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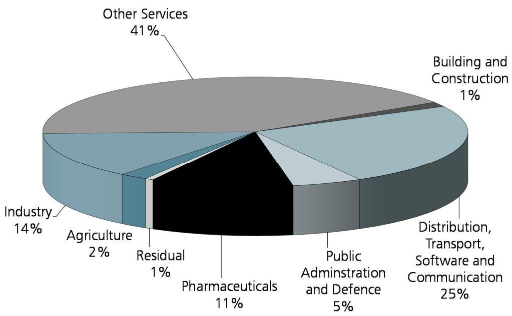
Research Report: Irish economy

Ireland and the Pharma Patent Cliff

Importance of pharma sector overstated

Pharmaceutical share of gross value added



Source: Central Statistics Office

Pharmaceutical patent cliff evident in industrial production and exports

- In September, pharmaceutical output fell by 35% and exports of organic chemicals declined by 33%.
- In 2011, pharmaceutical exports amounted to €50bn, 54% of total goods exports or 31% of nominal GDP.
- Temporary factors may partially explain the weak September figures, and the impact of the patent cliff on revenues may be more gradual than expected.

But importance of pharmaceutical sector wildly overstated

- Only around one-third of pharmaceutical export revenues count towards GDP. The value added of the pharmaceutical sector was €13.8bn in 2011 or just 8.7% of GDP.
- The large gap between revenue and value added reflects high import intensity, principally royalty and licence fee payments related to intellectual property.
- So sharp falls in pharmaceutical goods exports also show up in weaker services imports, limiting the impact on GDP.

Pharmaceutical sector employment and tax contribution low

- Just 22,500 were employed in the pharma sector in 2010.
- In 2010, €800m in corporation taxes came from pharma companies; if this figure halved, government revenues would fall by 0.25% of GDP.
- This is small compared with the planned budgetary adjustments of 2.1% in 2013 and 1.8% in 2014.
- The GNP impact of a reduction in pharma exports would most likely be negligible, but the gap with GDP (net factor payments) could narrow slightly.

Potential impact of patent cliff on Irish economy is wildly overstated

- **The September data have fuelled speculation that the pharmaceutical patent cliff could have a dramatic effect on the Irish economy, especially with further patents set to expire in 2013**

In September 2012, Irish output of basic pharmaceuticals fell 35%, new orders declined 26% and the value of exports of organic chemicals fell 32%. Nine of the top ten global manufacturing companies operate in Ireland. The September data have fuelled speculation that the pharmaceutical patent cliff could have a dramatic effect on the Irish economy, especially with further patents set to expire in 2013.

Typically, 80% of revenues tend to be lost when generic drugs come online. That said, patent expiration dates vary significantly across countries and pharmaceutical companies have a range of strategies to manage the impact on their revenues, including developing new products. So the effect on global revenues of the leading pharmaceutical companies may be more gradual than expected.

- **Any sharp decline in the value of Irish pharmaceutical exports will immediately lead to commensurate falls in services imports, limiting the impact on Irish GDP**

Pharmaceutical exports accounted for €50bn of revenues in 2011, close to one-third of Irish GDP. However, focusing on the export shares dramatically overstates the importance of the import-intensive pharmaceutical sector. In 2011, the pharmaceutical sector's value added contribution to Irish GDP was just €13.8bn. This means that approximately only one-third of export revenues from the pharmaceutical sector count towards Irish GDP. The remaining two-thirds of revenues are largely counted as imports of services, comprising licence and royalty fees by multinationals relating to intellectual property. So any sharp decline in the value of Irish pharmaceutical exports will immediately lead to commensurate falls in services imports, limiting the impact on Irish GDP.

The pharmaceutical sector accounts for just 1.2% of total Irish employment, well below its 8.7% share of GDP. In 2012, pharmaceutical sector foreign direct investments have remained strong – with job announcements of 1,000 so far this year. So the patent cliff has not had a detrimental impact on employment. The sector accounted for 20%, or €800m, of corporation tax revenues in 2010. However, if these tax receipts halved, government revenue would fall by 0.25% of GDP. While significant, this pales in comparison with planned budgetary adjustments of 2.1% of GDP in 2013, 1.8% in 2014 and 1.1% in 2015.

- **As the bulk of pharmaceutical sector value added is repatriated, the impact from any fall in pharmaceutical sector exports on GNP (which excludes net factor payments) will be very limited**

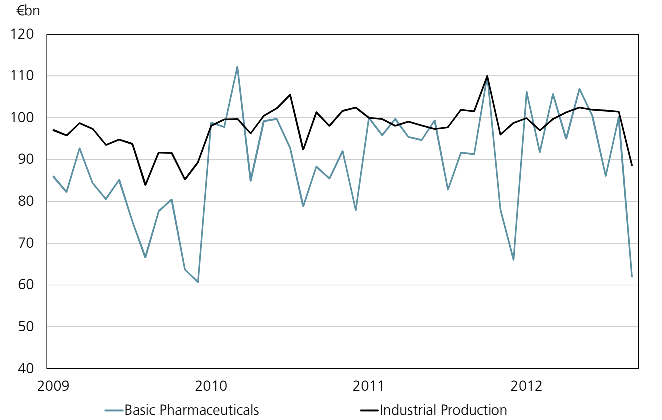
With labour productivity exceptionally high, and profits subject to the low 12.5% corporation tax rate, the bulk of pharmaceutical sector value added is repatriated. So the impact from any fall in pharmaceutical sector exports on GNP (which excludes net factor payments) will be very limited. A sharp decline in the €13.8bn of pharmaceutical sector value added could affect the gap between GDP and GNP but with little impact on the domestic economy. However, the burgeoning IT services sector could push up on multinational sector profits, serving to maintain the gap between GDP and GNP. Through 2010 and 2011, resilient export growth, largely relating to the multinational sector, has had little traction in helping Irish domestic demand to recover. Similarly, should pharmaceutical sector value added now temporarily contract, the impact on the real economy is likely to be negligible.

- Pharmaceutical sector output fell by 35% in September

Pharmaceutical output and exports drop sharply in September

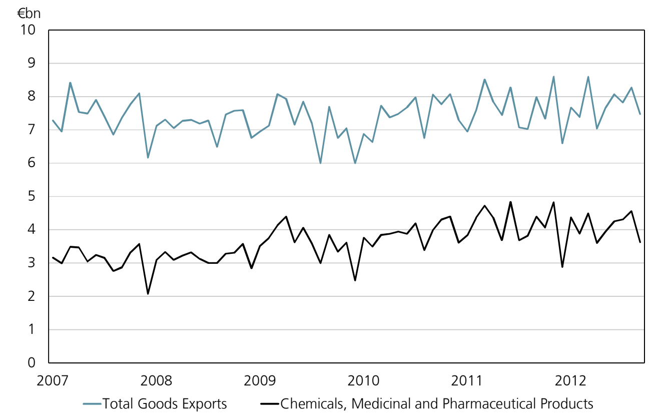
Basic pharmaceutical output fell 35.2% in September, and turnover by 25.4%, contributing to a 12.7% decline in aggregate industrial production. Basic pharmaceuticals have a weight close to 33% in overall output. New orders fell by 26%, so further declines in pharmaceutical sector output may be likely.

Figure 1: Irish industrial production



Source: Central Statistics Office

Figure 2: Irish goods export values



Source: Central Statistics Office

Irish goods exports fell from €8.3bn in August to €7.5bn in September, a 9.6% decline. This fall entirely reflected a 33% decline in organic chemicals exports and a 9.9% fall in medical and pharmaceutical products.

However, similar falls in pharmaceutical sector output and exports have occurred in the past. So we cannot rule out that temporary factors and volatility partially explain the weak September output and export figures. Of course, it may be that the impact of the pharmaceutical sector patent cliff on Irish output is now being felt.

- The revenue impact of the pharmaceutical patent cliff is expected to peak in 2012

The pharmaceutical patent cliff

The global pharmaceutical industry is currently managing its way through a highly volatile period, driven by a wave of patent expirations across most of its highest earning product base. The patent cliff began in earnest in 2009; its revenue impact is expected to peak in 2012 but will continue to be a material headwind until at least 2015.

Sector consultant EvaluatePharma estimates that in 2013 alone, patents will expire on drugs accounting for US revenues of some $29bn. This is equivalent to approximately 8% of US market revenues in 2011 (source: IMS Health).

- Exports of organic chemicals fell 33% in September
- 80% of revenues are expected to be lost to generics within 12 months of patent expiration

Generally, 80% of a product's revenues are expected to be lost to generic competitors in the first full year after patent expiry. However, there is significant variation across countries regarding regulatory frameworks, industrial policy, brand/generic distinctions and physician/pharmacy autonomy and incentives. Recent commentary on the patent cliff has focused on US patent expiration dates (Table 1). But the impact on global product revenues may often be gradual as the patent expirations vary (by years in some cases) between jurisdictions.

- **Patent expiration dates vary significantly across countries, and the pharmaceutical industry adopts a range of strategies to manage the impact on revenues**

Industry adopts many strategies to manage patent expirations – via intellectual property extensions, blocking litigation, product reformulations (that often carry new patent protection) and marketing partnerships with first-to-file generic companies. In certain instances, companies have negotiated with insurance providers to block pharmacies from dispensing generic products or offer insured patients a discount on the original brand. For example, the patent on the blockbuster biotech product Enbrel, almost exclusively produced in Ireland, has now been extended to 2016, although such extensions are exceptional.

Table 1: Estimated dates of patent expiration/generic market entry, US

Brand name	*2011 US retail sales*	*Date of patent expiration*
Singulair	**$4.4bn**	**August 2012**
Actos	**$2.8bn**	**August 2012**
Xopenex	$0.5bn	August 2012
Diovan	**$3.2bn**	**September 2012**
Detrol	$40m	September 2012
Revatio	$180m	September 2012
Comtan	$55m	September 2012
Lidoderm	**$1.1bn**	**November 2012**
Evoxac	$48m	December 2012
Atacand	$139m	December 2012
Duetact	$31m	December 2012
Actoplus Met	$426m	December 2012
Maxalt	**$594m**	**December 2012**
Propecia	$142m	January 2013
Tricor	**$1.1bn**	**January 2013**
Zometa	$5m	March 2013
Valcyte	$224m	March 2013
Zomig	$157m	May 2013
Visicol	$0.5m	May 2013
Fosamax	$30m	June 2013
Rilutek	$40m	June 2013
Temodar	$173m	August 2013
Cerezyme	$2m	August 2013
Niaspan	**$954m**	**September 2013**
Advicor	$42m	September 2013
AcipHex	**$858m**	**November 2013**
Vivelle-DOT	$233m	December 2013
Cymbalta	**$3.4bn**	**December 2013**

Source: Medohealth.com

- **Nine of the top ten pharmaceutical companies operate in Ireland**
- **Seven of the top ten 'blockbuster' drugs are produced in Ireland, with revenues now vulnerable to patent expiration**

The pharmaceutical sector in Ireland

According to the Industrial Development Authority (IDA), nine of the top ten global pharmaceutical companies are located in Ireland. In addition, seven of the top ten pharmaceutical 'blockbusters' drugs are produced in Ireland. The patents of many of these drugs have already expired or will do so in the near future (data for the US market are detailed in Table 1).

Pharmaceutical companies do not necessarily disclose which drugs are manufactured in Ireland. The IDA indicates that Pfizer, the world's largest pharmaceutical company, manufactures Lipitor, Viagra, Enbrel and Prevenar in Ireland. Similarly, the IDA indicates that GlaxoSmithKline's Irish operations manufacture some of the group's best-selling drugs.

We believe the following blockbuster products are produced in Ireland, with US patent expirations in parentheses: Lipitor (expired), Enbrel (January 2016), Actos (August 2012), Singulair (August 2012), Zyprexa (expired), Lexapro (expired), Diovan (September 2012), Tricor (January 2013) and Cymbalta (December 2013).

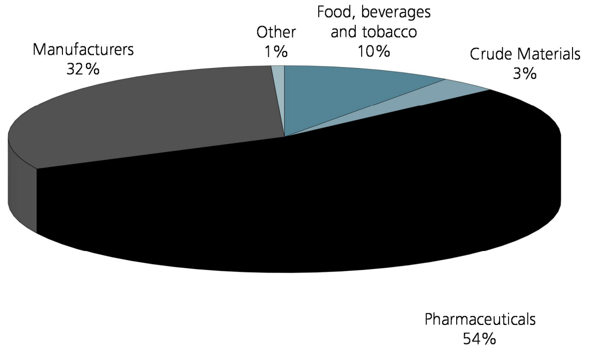
How important is the pharmaceutical sector to the Irish economy?

In 2011, exports of chemicals, medicinal and pharmaceutical products were €49.5bn, equivalent to 31% of nominal GDP. Figure 3 illustrates that these exports accounted for 54% of total goods exports.

- **The import-intensive pharmaceutical sector accounts for 8.7% of nominal GDP, well below the often quoted export shares**

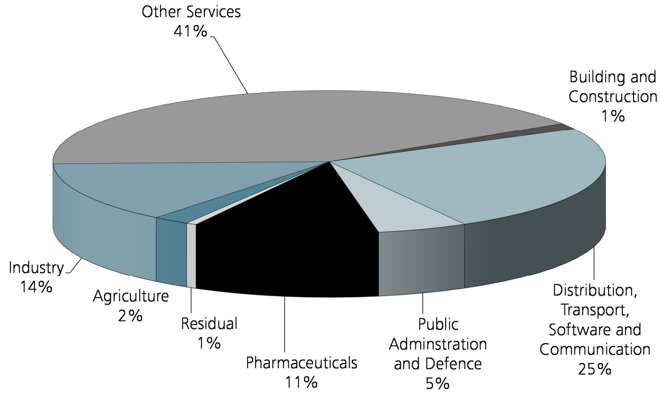
But the Irish pharmaceutical sector is highly import-intensive – mainly due to high costs relating to intellectual property. Irish pharmaceutical sector value added was just €13.8bn in 2011, or 8.7% of nominal GDP. In constant price terms, pharmaceutical value added was €15.5bn or 11% of GDP in 2011. Focusing on pharmaceuticals' share of exports therefore massively overstates the importance of the sector to the Irish economy.

Figure 3: Pharmaceutical share of goods exports



Source: Central Statistics Office

Figure 4: Pharmaceutical share of gross value added



Source: Central Statistics Office

- **Only one-third of pharmaceutical export revenues count towards GDP because of the corresponding costs relating to intellectual property**

Broadly speaking, only about one-third of pharmaceutical export revenues count towards Irish GDP. This is because royalties and licence fees made by the pharmaceutical sector are counted as a services import. In 2011, outward payments of royalties and licence fees were €29.2bn. These fees comprise (often intra-company) payments by the Irish branches of multinationals with respect to intellectual property. They are recorded as a services import and a cost (reducing value added) of the pharmaceutical sector.

Table 2: The pharmaceutical sector and Irish economy (€bn)

	2010	*2011*
Monthly physical trade in goods data		
Goods exports	89.7	91.2
Chemicals, medicinal and pharmaceutical products	46.7	49.5
National accounts, value added trade data		
Goods exports	82.6	84.9
Services exports	75.2	81.9
Total exports	157.8	166.8
Royalties/licence payments	28.3	29.2
Nominal GDP	156.5	158.9

Source: Central Statistics Office

- **Because the remaining revenues tend to be repatriated, the impact on GNP will be minimal**

Should Irish goods exports of pharmaceuticals continue to fall, there will be a corresponding decline in services imports, limiting the impact on nominal GDP. After accounting for high royalty fees and costs, the remaining pharmaceutical value added (€15.5bn in 2011) could be affected by the patent cliff, pushing down on GDP. However, because the profits of the Irish branches of multinationals are largely repatriated, the impact on GNP will be minimal.

Table 3: Gross value added at constant factor cost, constant market prices

	2010 €bn	*2011 €bn*	*2010 % total*	*2011 % total*
Agriculture forestry and fishing	3.2	3.0	2%	2%
Industry	34.1	35.2	24%	25%
Chemicals and pharmaceuticals	14.1	15.5	10%	11%
Computers and instrument engineering	2.9	2.7	2%	2%
Medicinal and dental instruments and supplies	2.4	2.5	2%	2%
Building and construction	2.4	2.0	2%	1%
Distribution, transport, software and communication	33.7	35.0	24%	25%
Public administration and defence	7.8	7.6	6%	5%
Other services	59.8	59.3	43%	41%
Total	140.5	143.0	100%	100%

Source: Central Statistics Office

The impact on GNP will be limited by the low labour intensity of the pharmaceutical sector. According to the Census of Industrial Production, there were just 22,542 persons engaged in the pharmaceutical sector in 2010 – down slightly from 23,656 in 2009[1].

[1] These are totals for NACE Rev 2 codes 20 and 21 relating to chemicals and chemical products and basic pharmaceutical products and preparations.

- **The pharmaceutical sector accounted for just 1.2% of employment in 2010**

So the pharmaceutical sector accounted for just 1.2% of total employment in 2010.

- **Pharmaceutical sector investments have continued in 2012 coupled with job announcements**

Recent data on pharmaceutical sector employment (albeit only available at a more aggregated level and including other sectors) provide no firm evidence of job cuts. Rather, the IDA has announced several significant foreign direct investments by multinational pharmaceutical companies. These include Allergan, Eli Lilly, Mylan and Amgen, with expected job increases of 1,000 associated with these investments.

Table 4: Irish employment (000s)

	2010	*2011*	*Q1 2012*
Total employment	1848	1810	1786
Industry	240	234	233
Modern sector	64.9	65.4	63.5
Chemicals, pharmaceutical products and preparations	22.5	n/a	n/a
Chemicals, pharmaceutical products and preparations; reproduction of recorded media, medical and dental instruments and supplies	42.1	42.3	43.8

Source: Central Statistics Office

- **Around €600-800m of corporation tax revenues could be at risk from the pharmaceutical patent cliff**

The Department of Finance has indicated that the pharmaceutical sector's contribution from 'the manufacture of chemicals, chemical products, and man-made fibres' to corporation tax was estimated at 12% in 2008, 17% in 2009 and 20% in 2010. This means that €600-800m of corporation tax revenues could be directly affected by the patent cliff. However, this is just 0.5% of nominal GDP.

- **Even if pharmaceutical sector receipts halved, this would only comprise 0.25% of nominal GDP**

If corporation tax receipts from the pharmaceutical sector halved, the impact on overall revenues would be close to 0.25% of nominal GDP. While perhaps significant in the context of one year's budget out-turn, this magnitude is immaterial relative to the planned fiscal consolidation of 2.1% of GDP in 2013, 1.8% in 2014 and 1.1% in 2015.

Table 5: Contribution of the pharmaceutical sector to corporation taxes (€bn)

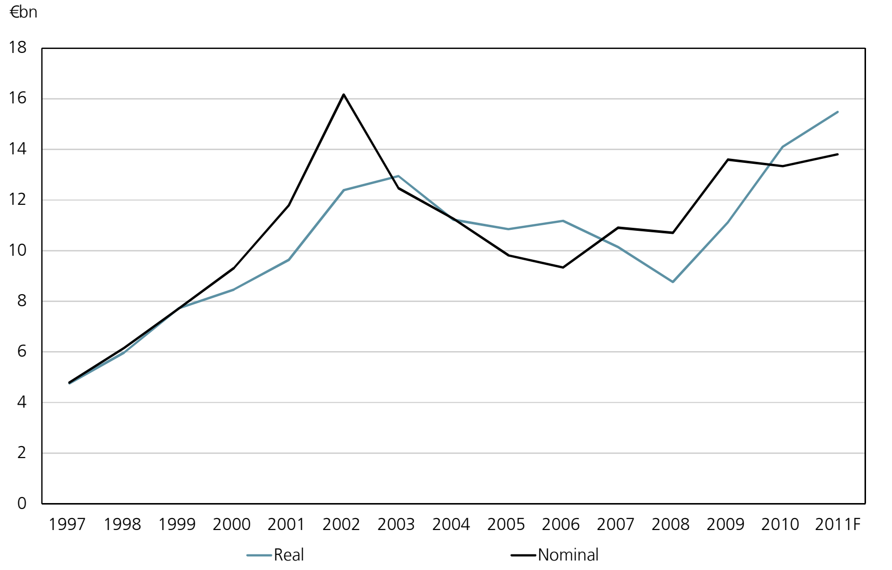
	2008	*2009*	*2010*
Total taxation	53.0	45.0	43.7
Corporation taxes	5.1	3.9	3.9
Contribution from pharmaceuticals	0.6	0.6	0.8
% of total	12%	17%	20%

Source: Department of Finance; Davy

Contribution of the pharmaceutical sector to Irish GDP has been very volatile through the last decade

Figure 5 illustrates that between 2002 and 2006 there was a sharp decline in pharmaceutical sector value added from €16bn to €9bn. However, any impact on nominal GDP was clearly masked by the booming domestic economy during this period and vice versa with respect to the rebound in pharmaceutical sector profits through 2006-2011. Indeed, through 2008-2010, employment in the sector has fallen slightly (from 23,656 to 22,542) despite a 24% rise in value added. Clearly, employment in the pharmaceutical sector is not closely related to value added.

Figure 5: Nominal and real pharmaceutical sector value added



Source: Central Statistics Office

In our most recent forecasts for the Irish economy, we noted that the resilience of the export sector has not translated into a material improvement in domestic demand. With import intensity and labour productivity of Ireland's export growth exceptionally high and dominated by the pharmaceutical and IT services sectors, there has been little traction onto domestic demand. Indeed, the recovery in pharmaceutical value added has been one factor pushing up the gap between GDP and GNP from 16% (€25.3bn) in 2008 to 25% in 2011 (€32bn).

Similarly, should pharmaceutical sector output now suffer temporarily due to the patent cliff, the impact on the domestic economy will most likely be negligible and the gap between nominal GDP and GNP may shrink somewhat. However, as in the 2000s, volatility in the pharmaceutical sector may be offset by developments elsewhere. For example, ongoing growth in services exports concentrated in the IT sector may serve to maintain the gap between GDP and GNP.

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