prior to LOE are overstated relative to what manufacturers actually received and more than third-party payers actually spent.

¹ The data used in preparing this brief were provided by Pfizer Inc. The opinions expressed represent only those of its authors, and do not represent the views or opinions of Bates White, LLC or of other Bates White employees or affiliates.

Although most products have life cycle trends that are broadly similar to the classical case discussed above, there is variation that depends on a variety of factors that we will not explore in this brief. Nevertheless, the patterns in the data we observe are generally different for orally administered products than they are for injected or infused products.

II.A. ORAL PRODUCT EXAMPLES

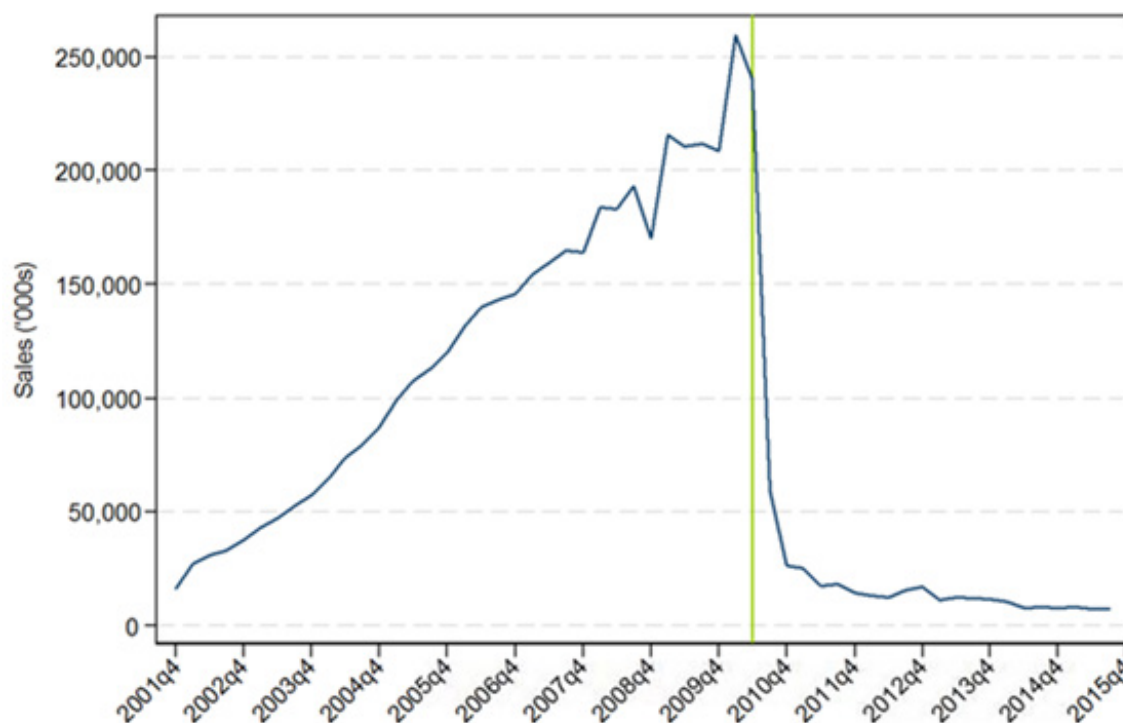
II.A.1. ANASTROZOLE

Anastrozole is an orally administered breast cancer therapy. It works by reducing the amount of estrogen in the body and thus helps interfere with (or even reduce) the growth of breast tumors.²

As indicated in Figure 1, Anastrozole experienced rapid growth in sales from the beginning of our observation period until the time it experienced LOE in the second quarter of 2010, with peak quarterly sales exceeding \$250 million.

As summarized in the table below the figure, sales grew at more than 30% per year over more than 8 years. Growth rates such as this would understandably give rise to concerns about future spending. However, as rapid as was its rise, the decline in sales following Anastrozole’s LOE is even more impressive. One year following generic entry, sales had fallen to just over 10% of peak levels, and five years later, sales were only about 3% of peak sales. Rapid declines in sales of this type seem to attract less attention than do trends showing growth, but they are an important element of the policy debate surrounding prescription drugs, and of discussions about the affordability of oncology therapies in particular.

Figure 1—Anastrozole



² More complete descriptions of each of the product examples presented here are available from the products’ FDA approved labels.

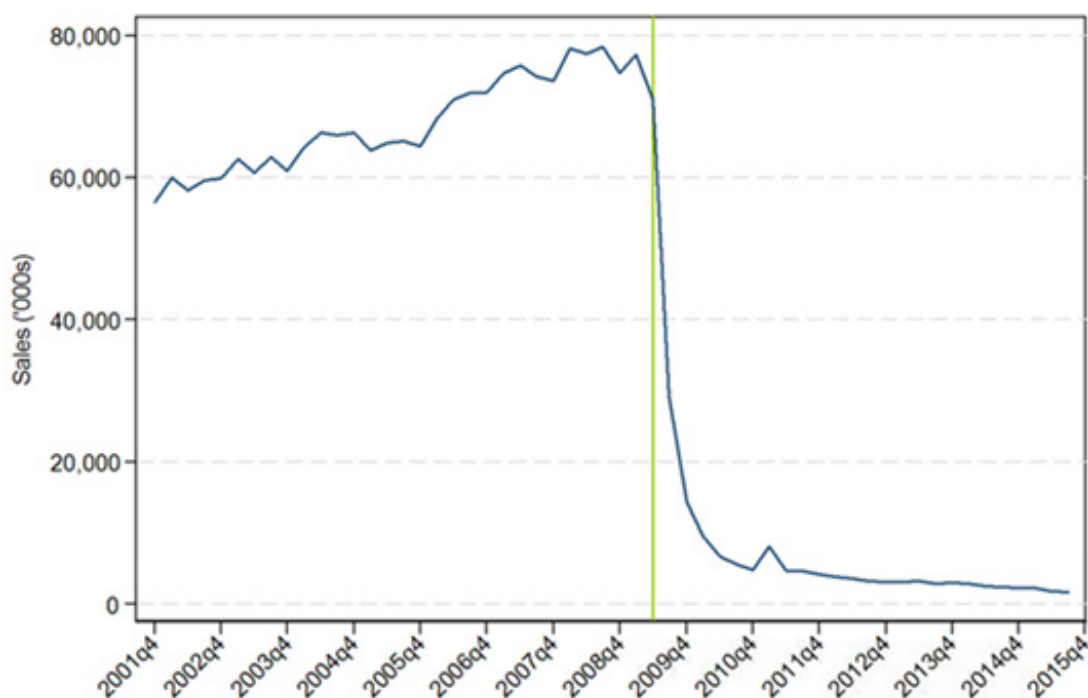
Anastrozole	1st Observation	LOE	# Years from 1st Obs to LOE	Annual Growth Rate to LOE	1 Yr after LOE	2 Yrs after LOE	5 Yrs after LOE
Quarter	2001 Q4	2010 Q2	8.5	31.5%			
Sales (\$000)	\$ 16,456	\$240,078			\$ 25,048	\$ 13,206	\$ 8,022
% of LOE Sales					10.4%	5.5%	3.3%

Source: Quintiles IMS Midas Data

II.A.2. BICALUTAMIDE

The second example from the group of oral products is illustrated in Figure 2. Bicalutamide is a metastatic prostate cancer treatment. Used in combination with other products, this drug slows growth of tumors by blocking the activity of male hormones in the prostate.

Figure 2—Bicalutamide



Bicalutamide	1st Observation	LOE	# Years from 1st Obs to LOE	Annual Growth Rate to LOE	1 Yr after LOE	2 Yrs after LOE	5 Yrs after LOE
Quarter	2001 Q4	2009 Q2	7.25	3.1%			
Sales (\$000)	\$ 56,488	\$ 70,884			\$ 6,710	\$ 4,690	\$ 2,481
% of LOE Sales					9.5%	6.6%	3.5%

Source: Quintiles IMS Midas Data

Bicalutamide sales did not grow nearly as rapidly, or attain nearly the same level as Anastrozole prior to LOE, but its patent cliff was essentially the same in relative magnitude. One year following LOE, its sales were about 10% of peak sales and five years later they were about 3.5% of peak.

II.B. INJECTABLE EXAMPLES

There are a variety of reasons why the market for injectable products is different than that for oral dosage forms. Manufacturing of oral forms is typically simpler and less costly and many other conditions often dictate that generic competition is less intense following LOE than it is for oral dosage forms. Despite these differences, we find clear patent cliff patterns in the life cycles of injectable oncology products, and offer two such examples below.

II.B.1. DOCETAXEL

Docetaxel is used in chemotherapy to treat several types of cancer (including breast, lung, prostate, stomach, and head/neck cancer). The product is often administered in combination with other products and works by slowing the growth of cancer cells.

As indicated in Figure 3, Docetaxel sales were observed for nine full years before LOE. During this period sales grew at a highly variable rate, averaging about 8% per year on average. Measured sales peaked two quarters before LOE at just over \$325 million per quarter. At the time it lost exclusivity, quarterly sales had fallen to just over \$286 million. Following LOE, it lost sales at a more gradual rate than either of the two oral products discussed above, but the reduction was substantial. Five years following LOE, sales were approximately 13% of sales just prior to LOE, and just under 12% of the overall peak sales.

Figure 3—Docetaxel



Docetaxel	1st Observation	LOE	# Years from 1st Obs to LOE	Annual Growth Rate to LOE	1 Yr after LOE	2 Yrs after LOE	5 Yrs after LOE
Quarter	2001 Q4	2010 Q4	9	8.1%			
Sales (\$000)	\$138,782	\$286,633			\$159,644	\$103,780	\$37,816
% of LOE Sales					55.7%	36.2%	13.2%

*Note: these data are for 4Q 2015, one quarter short of 5 years following LOE.

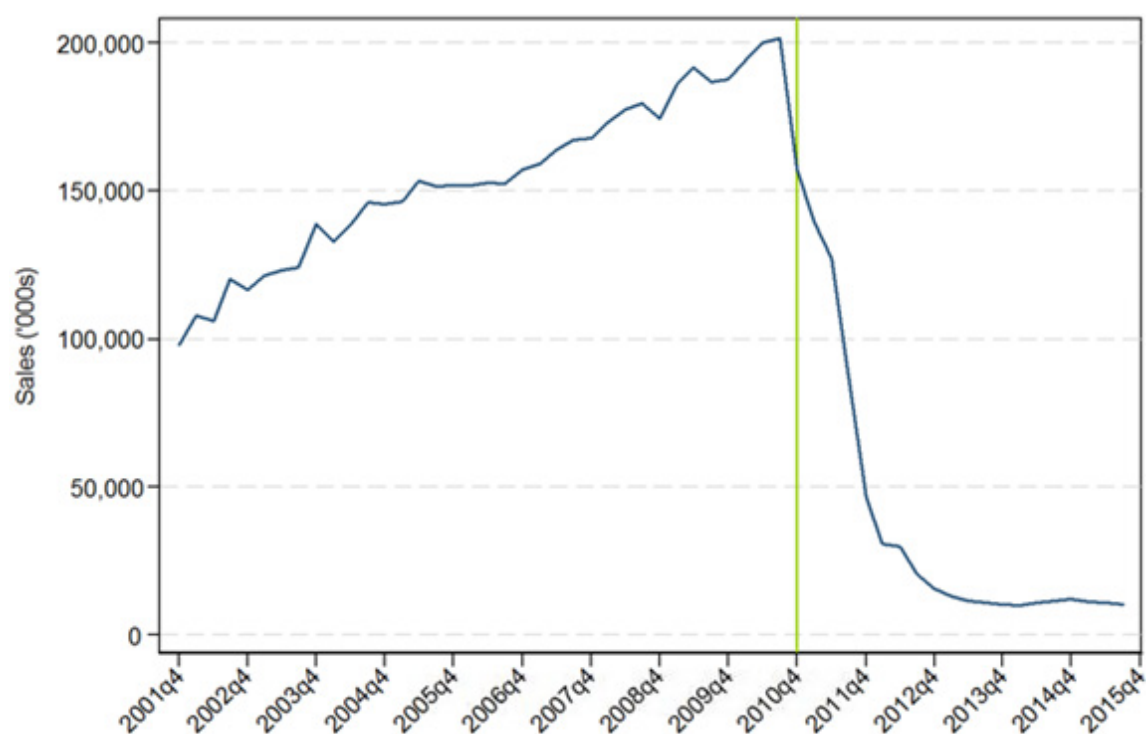
Source: Quintiles IMS Midas Data

II.B.2. GEMCITABINE

The final example in this set is Gemcitabine, which is also a form of chemotherapy used either alone or in combination with other products. It is also used to treat several different cancer types and works by retarding cell growth.

As illustrated in Figure 4, Gemcitabine exhibited fairly steady annual growth until reaching peak sales of nearly \$200 million per quarter in the quarter before LOE. During the quarter it lost exclusivity, sales had already fallen from their peak level to about \$158 million. Gemcitabine exhibited a much steeper fall in sales following LOE than did Docetaxel, with a pattern more similar to that observed for the oral product examples. By the end of our data (24 quarters following LOE), sales had fallen to 6.5% of sales at LOE and 5.1% of peak sales from the prior quarter. Sales had fallen to less than 10% of peak within two years after LOE.

Figure 4—Gemcitabine



Gemcitabine	1st Observation	LOE	# Years from 1st Obs to LOE	Annual Growth Rate to LOE	1 Yr after LOE	2 Yrs after LOE	5 Yrs after LOE
Quarter	2001 Q4	2010 Q4	9	5.3%			
Sales (\$000)	\$ 97,955	\$157,826			\$ 46,517	\$ 15,628	\$10,254
% of LOE Sales					29.5%	9.9%	6.5%

*Note: these data are for 4Q 2015, one quarter short of 5 years following LOE.

Source: Quintiles IMS Midas Data

III. POLICY IMPLICATIONS

Sales of new oncology products do not simply rise over time. They exhibit a life cycle characterized by changing sales over time. To be sure, not all products follow the regular patterns we have seen in these four examples. Certain products exhibit substantial swings over time, as changes in medical practice lead to changes in product utilization. Sometimes this happens prior to patent expiration so that LOE has little apparent effect on already low levels of sales. Other products exhibit different patterns.

Looking more broadly at oncology product sales patterns in our data, the general pattern exemplified here occurs more often than not. Aggregating sales patterns across products yields a clear patent cliff for both oral and injectable oncology drugs.³ This indicates that oncology products introduced in the future are highly likely to follow similar patterns. As patents expire and generic entry occurs, future expenditures on oncology therapies will be dampened, often by extremely large amounts. As policy makers, and others consider the future course of policies that will affect incentives for pharmaceutical innovation, it is important to bear these effects in mind.

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