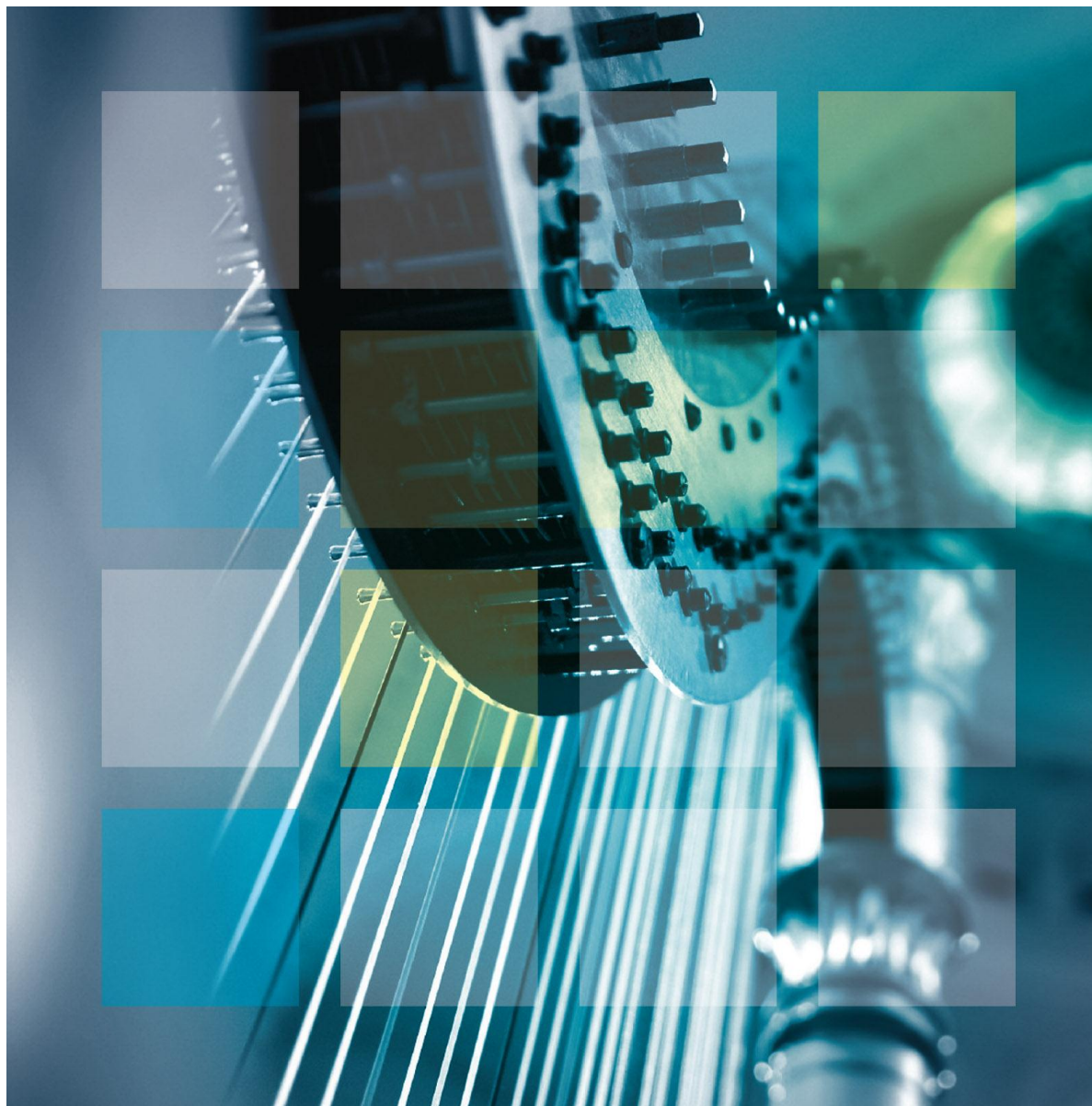


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THE IMPACT OF THE PATENT CLIFF ON PHARMA-CHEM OUTPUT IN IRELAND



An Roinn Airgeadais
Department of Finance



Abstract

Given the weight of the pharmaceutical sector in Irish GDP, this paper seeks to assess the impact of the current 'patent cliff' in the pharmaceutical sector on the Irish economy. Ireland has a well-established specialisation in pharma-chem production, with nine of the top ten multinational corporations located in Ireland. The sector accounts for approximately a quarter of total Irish exports though, due to its knowledge-intensive nature, its employment share and the labour income share in value add terms is relatively modest by comparison.

The clustering of a number of patented drugs going off patent in quick succession, including the global bestseller in 2011, which is assumed to be produced in a small number of locations including Ireland, is having an impact on pharma-chem output in Ireland. Both output and exports are down from their mid-2012 peaks, although the headline impact is likely to be offset to an (uncertain) extent by reduced imports of royalties.

Ireland is likely to continue to feel the impact of the patent cliff as drugs being produced in Ireland continue to come off patent. However, the magnitude is unlikely to be as great as has been felt in 2012 as drugs due to expire and are produced in some part in Ireland are of less value than those that have already come off patent to date. The impact on employment is unlikely to be as large as suggested by the fall in aggregate demand.

The patent cliff has been known about for a considerable length of time and the pharmaceutical industry has been planning for this event for a number of years through agreements with generic producers post-patent expiry, mergers and acquisitions, productivity improvements and a move towards the biopharmaceutical end. Of particular note, is the continued investment by the large multinationals in Ireland, which have experienced patent expiration, in the biopharmaceutical space. In terms of the biopharmaceutical sector, IDA figures suggest that €2 billion in capital expenditure is planned over the next three years, following €1 billion of investment over the past two to three years.

This paper sets out a number of simulations which use various export declines and import responses and suggests a net impact of a loss of 2 to 4 percentage points from GDP over a four-year horizon, depending on assumptions used. Corporation tax would probably reduce due to lower profitability in the sector. These simulations are illustrative only, and do not account for substitution on the supply or demand sides of the economy.

More generally, Ireland is a small open economy and has seen considerable shifts in the composition of economic activity over the years. The current growth in services exports points to the capacity for considerable change in the export mix over time.

The views expressed in this paper are those of the authors only and do not necessarily reflect the views of the Minister or the Department of Finance. The authors acknowledge all those that commented on the paper.

Shane Enright and Mary Dalton, Department of Finance



1. Introduction

Given the weight of the pharmaceutical sector in Irish GDP, this paper seeks to assess the impact of the current 'patent cliff' in the pharmaceutical sector on the Irish economy. The paper begins with an overview of the sector both at a global and national level. The second section examines recent trends in export and output data to assess the formal impact of the patent cliff on economic and fiscal activity. The third section models the potential impact on GDP, with the final section taking a more qualitative approach to the future of the sector in Ireland.

2. Overview

a. Global pharmaceutical sector

The global pharmaceutical sector was valued at just under €750 billion¹ in 2011. The sector is highly concentrated, with the top ten companies in the world accounting for a third of global sales. Currently, North America and Europe account for almost two thirds of the global market².

The sector is facing a number of challenges at present relating to over-capacity, significant R&D costs, a weak pipeline of new products and downward pricing pressures from healthcare payers³. However, the focus of this paper is the impact of the expiration of patents in the sector in Ireland.

Figure 1 shows the lifecycle of an innovative medicine. For every 5,000 to 10,000 compounds that enter the R&D pipeline, the pharmaceutical industry reports that only one receives approval⁴. To compensate for the high costs involved in researching and developing a new drug, companies may file a patent which protects them from competition for a specified period of time. Of the typical 20 year patent period – firms typically only get 8-10 years of effective patent protection before facing generic competition⁵. The average cost of researching and developing a new medicine is claimed by the pharmaceutical industry to be approximately €1.4 billion⁶. It is estimated that only three out of ten marketed medicines produce revenues that match or exceed R&D costs before they lose patent protection⁷.

¹ All figures converted from US prices using average exchange rate for 2012 of €1 = \$1.29

² IMS Health

<http://www.imshealth.com/portal/site/imshealth/menuitem.18c196991f79283fddc0ddc01ad8c22a/?vgnextoid=6521e590cb4dc310VgnVCM100000a48d2ca2RCRD&vgnnextfmt=default>

³ Forfás (2013) Making it in Ireland: Manufacturing 2020

⁴ PhRMA (2007) Drug Discovery and Development: Understanding the R&D Process

⁵ Pharmaceutical Healthcare Facts and Figures 2012

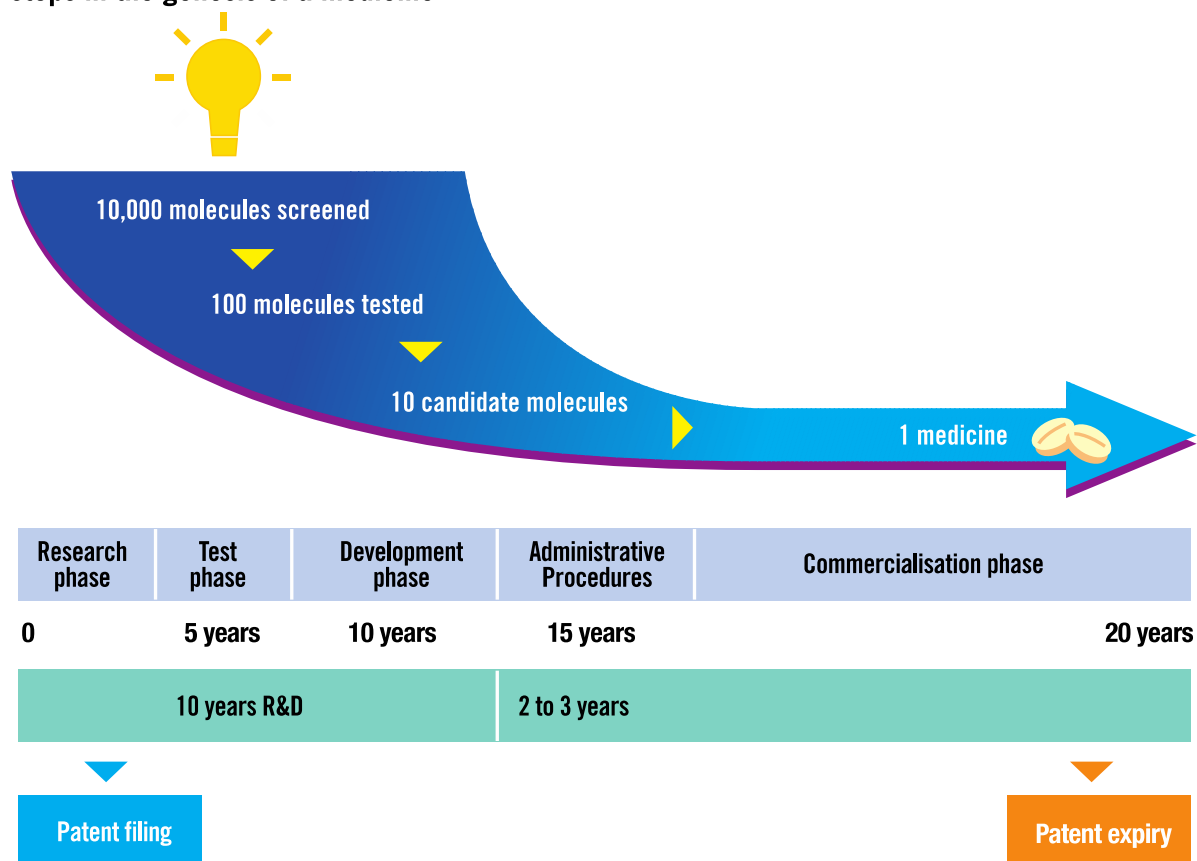
⁶ Association of the British Pharmaceutical Industry data (2012)

⁷ Pharmaceutical Healthcare Facts and Figures 2012



Figure 1. Lifecycle of an innovative medicine

**From concept to product:
steps in the genesis of a medicine**



Source: LEEM

What is known within the industry as a 'blockbuster' drug is a drug that generates more than a billion US dollars in revenue each year. Only a small number of drugs become blockbusters. Typically, companies are able to price well above the marginal cost of output due to patent protection. This is designed to allow companies to recoup the cost of research and development and in practice to cross-subsidise unsuccessful R&D. The current 'patent cliff' refers to a number of blockbuster drugs with about €200 billion in total global annual sales, which are set to go off patent between 2011 and 2016, the majority of which are concentrated up to 2013⁸. Taken as a percentage of global sales, the patent cliff impacts on about a quarter of the value of the sector.

⁸ EvaluatePharma <http://www.pharmaceutical-technology.com/features/featurethe-patent-cliff-rise-of-the-generics>



b. Pharmaceutical industry in Ireland

Up until the 1960s there was little or no pharmaceutical production in Ireland. This was altered significantly following the targeting of the fine chemicals industry, which included pharmaceuticals, by the IDA in the 1970s and the subsequent location of a number of foreign multinationals to Ireland⁹. The sector has continued to grow and in 2011 Ireland's share of global trade SITC¹⁰ codes 51 and 54 is particularly high. While the majority of these are involved in active pharmaceutical ingredients (API) and finished products in small molecules (chemical pharmaceuticals), Ireland has a strong and increasing capability in large molecules (biopharmaceuticals)¹¹. A number of factors have led to this growth:

- Demonstration effect - Ireland has built up a cluster of pharmaceutical companies over the past thirty years. The demonstration effect of a few successful early leaders is likely to have contributed to this growth, resulting in nine of the top ten global companies locating in Ireland.
- Comparative advantage - a study carried out by the Central Bank shows that Ireland has a high comparative advantage in predominantly foreign-owned sectors and principally in the broad chemicals sector¹².
- Track record - many foreign multinationals in the pharma sector located in Ireland 20 to 30 years ago. As a result, they have established a history of compliance with the regulatory agencies.
- A young highly-skilled workforce - 34 per cent of the population are under 25 years of age in 2011¹³. In addition, 47 per cent of those aged 25-34 years old have a tertiary education. This compares to an OECD average of 39 per cent for the same cohort in 2011¹⁴. The IMD World Competitiveness Yearbook 2012 ranks Ireland 1st in the world for availability of skilled labour, flexibility and adaptability of workforce and attitudes towards globalisation.
- Corporation tax rate - Ireland has a corporation tax rate on trading income of 12.5 per cent.

Ireland is home to nine out of the top ten global pharma/biopharma companies and manufactures in part or full six of the top ten blockbuster drugs¹⁵ coming off patent between 2011 and 2016¹⁶. This includes the bestselling drug in the world in 2011.

⁹ Van Egeraat C. and Curran, D. (2013) Spatial Concentration in the Irish Pharmaceutical Industry: The Role of Government Intervention and Agglomeration Economies, *Journal for Economic and Social Geography*, Volume 104, Issue 3, pp. 338-359

¹⁰ SITC stands for standard international trade classification. More details here:
<http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=28>

¹¹ Forfás (2013) Making it in Ireland: Manufacturing 2020

¹² Smyth (2005) 'Ireland's Revealed Comparative Advantage' in Central Bank Quarterly Bulletin 1, 2005

¹³ CSO

¹⁴ OECD (2013) Education at a Glance 2013: OECD indicators

¹⁵ Based on global sales in 2011

¹⁶ IDA Ireland

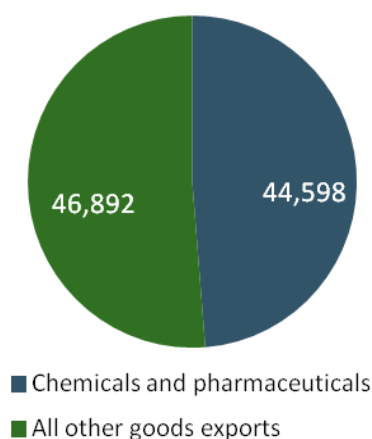


3. Recent trends in the Irish pharmaceutical sector

a. Impact on economic activity

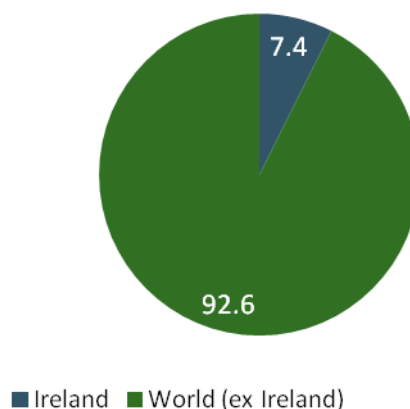
The share of pharma-chem in the Irish economy can be looked at on an expenditure¹⁷ basis and an output¹⁸ basis. The expenditure measure looks at exports of pharma-chem products, in particular organic chemicals (SITC category 51) and medical and pharmaceutical products (SITC category 54) which are reported on monthly by the CSO in the merchandise trade release. The sum of these two exporting sectors was just over €44 billion in 2012, about 27 per cent of GDP, and just under half of all merchandise exports (Figure 2) and just over €6.5 billion of merchandise imports, about four per cent of GDP. Much of the import content in the pharma sector relates to service imports in the form of royalties and licences, expanded upon in a later section. Ireland's share of global trade SITC codes 51 and 54 is particularly high at over 7 per cent in 2011 (see Figure 3), given Ireland's share in global trade of under 1 per cent. Obviously, the net impact on GDP of these exports is reduced by any import content, a topic which will be considered in a further section.

Figure 2. Irish merchandise exports (2012)



Source: CSO

Figure 3. Irish share of global pharma-chem exports 2011



Source: UN

The other method for estimating the contribution of the sector is to look at the value added component using the output approach to estimating gross value added (GVA)¹⁹. The most recent data are for 2012, and show that gross value added in the pharmaceutical sector was about 12 per cent of economy-wide GVA²⁰.

¹⁷ GDP on an expenditure basis measures final expenditure on goods and services in the economy. Demand by foreign residents for Irish goods and services (exports) is added to domestic demand and demand by Irish residents for foreign goods and services (imports) is subtracted to calculate GDP. (Final domestic demand + exports – imports = GDP)

¹⁸ The output measure of GDP measures the output of the economy by sectors, subtracts intermediate consumption (domestic and imported) to get value added by sector. (Output - intermediate consumption – imports = value added).

¹⁹ Gross value added is conceptually similar to GDP but examines production on a sectoral level rather than final expenditure type. Gross value added excludes product taxes and subsidies, although these are largely irrelevant for the pharma-chem sector.

²⁰ http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2012/nie_2012.pdf see table 4



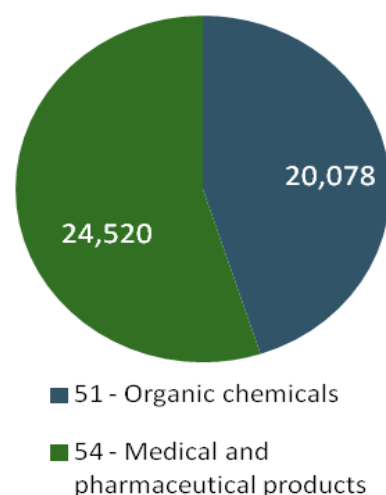
b. Exports

The tradable outputs of the pharma-chem sector include SITC²¹ categories 51 and 54, (see table 1 below)²². Broadly speaking, 51 consists of the active pharmaceutical ingredient (API) or bulk chemicals with 54 consisting of tableted or bottled (fill /finish) pharmaceuticals for final use²³. Both are produced in large volumes in Ireland with medical and pharmaceutical products (54) taking a slightly larger share (see below).

Table 1. Pharma products by SITC code

SITC Code	Title	Description	Value, (€m) 2012
51	Organic chemicals	Bulk chemicals (includes some non-pharma chemicals)	20,078
54	Medical and pharmaceutical products	Mainly tableted pharmaceuticals (includes some non-pharma products such gauze, etc	24,520

Figure 4. Exports of pharma by SITC code



Source: CSO External Trade Figures

Exports of pharma-chem products (using our definition of SITC categories 51 and 54 in value terms) grew solidly to almost 30 per cent of GDP in 2011. Since mid-2012, exports of both categories in value terms have been on the decline (Figure 5), although the pace of decline has slowed in the early months of 2013. The year-on-year fall in pharma-chem products is the largest sustained decline in recent years. It contrasts sharply with strong performance over the past half-decade or so, which included only a very slight contraction in 2008 when global trade was particularly weak. The weakness in pharma-chem exports has also been reflected in overall merchandise trade performance too. In real (volume) terms merchandise exports fell by 5.5 per cent year-on-year in the first half of 2013, leading to six successive quarters of year-on-year contraction.

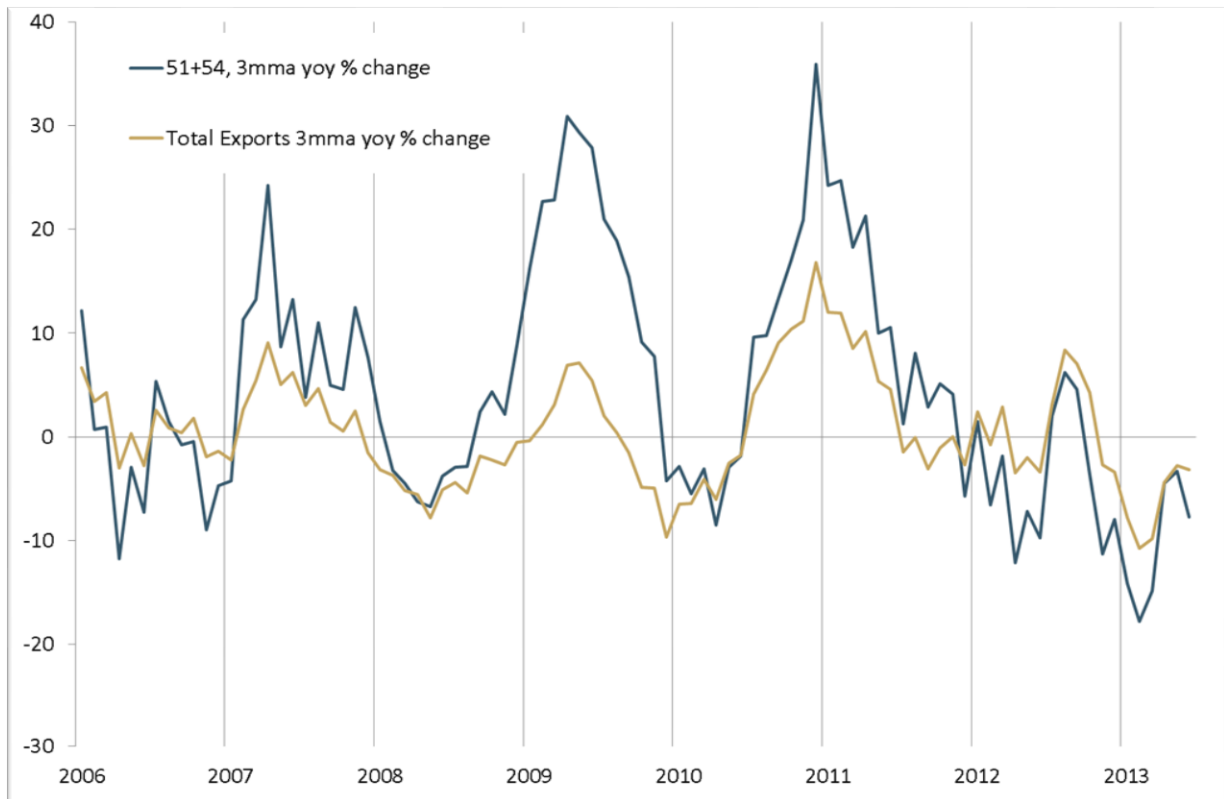
²¹ SITC stands for standard international trade classification (<http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=28>)

²² <http://www.cso.ie/en/releasesandpublications/externaltrade/>

²³ These categories contain some elements which are not strictly pharmaceutical products but they are sufficiently clear for high-frequency analysis.



Figure 5. Exports of pharmaceuticals and overall merchandise by value



Source: CSO, authors' calculations

Note: Data are presented in three-month moving average terms to smooth volatility

c. Industrial production and turnover

An alternative source for looking at the output of the pharma-chem sector is the CSO's industrial production and turnover series²⁴. Production is classified by NACE code²⁵ and the volume index measures physical output with the turnover index measuring value-based sales²⁶. Analysis focusses on NACE code 21 'basic pharmaceutical products and preparations'. Movement of the production and turnover series respectively can differ for two main reasons. One is that production can differ from turnover in a given month, with stock adjustments accounting for the difference. The second is that the turnover index takes into consideration price effects while the production index is volume only.

²⁴ For the latest release see here: <http://www.cso.ie/en/releasesandpublications/industry/>

²⁵ NACE is the French acronym for Statistical classification of economic activities in the European Community and more info can be found here: [http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Glossary:Statistical_classification_of_economic_activities_in_the_European_Community_\(NACE\)](http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Glossary:Statistical_classification_of_economic_activities_in_the_European_Community_(NACE))

²⁶ More background on the methodology can be found here: <http://www.cso.ie/en/surveysandmethodology/industry/cenindustrialproduction/>



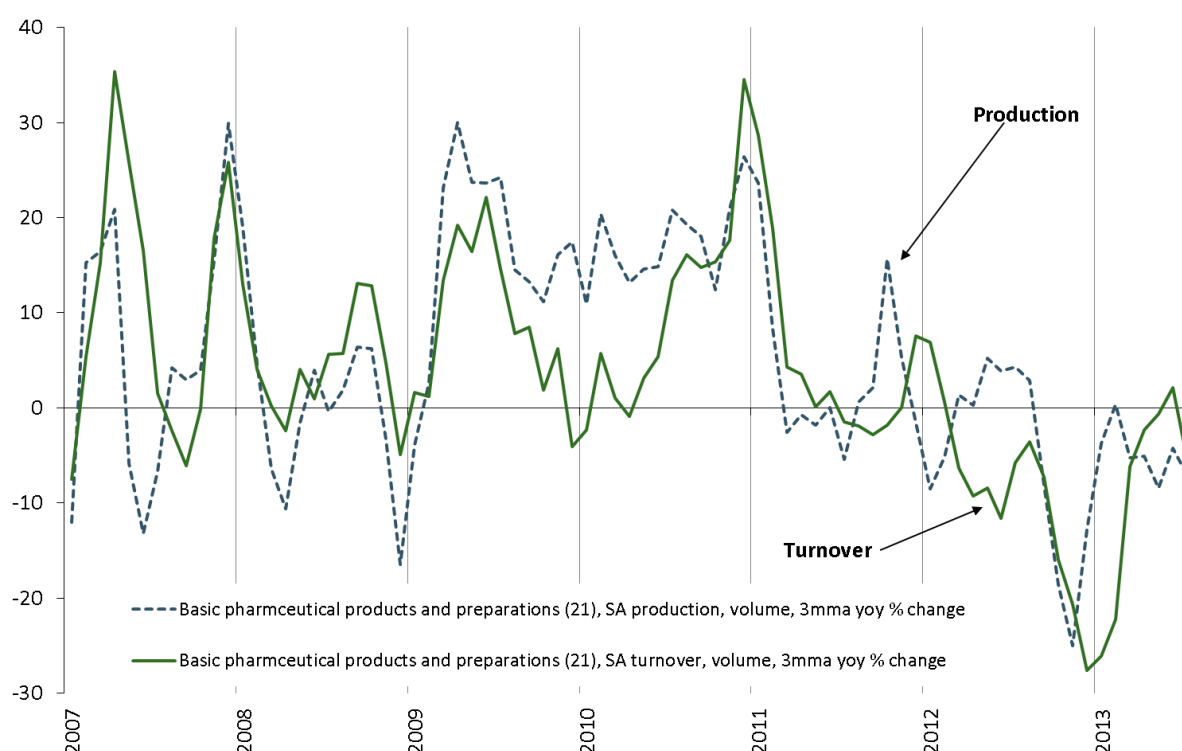
Table 2. Industrial production by NACE code

NACE Code	Title	Description	GVA, €m, 2005 ²⁷
21	Basic pharmaceutical products and preparations	Includes the majority of active ingredient and final outputs	10,081

Note: NACE code 20 chemicals and chemical products may contain some pharmaceutical content but is excluded from the analysis due to its size (8% of category 21) and as it may include other non pharma-related chemicals

Figure 6 shows the evolution of industrial production and turnover in level terms for NACE code 21 since 2007. The data are quite volatile despite smoothing by way of three-month moving average. Nonetheless the pattern is consistent with that of the export data. Production of pharmaceutical products peaked in the summer of 2012 and has fallen subsequently. There was some recovery in the early months of 2013 (in line with exports) but the highs of mid-2012 have not been recovered. On a three-month moving average basis production is down 14 per cent from peak. In recent months turnover (which measures value) has been weaker than production (which measures volume), which may be indicative of weakness on the price side in the post-patent environment. On a three-month moving average basis turnover is down 20 per cent from peak. To note, production of pharma-chem products which is not exported goes to the domestic Irish market. However the impact of domestic developments is essentially negligible given that over 90 per cent of production is destined for export.

Figure 6. Industrial production and turnover for NACE 21, 3mma, y-o-y change



Source: CSO, authors' calculations

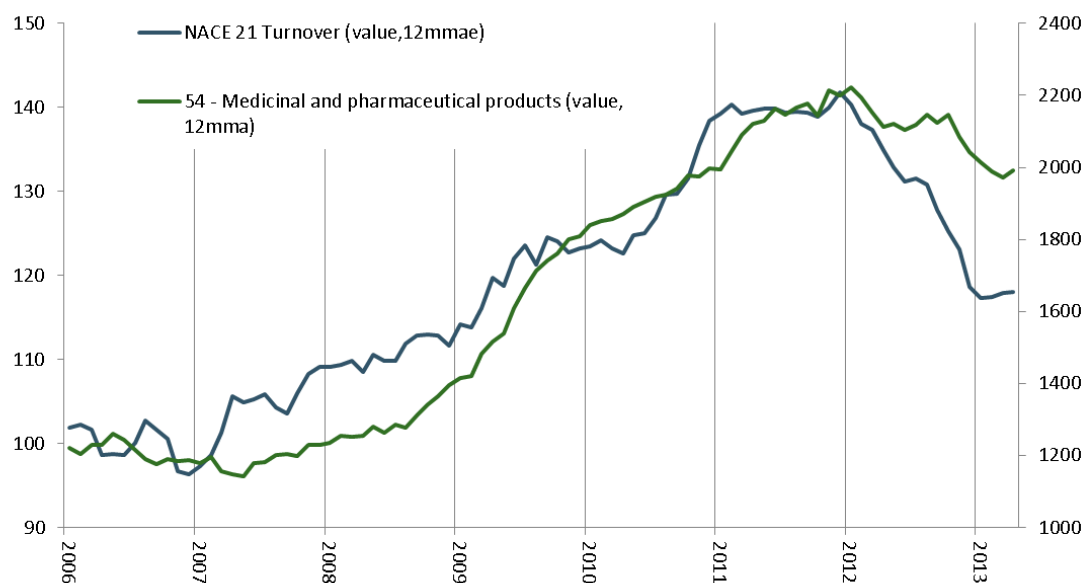
²⁷ The most recent GVA weights used are from 2005



d. Matching production and exports

Both production in and exports from the sector have shown similar dynamics in recent years. Since 2006 the trend in the level between turnover (by value) in industrial production (NACE 21) and exports (by value) of medical pharmaceutical products and preparations (SITC 54) has been broadly similar (Figure 7).

Figure 7. IP turnover (value) and NACE 54 (value) exports 2006-13



Source: CSO, authors' calculations

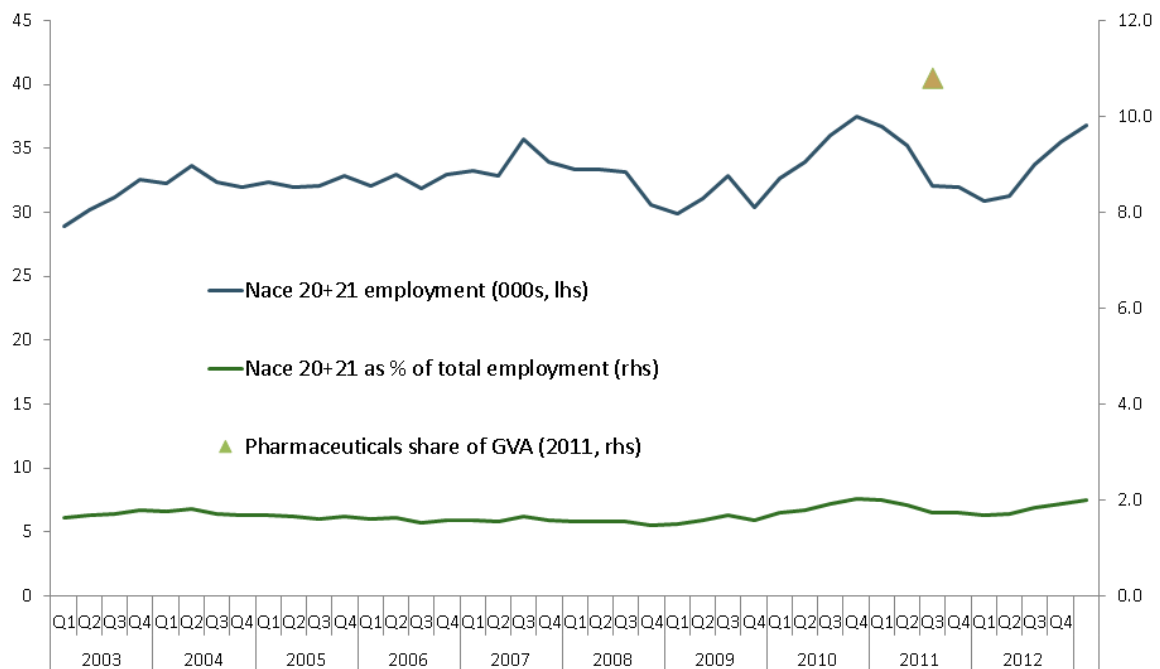
e. Labour market impact of pharma-chem sector

Direct employment in the pharma-chem sector is considerably lower than its share in value added or exports. Quarterly national household survey (QNHS) data on employment in NACE codes 20 and 21 showed an average of 36,800 employees in the sectors in early 2013 (Figure 8)²⁸. Both the absolute number and share have remained reasonably stable over the last decade or so and account for about 2 per cent of economy-wide employment. By comparison the share of pharma-chem in GVA is closer to 12 per cent. The very high GVA-per-worker numbers are more likely due to the highly profitable nature of production (explained later) than strong labour productivity *per se*.

²⁸ The CSO Census of Industrial Production suggests that 21,500 were employed in sectors 20 and 21 in 2011, considerably lower than the QNHS estimates. This may be due to both differences in survey definitions and sampling techniques.



Figure 8. Pharmaceutical employment and output



Source: CSO, authors' calculations

Data on numbers employed in agency-assisted firms²⁹ in the chemicals sector shows employment of 25,200 in 2012³⁰. This figure is up 1.3 per cent on the previous year. Employment in the sector is highly skilled with approximately half of those working in the sector having a third level qualification and a quarter of all PhD researchers in Irish industry employed in the sector. Consequently the average wage level is significantly higher in the chemicals sector compared to the manufacturing sector as a whole. 2011 figures show average payroll costs per employee of €73,000 in the chemicals sector versus €50,000 in the manufacturing sector as a whole³¹.

f. Geographical destination of exports

Pharmaceutical exports from Ireland are highly concentrated with North America and Europe accounting for approximately 85 per cent of exports. Exports of pharma-chem products by destination has shown a marked compositional shift since the start of 2012 however, with the share of exports destined for the US down considerably, possibly indicative of patent expiry. Overall, exports of pharmaceutical products and preparations (SITC code 54) fell 7 per cent in value terms in 2012, and are down 10 per cent year-on-year in the twelve months to July 2013. By contrast exports to the US fell by almost half in 2012, much greater than the aggregate fall, and are down a fifth in the twelve months to July. In compositional terms the falls were offset initially by growth to all other

²⁹ Agency assisted firms refers to all manufacturing and services companies supported by the enterprise development agencies of IDA Ireland, Enterprise Ireland, Shannon Development and Údarás na Gaeltachta,.

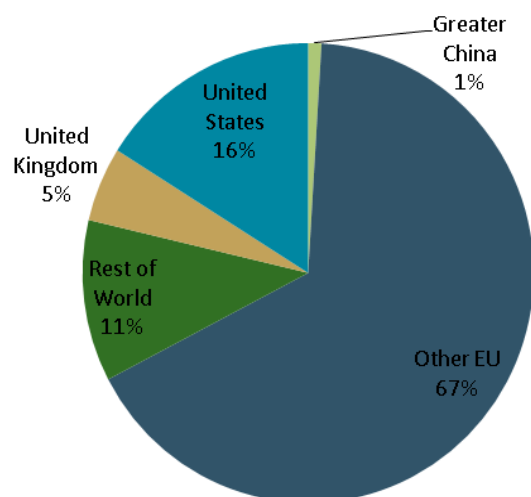
³⁰ Forfás (2013) Annual Employment Survey 2012

³¹ Forfás (2013) Annual Business Survey of Economic Impact 2011



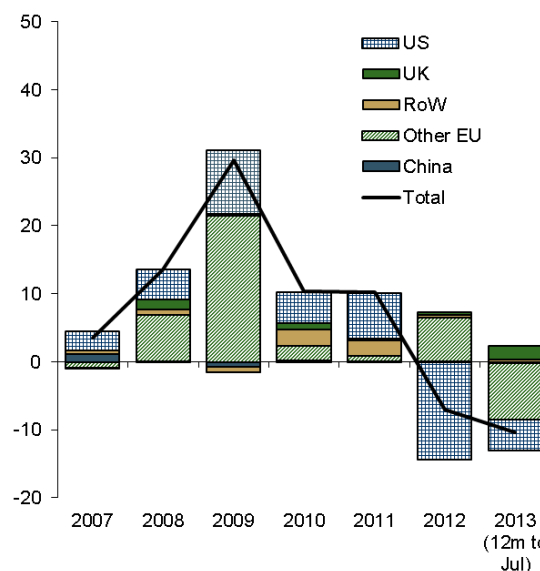
geographical areas, in particular EU excluding UK, although this is now falling too. Exports of organic chemicals (51) although not presented are not showing as pronounced a geographical trend.

Figure 9. Pharma-chem exports by destination (54), 2012



Source: CSO

Figure 10. Exports by destination (54), 12mma y-o-y growth rates and geographical contribution (in pp)



Source: CSO, authors' calculations

There are several potential explanations (not necessarily mutually exclusive) as to why this fall in exports to the US might be the case:

- Patents generally expire first in the US, and the decline may be a leading indicator of reduction in production for other geographical destinations.
- A contrasting explanation is that the primary destination after Ireland for some drugs can be trans-shipment hubs such as Belgium, and may not reflect changes in geographical demand but firm-specific changes in supply chain management.
- Finally, concentration in the sector is large and the fall-off in supply to the US may reflect product-specific production decisions.

g. Import share of pharma-chem sector

In calculating the net impact on macroeconomic aggregates of any pharma downturn it is essential to have an estimate of the import content of the sector as a whole. For this approach we examine the sector using the output approach, looking specifically at gross value added (GVA). GVA is calculated by taking the output of a sector and subtracting 'intermediate consumption', essentially everything that takes place before the production process in a particular sector commences and before product taxes and subsidies are paid. Estimates of the intermediate consumption of each sector of production broken down by NACE code are estimated by the CSO most recently in the 2009 'Supply and Use Tables for Ireland'³², in particular Table 2 'Use Table at purchasers' prices'. Estimates are produced for 58 sectors, some by individual NACE code and some which aggregate NACE codes. Outputs of specific sectors by value are shown in columns, with intermediate consumption by value

³² http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2009/supplyuse_2009.pdf



from other sectors are shown in the rows. It shows both how much the intermediate consumption is for each sector, and from which sectors they have come. Once intermediate consumption is accounted for, gross value added then consists of compensation of employees, net operating surplus (profits), consumption of fixed capital (depreciation) and taxes less subsidies. Of relevance for this exercise are chemicals and chemical products (20) and pharmaceutical products and preparations (21). Table 3 sets out the main results of the tables in stylised form.

Table 3. Main results supply and use tables - Ireland

Industry		Chemicals and Chemical Products (20)		Basic pharmaceutical products (21)		All pharma-chem (20 & 21)	
Product		€m	% of sectoral output	€m	% of sectoral output	€m	% of sectoral output
Rental and leasing services (77)	(a)	421	18.6	12662	36.3	13083	35.2
All other inputs	(b)	869	38.3	8520	24.4	9389	25.3
Total intermediate consumption (a+b)	(c)	1290	56.9	21182	60.7	22472	60.5
<i>Of which imported (share imputed from 2005)</i>							51.3
Compensation of employees	(d)	350	15.4	1188	3.4	1538	4.1
Net operating surplus	(e)	469	20.7	11975	34.3	12444	33.5
Consumption of fixed capital	(f)	148	6.5	494	1.4	642	1.7
Net taxes on production	(g)	9	0.4	47	0.1	56	0.2
Gross value added at basic prices (d+e+f+g)	(h)	976	43.1	13705	39.3	14681	39.5
Output at basic prices (c+h)		2266	100.0	34887	100.0	37153	100.0

There are four key points to note from this table. First, the share of intermediate consumption in pharma-chem output (at about 61 per cent) is high. Second, a full 35 per cent of gross output is accounted for by rental and leasing services, which are to a large extent the payment by Irish production facilities for the right to produce patented drugs, with the payment usually flowing to a multinational parent or otherwise in the form of a royalty. Third, the sector is particularly profitable, with net operating surplus at one third of gross output. The high profitability of the sector is likely reflective of the large intellectual property content and monopoly production granted to patent holders, with pricing at substantially above marginal cost. Finally we assume the import share of gross output is 51 per cent, on the assumption that 84 per cent of intermediate consumption is imported. This final assumption is sourced from 2005 input-output tables, as no more recent data are available³³.

³³ http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2005/inputoutput_2005.pdf



An import share of 50 per cent suggests import elasticity to GDP of about one half³⁴, namely that a one per cent change in exports is associated with a half per cent change in imports. The elasticity of pharma-chem exports to GNP (gross national product) is much smaller, and probably close to zero. This is because the sector is dominated by multinationals so we assume that most profits are recorded as factor outflows in the balance of payments, which accounts for some of the difference between GDP and GNP. However the component of profits which is taxed in Ireland would not be repatriated and would be recorded as GNP.

h. Accounting for the price-volume split

Any shift from patent to generic production is likely to be treated as a decline in volume rather than a decline in price, which is a somewhat counter-intuitive result. Consider the example where an Irish plant continues to manufacture the same drug (in chemical compound terms) where the patent has been lost. In a given month the patented version will leave the relevant price index and the generic equivalent will enter. The CSO will treat the generic equivalent as a new product, rather than the same product at a lower price. This will mean that any decline in the value of production would be accounted for as a volume shift³⁵ as there is no change in the price index per se.

In practice the process may be more gradual and nuanced. Residual brand loyalty can exist in a post-patent environment, and production is unlikely to decline to zero immediately after patent expiration. However, from discussions with industry experts it is unlikely that large pharma companies based in Ireland will continue to manufacture off-patent equivalents on the same assembly lines as patent production.

4. Quantitative simulations on the impact of the patent cliff

a. Simulations of the impact of pharma-chem output loss on GDP

This section sets out the impact of a decline in overall pharma-chem exports on Irish GDP over a number of years under a number of different assumptions. A series of simulations of the net impact on GDP of a loss of pharma-chem output are set out below. Two scenarios for export performance are modelled (large decline and small decline); and the impacts of three import intensities are modelled as well (low import intensity, medium import intensity and high import intensity). The impact of a change in GDP is also a function of the weight of the pharma-chem export sector in GDP. An assumption of a four-year loss period is made with reference to industry estimates of patent loss occurring mainly between 2012 and 2016³⁶. The approach is 'top-down' in nature by necessity. More detailed data on which drugs are manufactured in Ireland and in what magnitude are not available for commercial reasons. As such it is not possible to model the falling off patent of certain drugs and their precise impact on production and exports.

³⁴ However, a considerable degree of caution surrounds input-output estimates. They are generally valid for changes at the margin, a more structural decline in output could potentially be accompanied by a shift in the profit/import mix, particularly if the average value-added content of post-patent pharma output was lower.

³⁵ ESRI (2013) 'The Effect on Major National Accounting Aggregates of the Ending of Pharmaceutical Patents' in Quarterly Economic Commentary, Autumn 2013.

³⁶ <http://www.imshealth.com>. Medicines_Outlook_Through_2016_Report.pdf see slide 24



Table 4. Simulations of output decline

Large pharma-chem export decline (8 per cent p/a)						
Year	1	2	3	4	5	Four-year GDP loss
Import content						
High import content (66%)	100.0	99.4	98.9	98.4	97.9	2.1
Baseline import content (50%)	100.0	98.8	97.8	96.8	95.9	4.1
Low import content (33%)	100.0	98.6	97.2	96.0	94.9	5.1
Small pharma-chem export decline (4 per cent p/a)						
Year	1	2	3	4	5	Four-year GDP loss
Import content						
High import content (66%)	100.0	99.7	99.4	99.2	98.9	1.1
Baseline import content (50%)	100.0	99.4	98.9	98.3	97.8	2.2
Low import content (33%)	100.0	99.3	98.6	97.9	97.3	2.7

Figure 11. Large output decline

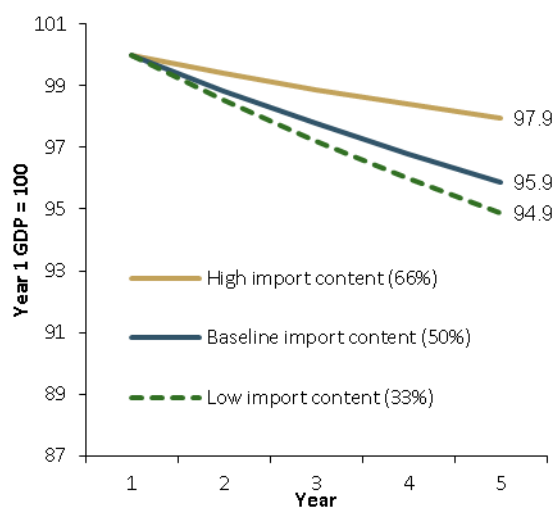
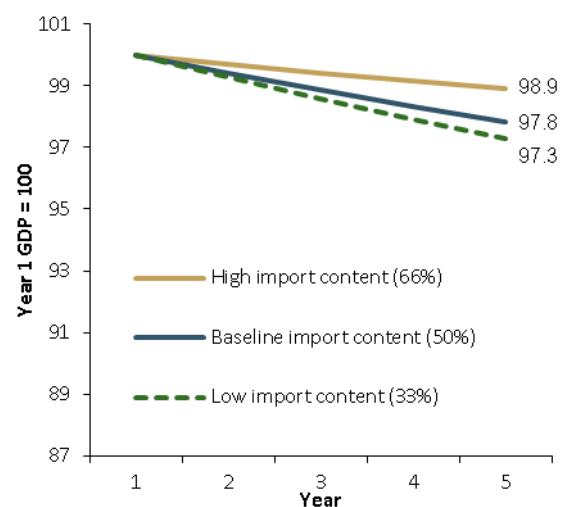


Figure 12. Small output decline



Source: author's calculations

The results suggest a central estimate of a 4 per cent loss of output in the large output decline scenario. In the small output decline scenario a central estimate of a loss of 2 per cent is found. In both scenarios the results depend on the assumed import intensity in each case, if the import response is smaller than the export decline then the net impact on GDP will be lower, and vice versa. The annual impact tapers slightly over time in response to the shrinking weight of pharma in GDP as exports contract.



These simulations should be considered in conjunction with a number of key facts :

- Trend growth is generally assumed to be positive over the medium term and the simulations should be benchmarked against a baseline of positive growth.
- Furthermore, this is a partial equilibrium approach which does not account for any structural change in response to the pharma-chem sector or for any other reason. Ireland's economy is particularly open and several large structural changes have been observed in recent decades. For example, computer, electronic and optical products shrank from 3.8 per cent of GVA in 2001 to 1.8 per cent in 2011. By contrast computer programming, consultancy and information service activities (62,63) grew from 1.5 per cent of GVA in the 1990s to just under 3 per cent in the years to 2011. The potential for growth in one sector to substitute for loss in another is very real over the medium to long term.
- The ending of patent protection is likely to reduce exports which are recorded as debits in the balance of payments. However repatriated profits and imports (both credits) would both decline substantially as well - meaning a slightly negative impact on the current account is to be expected. This is not modelled.

b. Corporation tax implications

Ireland's corporation tax take measured just over €4bn in 2012 (2.4 per cent of GDP), and discussions with the Irish Revenue Commissioners suggest that the share sourced from NACE codes 2110 and 2120 is substantial. For the purposes of the paper, the baseline working assumption is that a reduction in pharma-chem output would result in reduced profitability for the sector, with an associated fall in taxable profits. However profitability could be maintained to some extent in the face of output loss if reduced output means a reduction in imports of licences. The specific implications for the corporation tax take from any decline in pharma-chem output are not modelled in this paper.

In more qualitative terms, Ireland's corporation tax take has always been both concentrated and more prone to changes in composition over the years, compared to more stable forms of revenue such as labour taxation or VAT. The patent cliff is unlikely to have net positive implications for the revenue take over the medium term, and the risks are clearly weighted to the downside in this regard.

c. Implication of fiscal consolidation

In Ireland, the Health Service Executive (HSE) accounts for a large share of drug purchases, although developments domestically are unlikely to have a noticeable impact on production in Ireland due to the size of the export market. As part of the government's multi-annual fiscal consolidation strategy, a series of measures designed to reap savings from drug purchases have been introduced. The *Health (Pricing and supply of medical goods) Act 2013* was enacted in May 2013³⁷. The Act provides for the introduction of a system of generic substitution and reference pricing to promote price competition and deliver lower medicine prices for both the state and patients in coming years. Total HSE spend on drugs in 2011 was estimated at €1.8 billion in 2011, or (1.1 per cent of GDP). By comparison with the scale of exports in the same year (€47 billion, or 29 per cent of GDP), the impact of any domestic reforms to reduce prices in Ireland is likely to be very small on Irish output. Nonetheless, fiscal consolidation in Europe has focussed on drug prices in recent years, given that other health inputs such as wages tend to be less negotiable. This process is likely to continue over the medium term and will weigh on values (if not necessarily volumes) over this period.

³⁷ <http://www.irishstatutebook.ie/2013/en/act/pub/0014/index.html>



d. Upside risks

Industry has been planning for the patent cliff for a number of years now and has taken a several steps to try and mitigate the impact of the patent cliff:

- In the lead up to the expiration of specific patents, companies have taken a number of initiatives to try and lessen the immediate impact. Some branded pharmaceutical companies have signed exclusive supply agreements with generic distributors to manufacture and sell generic tablets for a specified time period. Some companies have also succeeded in extending patent protection³⁸.
- There has been significant merger and acquisition activity in recent years as many of the larger pharmaceutical multinationals attempt to diversify operations and enhance their product pipeline. Some of the most high profile mergers of recent years include Pfizer's acquisition of Wyeth and Merck's merger with Schering-Plough.
- Irish subsidiaries are repositioning themselves in the global value chain as 'strategic launch plants and flexible multi-product plants' that can produce the high-value stages of the chemical pharmaceutical process as well as small volume, high value niche products³⁹.
- Companies are investing more in R&D as Ireland has improved its R&D offering in recent years through the introduction and subsequent enhancement of the R&D tax credit. Added to this, Ireland has invested heavily in science and technology infrastructure over the last decade making it a more attractive location to conduct high value R&D.
- Companies are moving more towards the production of biopharmaceuticals⁴⁰ which requires a greater level of skill and process R&D effort and as a result is harder to replicate. Biopharmaceuticals account for around 10 to 15 per cent of the current pharmaceutical market and growing at a faster rate than the market as a whole⁴¹. Ireland now has over ten large-scale biopharmaceutical facilities⁴².

It is also worth highlighting that the pharmaceutical sector has large sunk costs associated with its plants, with individual plants costing in the region of €250 million. Therefore the mobility of the sector may be restricted in a way that many service sectors would not be.

³⁸ Davy (2012) Ireland and the Pharma Patent Cliff

³⁹ Van Egeraat (2012) The State of the Irish pharmaceutical industry in Future Science

⁴⁰ Biopharmaceuticals are defined as pharmaceuticals manufactured by biotechnology methods, with the products having biological sources, usually involving live organisms or their active components.

⁴¹ European Biopharmaceutical Enterprises http://www.ebe-biopharma.org/index.php?option=com_content&task=view&id=26&Itemid=102

⁴² Van Egeraat (2012) The State of the Irish pharmaceutical industry in Future Science



5. Future of the sector

Despite the known impact of the patent cliff, the future of the pharmaceutical sector is assessed to be stable over the medium term according to Moody's Investor Services as fewer major blockbusters expire and firms return to earnings growth in 2013⁴³. Research conducted by Accenture in August 2012 showed that forecast global sales lost to patent expiry would peak in 2012 at approximately €30 billion before falling back to €17 billion in 2013 and hovering around the €14 billion per annum mark to 2016⁴⁴.

Global spending on pharmaceuticals is set to continue to grow, however it is expected there will be a change in the composition of growth. The US and Europe are forecast to decline in market share as patents continue to expire and economies attempt to cut costs. In addition, spending on generic pharmaceuticals is expected to increase at a faster rate than global brands⁴⁵.

Globally, innovation in the pharmaceutical sector is now shifting towards personalised healthcare. This effectively means developing solutions that are tailored to the needs of the patient. Personalised healthcare is leading growth in innovative delivery mechanisms, companion diagnostics, niche busters and a shift toward biologics - which at the same time is seeing consolidation in the market⁴⁶. This is likely to be low-volume but a high-value area. Biopharmaceuticals will account for an increased share of spending by 2016, with spending set to double from €72 billion in 2006 to approximately €160 billion by 2016⁴⁷.

6. Conclusions

Given the weight of the pharmaceutical sector in Irish GDP, this paper seeks to assess the impact of the current 'patent cliff' in the pharmaceutical sector on the Irish economy. Ireland has a well-established specialisation in pharma-chem production, with nine of the top ten multinational corporations located in Ireland. The sector accounts for approximately a quarter of total Irish exports though, due to its knowledge-intensive nature, its employment share and the labour income share in value add terms is relatively modest by comparison.

The clustering of a number of patented drugs going off patent in quick succession, including the global bestseller in 2011, which is assumed to be produced in a small number of locations including Ireland, is having an impact on pharma-chem output in Ireland. At the time of writing (late-2013) both output and exports are down from their mid-2012 peaks, although the headline impact is likely to be offset to an (uncertain) extent by reduced imports through royalty payments.

Ireland will continue to feel the impact of the patent cliff as drugs which are aware of being produced in Ireland continue to come off patent. However, the magnitude is unlikely to be as great as has been felt in 2012 as drugs due to expire that are produced in some part in Ireland are of less value than those that have come off patent to date. The most significant drug left to come off patent that is produced in Ireland is due to expire in 2016⁴⁸.

⁴³ http://www.moodyys.com/research/Moodyys-Stable-outlook-for-global-pharmaceutical-industry-due-to-return--PR_271447

⁴⁴ Accenture (2012) Beyond the Patent Cliff – Signs of Recovery on Biopharma's New Normal

⁴⁵ IMS Institute (2012) The Global Use of Medicines: Outlook Through 2016

⁴⁶ Forfás (2013) Making it in Ireland: Manufacturing 2020

⁴⁷ IMS Institute (2012) The Global Use of Medicines: Outlook Through 2016

⁴⁸ Davy (2012) Ireland and the Pharma Patent Cliff

<http://www.davy.ie/content/pubarticles/patentcliff20121128.pdf>



The impact on employment is unlikely to be as large as suggested by the fall in aggregate demand. Employment in the sector accounts for less than 2 per cent of total employment. Those employed are highly skilled and in general better-educated employees are less likely to face skills mismatches in the event of a demand shock, compared to, say, and the situation in the wake of the construction collapse.

In addition, the pharmaceutical industry has been planning for this event for a number of years through agreements post-patent, mergers and acquisitions, productivity improvements and a move towards the biopharmaceutical end. Of particular note, is the continued investment of the large multinationals in Ireland, which have experienced patent expiration in the biopharmaceutical space. In terms of the biopharmaceutical sector, IDA figures show that €2 billion in capital expenditure is planned over the next three years, following €1 billion of investment already over the past two to three years.

A number of illustrative simulations which use various export declines and import responses suggest a cumulative loss 2 per cent of GDP in a small decline scenario and 4 per cent of GDP in a large decline scenario over a five-year horizon. Corporation tax would probably fall due to lower profitability in the sector.

More generally, Ireland is a small open economy and has seen considerable shifts in the composition of economic activity over the years. The current growth in services exports points to the capacity for some substitution on the supply side of the economy.