



ESRI Research Note

*The Effect on Major National Accounting
Aggregates of the Ending of Pharmaceutical
Patents*

John FitzGerald

The Effect on Major National Accounting Aggregates of the Ending of Pharmaceutical Patents

John FitzGerald*

Over the last couple of years a number of drugs produced by the pharmaceutical sector in Ireland have fallen out of patent. This change in patent status has had a big effect on the value of gross output in the sector and, because of the importance of the sector, these changes have impacted on key economic aggregates. The purpose of this note is to explain how these changes impact on the national accounts.

To simplify the exposition we first concentrate on the effects of the loss of patent on the profits of the pharmaceutical sector and how this loss is treated in the national accounts. In our conclusions we briefly consider how the loss of patent may result in a loss of employment and related real value added in Ireland.¹

The fastest growing sector in Irish manufacturing in recent decades has been pharmaceuticals. Many of the top firms in the industry have located plants in Ireland, providing a significant share of world output of particular drugs from these plants. These pharmaceutical firms have been attracted to Ireland for a number of reasons: the low corporation tax rate; the availability of specialist skilled labour; serviced sites and a suitable regulatory regime. Many of the drugs being produced in the Irish plants have been developed relatively recently and are covered by patents. The duration of the patents ensures that the firms can, over time, recover the huge cost of developing modern pharmaceuticals.

The patents are for limited periods and, once they run out, it is open to other firms anywhere in the world to produce generic equivalents of the drugs previously covered by patent². Even without the entry of generic equivalents into the market, the ending of patent cover means that the firm's profits from

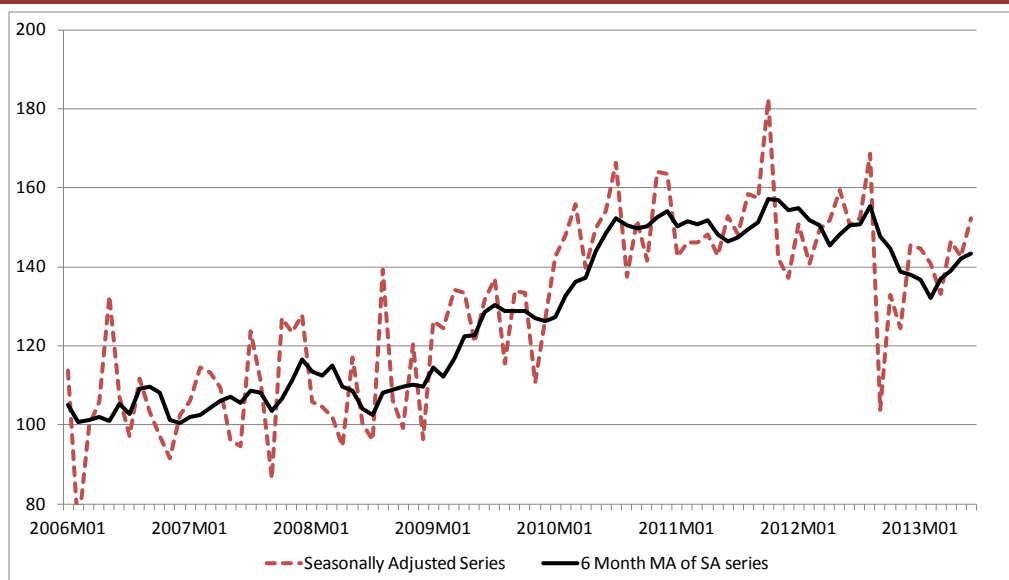
¹ Because the wage bill is under 5 per cent of the turnover in the sector, big changes in the turnover of the sector, and hence in profits of the sector, can have a much bigger effect on national accounts aggregates than changes in the wage bill.

² The patents may run out at different dates in different jurisdictions. This may mean that the effects of the ending of a patent are spread over a number of quarters, or even years.

producing and selling the drugs are likely to fall. In particular, the owners of the original patent may drop the price of the pharmaceuticals to discourage market entry by suppliers of generic equivalents. If the capital cost of establishing production of a particular generic drug is high (including the cost of getting US Food and Drug Administration (FDA) approval), then the owner of the existing plant can discourage entry by dropping the price to a level that would make it uneconomic for a new entrant.

While the patent lasts the profits for the owner of the patent are very high. (Over the life time of the drug, when the cost of research and development is included, the true economic profits will be substantially lower than the accumulated profits from actually manufacturing the drug – the cost of manufacture is small relative to the R&D costs). The practise with most of these pharmaceutical firms is that the drugs are sold from Ireland and the profit – the sale price less the short-run cost of production - arises in Ireland. However, the firms also pay very substantial royalties to their parent company for the right to produce the drug³. To the extent that such royalties are paid abroad the profits in Ireland are reduced and, hence, the taxes arising in Ireland are also reduced. The outflow of royalties also reduces the value added arising in Ireland. These royalty payments are treated as services imports in the national accounts and the residual profits due to the foreign multinational parent are treated as profit repatriations, part of net factor income in the national accounts.

FIGURE 1 Real Output of Pharmaceuticals (NACE21), Seasonally Adjusted



Source: Central Statistics Office, *Industrial Production and Turnover Index*

³ Of course the parent company may choose to receive the royalties in a jurisdiction other than where it has its headquarters or where the research was actually undertaken.

It has been known for some considerable time that patents on a number of very important and profitable drugs would run out in this decade.⁴ The effect of key patents running out is that the value of output of the firm will fall by a very significant amount, even if the firm continues to produce the same chemical compound after the patent expires. Given the importance of the pharmaceutical sector to Ireland, such changes may well affect macro-economic aggregates in a noticeable fashion.

Figure 1 shows both the raw seasonally adjusted series for the volume of output of the Pharmaceuticals sector (NACE 21) and a 6 month moving average of that series. As can be seen from the Figure, the monthly series shows a lot of noise but it is useful in identifying where significant changes in trend may have occurred. These data suggest significant falls in output at the end of 2011 and in the late summer of 2012.⁵ This was almost certainly primarily because a drug (or drugs) dropped out of patent around the time of the change in trend.

The smoothed 6 month moving average series shows a very rapid rise in the volume of output from 2009 to 2010. However, the pattern of growth changed towards the end of 2011. The smoothed series falls from then until the late spring of 2012. There was some further growth in output until August 2012 when the trend changed again resulting in another step change downwards in output. This shows up in Figure 1 as a marked change in direction in the series for the 6 month moving average of output from the autumn of 2012 until the spring of 2013. The smoothed series reverted to growth from March 2013 through to June.

The pattern of change shown by the series suggests two discrete changes, probably due to patent status changes, leading to once off declines in the value of sales and, hence, of output. However, these discrete downward adjustments in sales in those months are superimposed on a tendency for output elsewhere in the sector to rise in the absence of the expiry of patents.

While there are no published data on the actual magnitude of the effect of the ending of patents on the value and volume of the gross output (turnover) of the sector, a possible crude estimate of the magnitude of the effect can be derived on certain very restrictive assumptions. In June 2013 the 6 month moving average

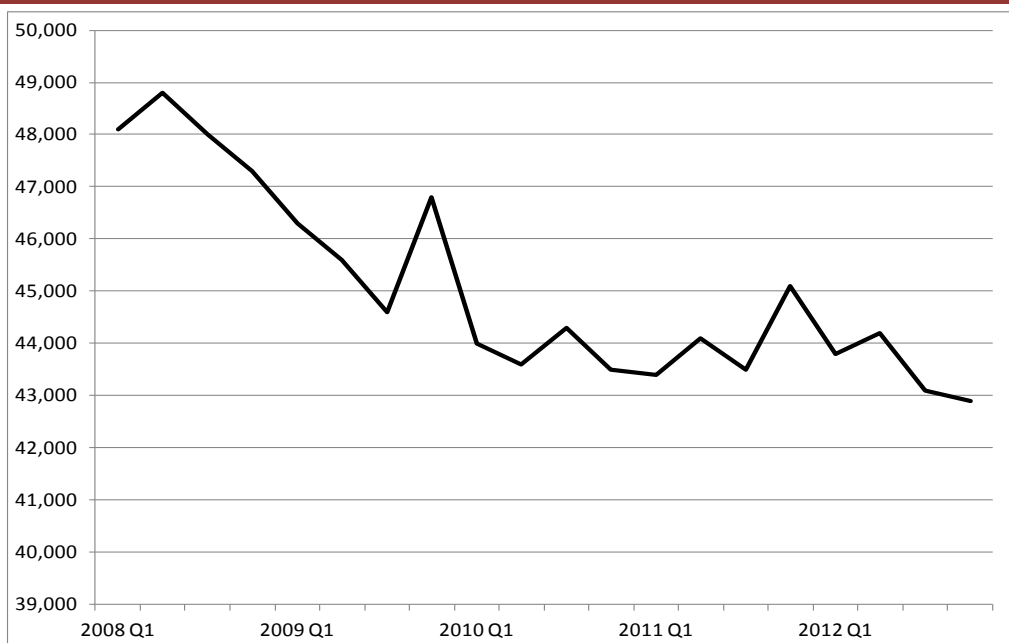
⁴ An example of such a drug is Lipitor. The patent for Lipitor, produced by Pfizer, ran out in the US in 2011 and in Europe in 2012. According to Pfizer's annual report, sales revenue from the drug worldwide fell in 2012 by \$5.6 billion. Ireland was a major site for the production of that drug.

⁵ These changes roughly coincide with the expiration dates for the patent for Lipitor in the US and in Europe. However, quite a number of other drugs have also fallen out of patent over the last two years.

of the index of the volume of gross output in the sector was down 8 per cent on its peak level (in 2012). If all of the fall in output were due to the loss of patents this would provide a crude estimate of the effect of the change. However, to the extent that there was a trend increase in output of drugs not covered by the patent status change, this number would underestimate the effects of the drugs dropping out of patent. On the other hand, if the EU recession was contributing to a fall in output, this estimate could exaggerate the effects of the patent status changes. On balance, because of the apparent underlying growth in the series discussed above, this estimate of the effect on the volume of output is likely to be conservative. In any event, this number should be considered as being purely illustrative in nature.

Figure 2 shows the path of employment in the broad sector of chemicals and pharmaceuticals (NACE sectors 20 and 21). While there was a substantial drop in the period to 2010, employment flattened out thereafter. However, there was some further fall in employment in the last two quarters of 2012 coinciding with the likely ending of patents, suggesting a real fall in output however it is measured. As discussed later, this fall in output, because it affected employment, would have also affected the volume of value added in the sector. However, compared to the changes in value arising from the loss of profits / royalties, the effect of the change in the wage bill on the volume of value added (and hence of GDP and GNP) would have been more limited. To simplify the exposition we concentrate first on the potential effects of the loss of patent status on profits and royalties and return at the end of this note to the effect on the wage bill and value added.

FIGURE 2 Employment in Chemicals and Pharmaceuticals



Source: Central Statistics Office, *Census of Industrial Production*

Taking the *Census of Industrial Production* figure for the turnover of the sector in 2010, projecting it forward to 2011 using the turnover index, this would suggest gross output for the sector in 2011 of around €38 billion. This would mean that an 8 per cent fall in output would amount to around a €3 billion loss of revenue. This would also amount to a fall in merchandise exports of around 3.5 per cent.

One would normally expect that the direct effect of the changes in the profitability of foreign owned drug companies on Irish national income would be quite limited. The multinational owner of the plant would receive lower profits corresponding to lower sales revenue and one would expect that the net effect on the volume of Irish output would be zero. However, because of national accounting conventions, it actually has an appreciable effect on a number of the components of national income, while probably leaving real GNP largely unchanged.

The first item that it affects is the volume of gross output in the industrial sector, as measured by the output volume index. This is due to the way changes in patent status are treated in calculating the volume index. For national accounting purposes the drug covered by the patent is treated as a different product from the equivalent generic drug, which in all other respects is similar to the patented drug. Thus, when a drug falls out of patent but the firm continues to produce the same chemical compound without patent protection, it is treated as a different product. At the same time, as a result of the change in patent status, there is a dramatic fall in revenue from selling the drug in the month when the patent ends.

To calculate the volume of output the CSO takes the value of sales and deflates it by a suitable price index. This price index includes only drugs which were on sale both in the last month when the patent applied and in the first month when the patent had ended. Because the ending of the patent is treated as giving rise to a new drug, this drug (whether patented or generic) is excluded from the price index. Thus the price index does not change between the two months, while the value of sales of the specific drug, which loses its patent protection, falls dramatically. As a result, all of the fall in the value of sales due to the loss of patent protection is treated as a fall in the volume of production. While this may seem counterintuitive it is the standard national accounting practise.

The ultimate effects of this national accounting treatment on the key national accounts aggregates depends crucially on whether the fall in the company's revenue results in a fall in royalty payments or a fall in the profitability in the company in Ireland. While, in practise, some companies may not pay royalties

and earn profits in Ireland, it is simpler to consider the two approaches separately. Set out below are illustrative examples of how these two eventualities are treated in the national accounts. In each case the numbers used are purely illustrative.

Changes in Royalty Payments

Table 1 uses these illustrative numbers to show how a fall in revenue of €3 billion would be treated in the national accounts in the case where all of the loss of revenue results in a fall in imports of royalties (payments abroad of royalties). In this case the value of gross output would fall by the €3 billion as would the value of exports. However, the firm would no longer pay royalties or licenses to the parent firm for the patent. The result would be a fall in imports of royalties of €3 billion and a corresponding fall in inputs (of royalties) used by the firm. The net result of these transactions would be to leave GVA in the sector unchanged and also to leave GDP and GNP unchanged.

TABLE 1 Illustrative National Accounts Treatment of ending of patent:
Fall in Import of Royalties, €millions, current prices

Output				Expenditure			
	Before	After	Change		Before	After	Change
Gross output	38,000	35,000	-3,000	Exports	36,000	33,000	-3,000
Royalties (services imports)			-3,000	Imports	22,000	19,000	-3,000
GVA	14,000	14,000	0				
Wages	1,300	1,300	0				
Profits	12,700	12,700	0				
Corporation tax	1,588	1,588	0				
Profits after tax	11,113	11,113	0				
GDP	14,000	14,000	0	GDP	14,000	14,000	0
Factor Income	0	0		Factor Income	0	0	
GNP	14,000	14,000	0	GNP	14,000	14,000	0

In real terms there would be a corresponding fall in the volume of gross output and of exports. This would be exactly matched by a fall in the volume of imports of royalties. This would mean that the deflator for exports would change consistent with the change in the deflator for output. Similarly the deflator for services imports of royalties, whether used as an import or classified as an input, would change to ensure that the volume change in imports (in € billion) was identical to the volume change in exports. This would mean that, to ensure consistency, the volume of GVA in the sector would be derived using what is referred to as the double deflation method, rather than by applying the same deflator that is used for gross output. This means that the deflator applied to the inputs (of royalties) would be different from the implied deflator for value added.

The result would be that all of the fall in the volume of gross output would be reflected in the fall in the volume of imported inputs, with the result that there would be no change in the volume of GVA (or in its deflator).

This treatment would mean that there would be large visible changes in the national accounts and other published data for gross output and also for exports and imports, but there would be no effect on GDP or GNP. This seems sensible where the volume of the physical output of the pharmaceutical sector was unchanged and the only change was in the profitability of the parent firm.

Changes in Profits

An alternative possible treatment would be that the firms involved take the effects of the loss of patent as a reduction in their profits earned in Ireland. This is illustrated in Table 2. In this case the value of gross output and exports would also fall by €3 billion. However, in this case the loss of revenue would not result in a fall in royalties paid as imports of services (or a fall in inputs). Instead the value of GVA arising in the sector would also fall by €3 billion. In turn, with the wage bill unchanged, the reduction in profits would also amount to €3 billion. To the extent that these profits were taxable in Ireland the fall in profits would result in a fall in domestic corporation tax revenue. Here it is assumed for illustrative purposes that all of the reduction in profits was taxable at the 12.5 per cent rate so that tax revenue would fall by €0.375 billion.

TABLE 2 Illustrative National Accounts Treatment of ending of patent:
Fall in Irish Profits, €millions, current prices

Output				Expenditure			
	Before	After	Change		Before	After	Change
Gross output	38,000	35,000	-3,000	Exports	36,000	33,000	-3,000
Royalties (services imports)			0	Imports	22,000	22,000	0
GVA (Gross Value Added)	14,000	11,000	-3,000				
Wages	1,300	1,300	0				
Profits	12,700	9,700	-3,000				
Corporation tax	1,588	1,213	-375				
Profits after tax	11,113	8,488	-2,625				
GDP	14,000	11,000	-3,000	GDP	14,000	11,000	-3,000
Factor Income	0	0	-2,625	Factor Income		-2,625	-2,625
GNP	14,000	13,625	-375	GNP	14,000	13,625	-375

As discussed above, the reduction in GDP (GVA arising in the sector) would be €3 billion. However, unlike the earlier case, the profits accruing to the foreign owner of the firms (Factor Income paid abroad) would only fall by €2.625 billion, reflecting the fact that domestic taxes would also fall (in this illustrative case by

€0.375 billion). The net effect would be a substantial fall in GDP but only a small fall in GNP, equivalent to the loss of tax revenue. In volume terms the effects would be similar to the value effects shown above, assuming that the price deflators for all relevant items handle the ending of the patent in a consistent manner.

Possible Impact on National Accounts

These two examples show that, depending on which of these accounting models is adopted by the firms experiencing a loss of patents, it can make a big difference to the national accounts. Where the impact of the ending of patents is chiefly on royalty payments, there would be no effect on GDP but substantial effects on exports and imports; in the case where all the effect is on profits, there would be a similar large impact on exports but also, in this case, on the trade balance and on GDP in both value and volume. In the case where profits fall there could also be a small impact on GNP and the current account of the balance of payments (equivalent to the lost tax revenue).

Table 3 provides an estimate of the possible impact on key national accounts aggregates under the two different accounting treatments. As discussed above, in each case the fall in gross output as a result of the ending of the patents is assumed to be around 8% of the 2011 level of gross output. (As indicated earlier, this number is very crude and is used for illustrative purposes.) It is also likely that the effects of the changes would have been spread over 2012 and 2013. Hence the estimates shown in Table 3 are for the cumulative impact of the loss of patents.

TABLE 3 Possible Cumulative Impact on Key Economic Aggregates using Illustrative Numbers

	€ billion	Accounting Treatment	
		Royalties %	Irish Profits %
Merchandise exports	85.9	-3.5	-3.5
Exports	165.8	-1.8	-1.8
Imports	127.9	-2.4	0.0
GVA manufacturing	31.5	0.0	-9.7
GDP	158.7	0.0	-1.9
GNP	127.0	0.0	-0.3

Whichever treatment is used, the impact on merchandise exports would have been to reduce them in both volume and value by around 3.5 per cent. In the first six months of 2013 the volume index for merchandise exports has been substantially lower than in 2012.

The effect on imports depends on the way the companies treat the effects of the fall in revenue. In the case where royalty payments fall, the reduction in the value and volume of imports, while of the same absolute magnitude as the change in exports, would have been around 2.4 per cent. However, if all of the impact was on domestic profits then the impact on imports would have been zero.

In the case where companies just reduce their payment of royalties there would be no other effects on GVA, GDP or GNP. However, in the case where all of the fall in revenue shows up as a fall in profits in Ireland, the negative impact on GVA in manufacturing would be very large at around 9.7 per cent. This would result in a reduction in GDP of 1.9 per cent. While there would have been no impact on GNP in the case of a reduction in royalty payments there could be a small impact (-0.3 per cent) in this case as a result of a possible loss of tax revenue.

Whichever treatment is used by firms when accounting for the loss of patent income, the effects on real GNP are likely to be small. This correctly reflects the fact that nearly all of the direct cost of the loss of patent protection accrues to the foreign owners of the plants located in Ireland. This emphasises the importance of concentrating on the trend of GNP rather than the trend of GDP when trying to understand underlying developments in the Irish economy.⁶

To the extent that the loss of revenue from the ending of the patents is treated as a reduction in imports of royalties, as indicated above, it would mean that both GDP and GNP (value or volume) would be largely unaffected by the change in patents unless the plant closes. Instead, in the national accounts figures for 2012 and 2013 the main effect would be to reduce exports and imports by a similar absolute amount in value and volume. However, as discussed in this *Quarterly Economic Commentary*, the published Quarterly National Accounts for the first two quarters of 2013 are best reconciled with other labour market data for the same period if the ending of the patents has resulted in a substantial reduction in the profits of the companies recorded in Ireland rather than through a reduction in royalties.

Possible Permanent Impact on GNP

The longer term economic impact of the ending of the patents may be more substantial than the short-term impact. As shown here, whichever treatment is used the impact of a loss of sales revenue for a foreign firm should wash out of

⁶ However, account must be taken of the effect of the earnings of redomiciled PLCs. as discussed in the Spring 2012 QEC.

the national accounts, leaving Irish GNP largely unchanged. However, if employment is lost because a plant shuts down or if tax revenue falls there would be a real impact on GNP.

While the need to undertake major investment in physical plant and in obtaining permits in order to produce generic equivalents of what are very sophisticated drugs provides a substantial barrier to entry, in the longer term production of these generic drugs could move from Ireland to lower cost locations. In particular, if a company has suitable plants elsewhere where costs are lower, the production could be relocated by the company.

Already there have been announcements of closures and job losses in Ireland as a result of patents ending.⁷ These closures involve the movement of the manufacture of the out of patent drugs to locations outside Ireland. In this case there is a real impact on GNP and GDP amounting to the loss of the wage bill and any taxes paid in Ireland by the companies concerned. If the fall in employment in the last two quarters of 2012 is indicative of a movement of production of generics to other countries, this would have an impact on GVA in the pharmaceuticals sector and on GDP and GNP. However, the magnitude of the impact on aggregates such as exports would be much smaller than in the case of the reduction in profits because of the ending of the patent. This is because the wage bill in the sector is less than 5 per cent of the gross output of the sector in Ireland.

⁷ Pfizer have already announced the closure of a plant in Ireland and resulting job losses as a consequence of the loss of the Lipitor patent.