

## **The Impact of the Patent Cliff on Pharma-Chem Output in Ireland**

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(read before the Society, 6th March 2014)

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**Abstract** 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 about 11 per cent of value added although due to its knowledge-intensive nature its share in employment and the labour share of value added are modest by comparison. Ireland is the production base for a number of patented drugs which have gone or are going off patent in quick succession, including the global bestseller in 2011. These expiries are having an impact on pharma-chem production 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 in coming years. A working paper by the same authors was released last October setting out a number of simulations which used various export declines and import responses and suggests a net impact of a loss of two to four percentage points from GDP over a four-year horizon, depending on assumptions used. This paper builds on that working paper, looking at high-frequency developments the latter half of 2013, as well as the impact on employment in the sector following a number of announcements in relation to job losses and plant closures in 2013.

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**Keywords:** patent cliff, pharma-chem, employment, Ireland

**JEL Classifications:** J21, O30

### **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 billion<sup>2</sup> in 2012. The sector is highly concentrated, with the top ten companies in the world accounting for about a third of global sales. Currently, North America and Europe account for almost two thirds of the global market<sup>3</sup>.

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 payers.<sup>4</sup> However, the focus of this paper is the impact of the expiration of patents in the sector in Ireland.

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<sup>1</sup> 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.

<sup>2</sup> All figures converted from US prices using average exchange rate for 2012 of €1 = \$1.29

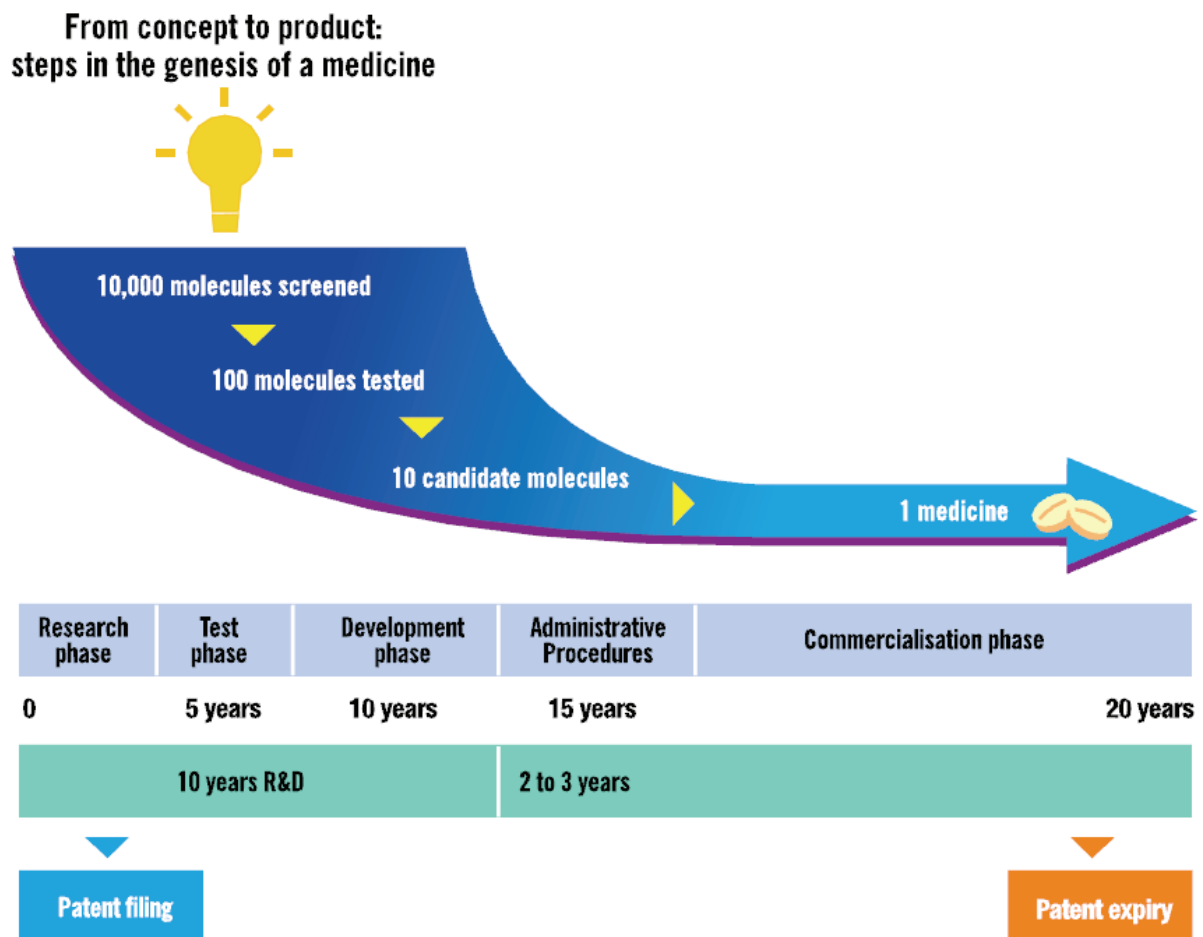
<sup>3</sup> IMS Health

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

<sup>4</sup> Forfás (2013) Making it in Ireland: Manufacturing 2020

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 approval.<sup>5</sup> 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 competition.<sup>6</sup> The average cost of researching and developing a new medicine is claimed by the pharmaceutical industry to be approximately €1.4 billion.<sup>7</sup> It is estimated that only three out of ten marketed medicines produce revenues that match or exceed R&D costs before they lose patent protection.<sup>8</sup>

Figure 1. Lifecycle of an innovative 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 2013.<sup>9</sup> Taken as a percentage of global sales, the patent cliff impacts between a quarter and a third of the value of the sector.

<sup>5</sup> PhRMA (2007) Drug Discovery and Development: Understanding the R&D Process

<sup>6</sup> Pharmaceutical Healthcare Facts and Figures 2012

<sup>7</sup> Association of the British Pharmaceutical Industry data (2012)

<sup>8</sup> Pharmaceutical Healthcare Facts and Figures 2012

<sup>9</sup> 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 Ireland.<sup>10</sup> The sector continued to grow and in 2012 Ireland's share of global trade SITC<sup>11</sup> codes 51 and 54 was particularly high at around 4 per cent. 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).<sup>12</sup> 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 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 sector.<sup>13</sup>
- 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 were under 25 years of age in 2011.<sup>14</sup> 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 2011.<sup>15</sup> 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 the top ten global pharma/biopharma companies and manufactured/manufactures in part or full six of the top ten blockbuster drugs<sup>16</sup> coming off patent between 2011 and 2016.<sup>17</sup> This includes the bestselling drug in the world in 2011.

## **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 expenditure<sup>18</sup> basis and an output<sup>19</sup> 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 close to €40 billion in 2012, about 24 per cent of GDP. It accounts for 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 high at close to 4 per cent in 2012 (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.

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<sup>10</sup> 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

<sup>11</sup> SITC stands for standard international trade classification. More details here:

<http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=28>

<sup>12</sup> Forfás (2013) Making it in Ireland: Manufacturing 2020

<sup>13</sup> Smyth (2005) 'Ireland's Revealed Comparative Advantage' in Central Bank Quarterly Bulletin 1, 2005

<sup>14</sup> CSO

<sup>15</sup> OECD (2013) Education at a Glance 2013: OECD indicators

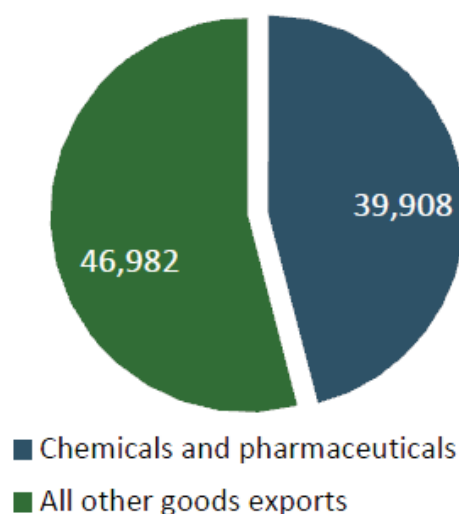
<sup>16</sup> Based on global sales in 2011

<sup>17</sup> IDA Ireland

<sup>18</sup> 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)

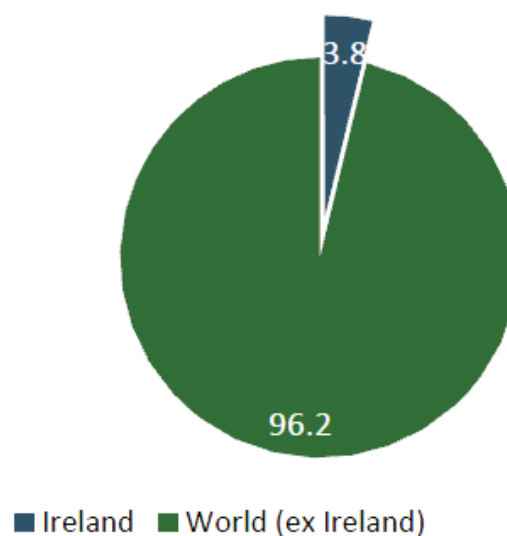
<sup>19</sup> The output measure of GDP measures the output of the economy by sectors, subtracts intermediate consumption (domestic and imported) to get value added by sector. (Output - intermediate consumption – imports = value added).

**Figure 2. Irish merchandise exports (2012)**



Source: CSO

**Figure 3. Irish share of global pharma-chem exports (2012)**



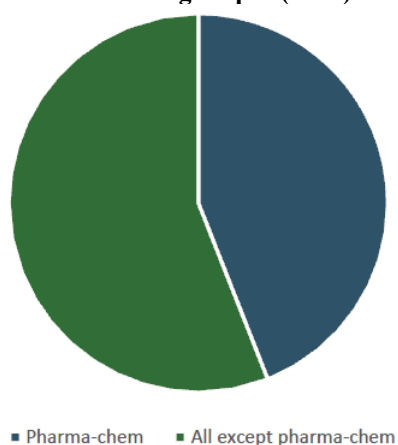
Source: UN

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).<sup>20</sup> The most recent complete set of data are for 2012, and show that gross value added in the pharmaceutical sector was about 11 per cent of economy-wide GVA.<sup>21</sup>

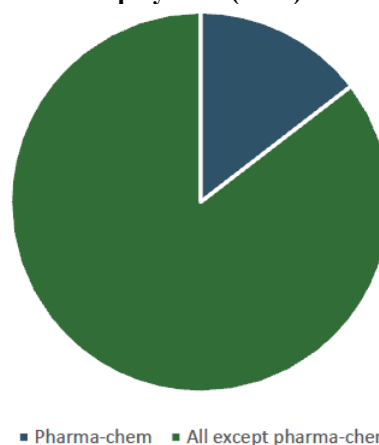
**b. Structure and size of industry**

The CSO's Census of Industrial production provides some useful insights on the structure of the pharma-chem manufacturing sector in Ireland. NACE sectors 20 and 21 (which broadly correspond to pharma-chem activity) accounted for under half of gross industrial output in value terms in 2011, at €38.7bn. The employment share was considerably lower, at 23,000 or 17 per cent,<sup>22</sup> evidence of the high value-added content of the sector (see Figures 4 and 5).

**Figure 4. Pharma-chem share of gross manufacturing output (2011)**



**Figure 5. Pharma-chem share of Industrial employment (2011)**



Source: CSO, authors' calculations

Note: all data for 2009, 'all other' excludes NACE sector 17 due to data availability

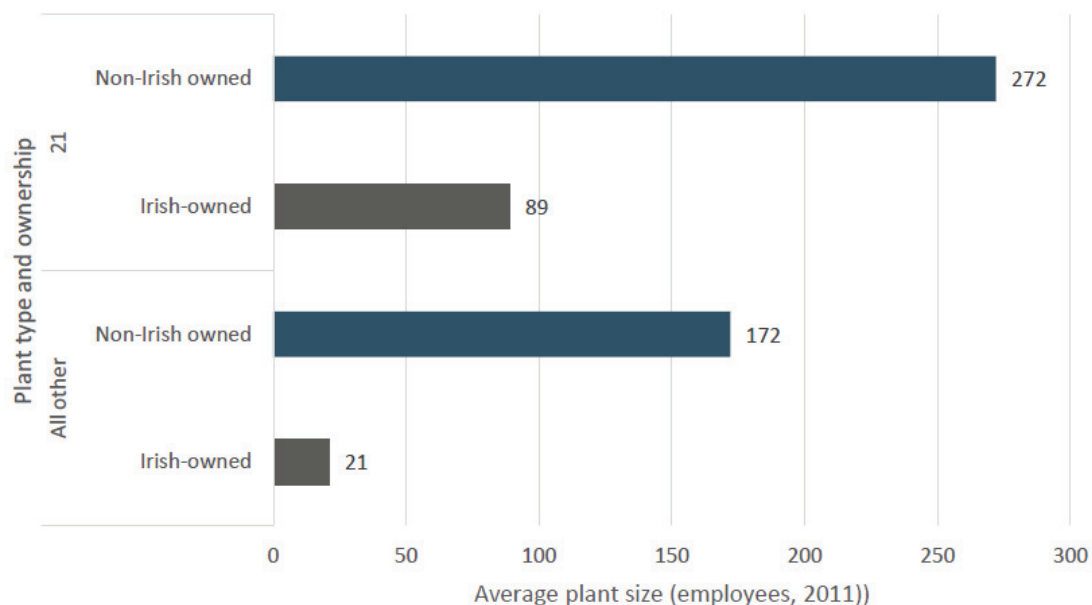
<sup>20</sup> Gross value added is conceptually similar to GDP but examines production on a sectoral level rather than final expenditure type. Gross value added excludes product taxes and subsidies, although these are largely irrelevant for the pharma-chem sector.

<sup>21</sup> [http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2012/nie\\_2012.pdf](http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2012/nie_2012.pdf) see table 4

<sup>22</sup> Different estimates of employment in the sector are referenced in the paper. These relate to size and scope of coverage of different surveys and are explained where relevant.

In general average employment by industrial unit is considerably larger in non-Irish owned firms. Outside the pharma-chem sector Irish-owned firms engaged just over 20 per industrial unit with non-Irish owned firms engaging 172. This pattern can be observed but to a greater extent for firms in the NACE code 21 engaged in pharma-chem activity (see Figure 6) with plant size above average for both Irish and non-Irish owned firms. Turnover by firm size in sectors 20 and 21 is regrettably unavailable presumably due to data confidentiality concerns.

**Figure 6: Average firm size by NACE classification and ownership type**



Source: CSO, authors' calculations

Note: Data are for 2010 for all other sectors, 2011 for sector 21 due to data availability

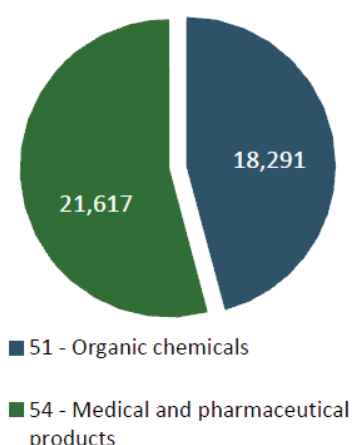
### c. Exports

The tradable outputs of the pharma-chem sector include SITC<sup>23</sup> categories 51 and 54, (see table 1 below).<sup>24</sup> 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 use.<sup>25</sup> 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)	21,617
54	Medical and pharmaceutical products	Mainly tableted pharmaceuticals (includes some non-pharma products such gauze, etc)	18,291

**Figure 7. Exports of pharma by SITC code 2012**



Source: CSO External Trade Figures

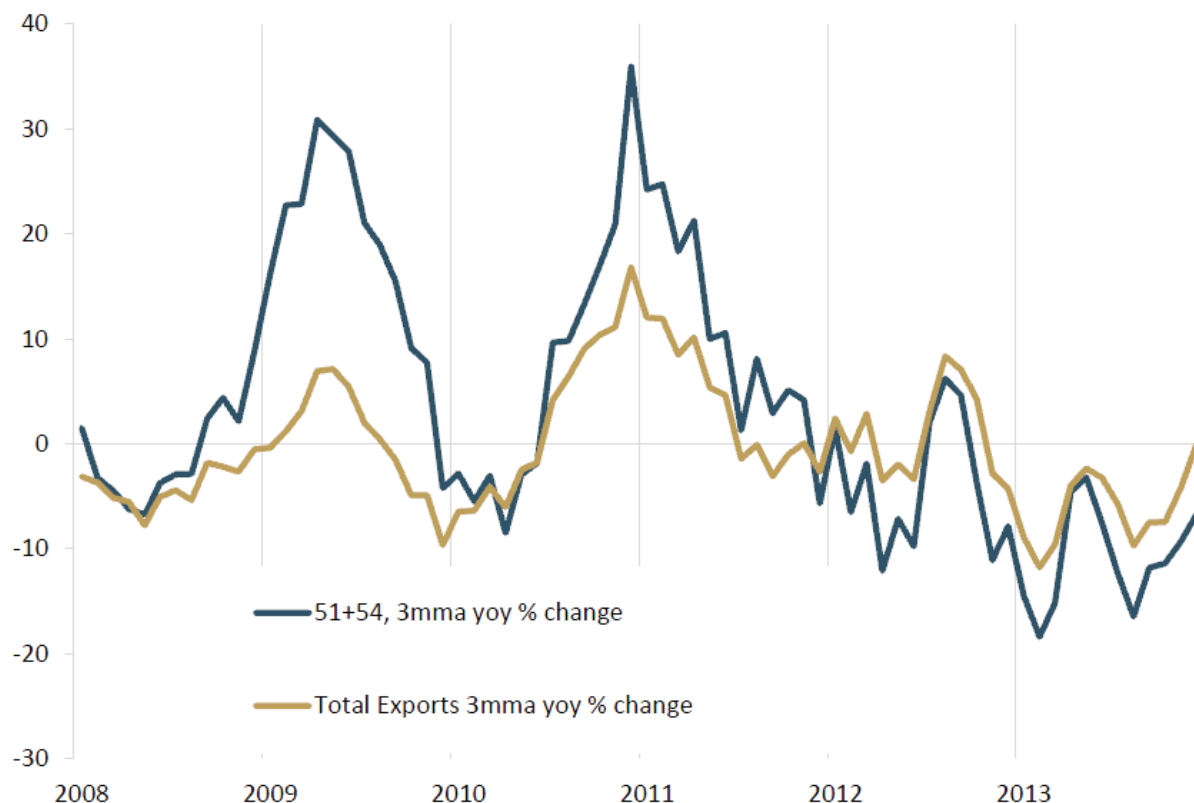
<sup>23</sup> SITC stands for standard international trade classification (<http://unstats.un.org/unsd/cr/registry/regcst.asp?Cl=28>)

<sup>24</sup> <http://www.cso.ie/en/releasesandpublications/externaltrade/>

<sup>25</sup> These categories contain some elements which are not strictly pharmaceutical products but they are sufficiently clear for high-frequency analysis.

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 8). The fall was greatest in the early part of 2013, although it has levelled off somewhat in recent months. The cumulative decline contrasts sharply with the 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 in year-on-year terms for seven successive quarters to the third quarter of 2013.

**Figure 8. 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

#### **d. 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 series.<sup>26</sup> Production is classified by NACE code<sup>27</sup> and the volume index measures physical output with the turnover index measuring value-based sales.<sup>28</sup> 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.

<sup>26</sup> For the latest release see here: <http://www.cso.ie/en/releasesandpublications/industry/>

<sup>27</sup> 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))

<sup>28</sup> More background on the methodology can be found here: <http://www.cso.ie/en/surveysandmethodology/industry/cenindustrialproduction/>

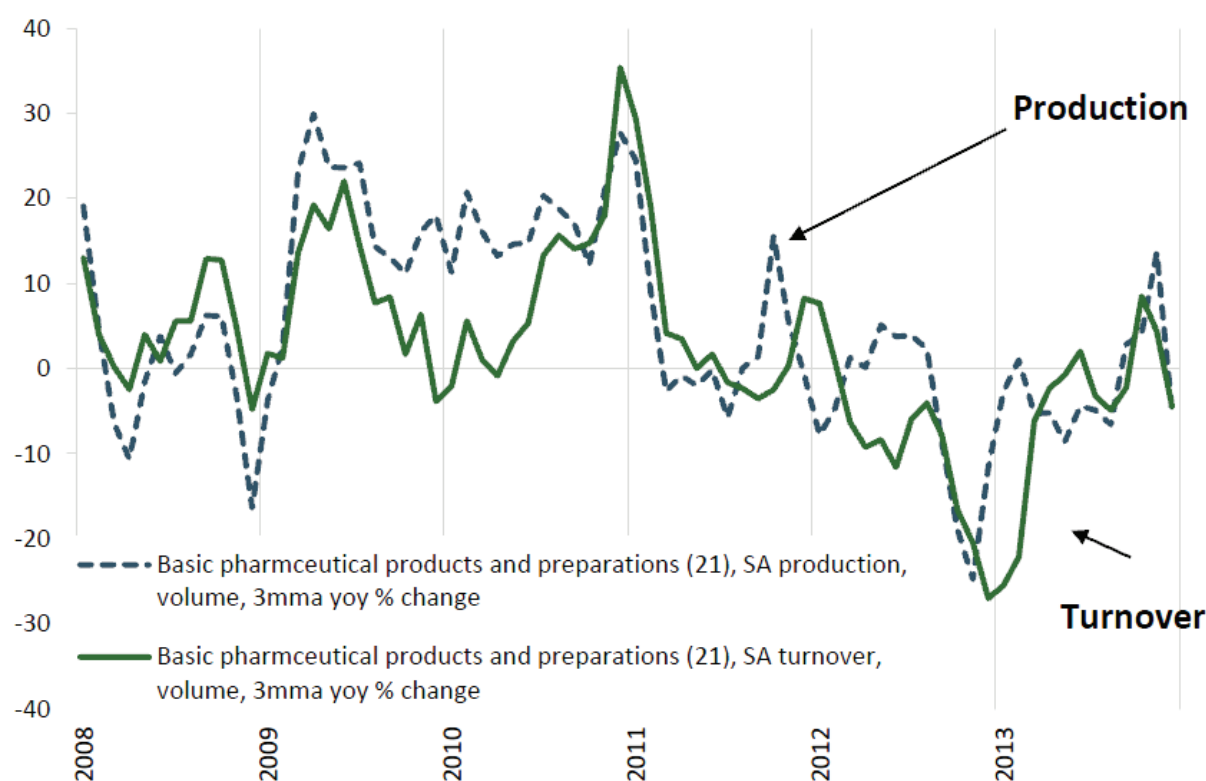
**Table 2. Industrial production by NACE code<sup>29</sup>**

NACE Code	Title	Description	GVA, €m, 2005
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 9 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 sharply since. There was some recovery in the latter half of 2013 both in production and turnover but the considerable losses of late 2012 have not been recovered with the indices down 20 per cent from peak in volume terms and 30 per cent in value terms. 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 9. Industrial production and turnover for NACE 21, 3mma, y-o-y change**



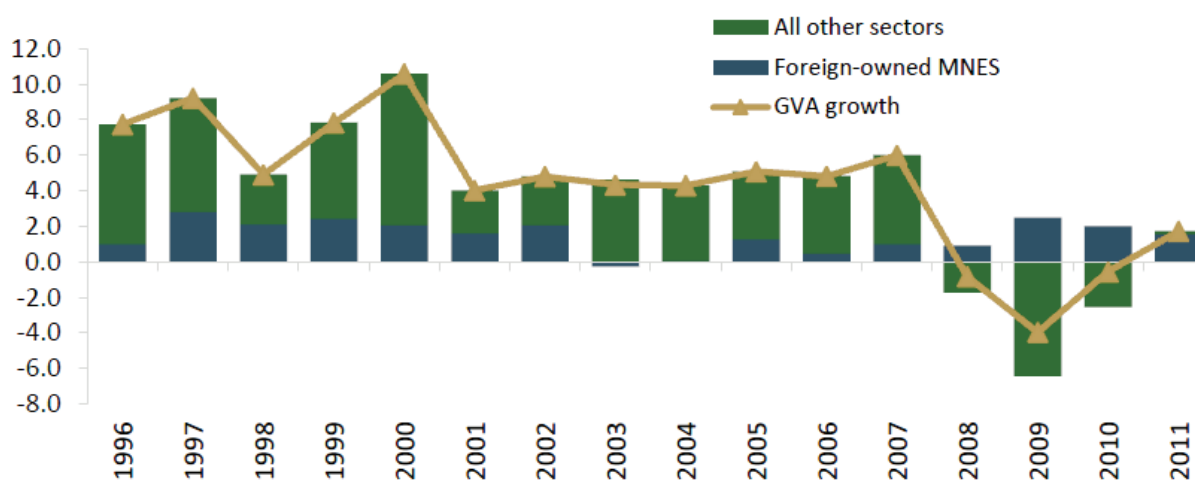
Source: CSO, authors' calculations

<sup>29</sup> The most recent GVA weights used are from 2005

### e. Share of multinational activity in gross value added

In explaining the recent short-run dynamics it is worth recalling the considerably good run of production in the years to 2012. The 2007-11 period saw a particularly strong period of output growth from the multinational sector based in Ireland, of which the pharma-chem sector comprises a considerable share. CSO figures released in late 2012<sup>30</sup> show GVA at basic prices split between the indigenous and foreign-owned multinational sectors, with the threshold for inclusion in the foreign-owned MNE sector if 85 per cent of turnover in the sector is accounted for by these firms. The chart below shows the sharply divergent trends in the performance of the two sectors over the 2007-2011 period. Overall GVA at constant factor cost fell by 3 per cent over the period. However the foreign-owned multinational sector grew by 39 per cent with all other sectors declining by 12 per cent. Figure 9 below sets out the growth contributions in more detail. This divergent performance saw the share of multinational activity rise to a full 25 per cent of GVA in 2011, up from 19 per cent in 2007. This sectoral re-allocation of labour probably overstated some of the apparent unit labour cost-deflated real effective exchange rate (REER) improvements over the period (for more detail see O'Brien and Scally 2012<sup>31</sup>).

**Figure 10. Gross value added at constant factor cost by sector, growth (%) and contributions (pp) 1996-2011**



Source: CSO, authors' calculations

### f. 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. Given the predominance of foreign multinationals in the pharmaceutical sector, we look at IDA client's employment in NACE 20 and 21 as a share of total employment in the economy. Both the absolute number and share have remained reasonably stable over the last decade or so and account for about 1 per cent of economy-wide employment.

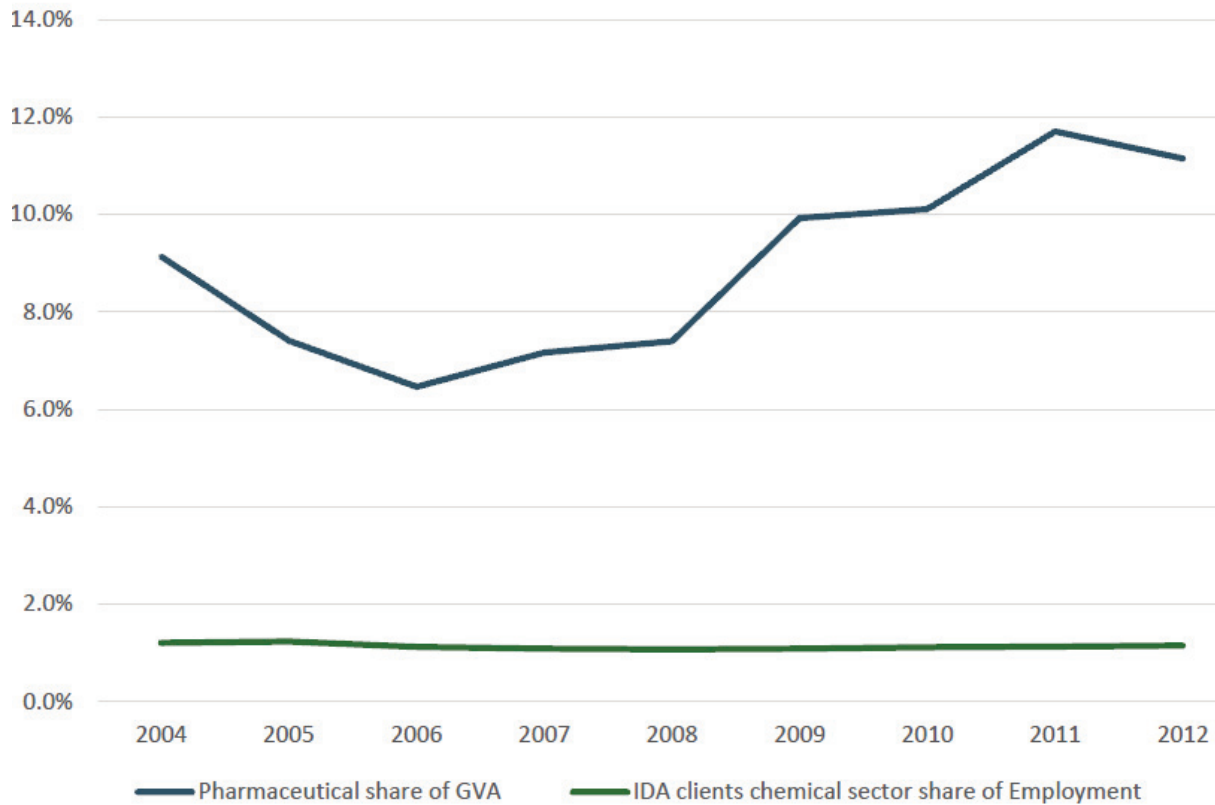
Despite the low share of employment, the share of pharma-chem in GVA was closer to 11 per cent in 2012. The very high GVA-per-worker numbers are more likely due to the highly profitable nature of production (explained later) than strong labour productivity per se.

<sup>30</sup> <http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2011/fimeos20062011.pdf>

<sup>31</sup> <http://www.centralbank.ie/publications/Documents/Cost%20Competitiveness%20and%20Export%20Performance%20of%20the%20Irish%20Economy.pdf>



**Figure 11. Pharmaceutical employment and output**



Source: CSO, IDA, authors' calculations

Data on numbers employed in IDA-assisted firms in the chemicals sector shows employment of 21,675 in 2013. This figure is up 2.7 per cent on the previous year. Table X below shows that there has been net job creation in the sector for the last two years as new jobs created outweigh jobs lost in the sector.

**Table 3: Employment in IDA client companies in NACE 20 and 21**

	2005	2006	2007	2008	2009	2010	2011	2012	2013
<b>Total</b>	<b>24,209</b>	<b>23,151</b>	<b>23,276</b>	<b>22,795</b>	<b>21,342</b>	<b>21,082</b>	<b>20,945</b>	<b>21,102</b>	<b>21,675</b>
Net Change	1,267	-1,058	125	-481	-1,453	-260	-137	157	573
Gross Gains	2,485	857	1,139	744	642	1,009	1,146	1,491	1,122
Gross Losses	-1,218	-1,915	-1,014	-1,225	-2,095	-1,269	-1,283	-1,334	-549

Source: IDA

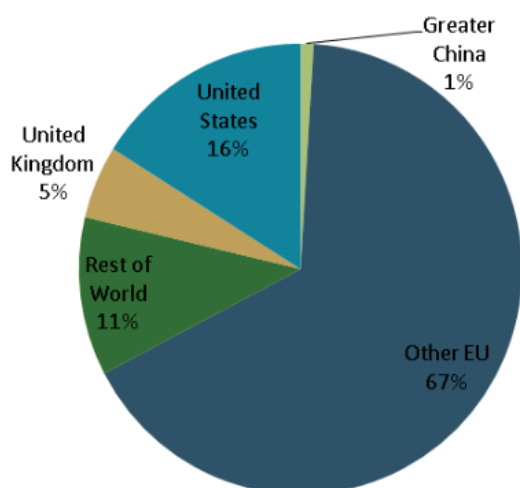
Employment in the sector is highly skilled with approximately half of those working in the sector having a third level qualification and a quarter of all PhD researchers in Irish industry employed in the sector. Consequently the average wage level is significantly higher in the chemicals sector compared 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 whole.<sup>32</sup> CSO Census of Industrial Production (CIP) data are consistent with this, showing an average wage of approximately €60,000 in the foreign-owned NACE 21 sector compared to about €45,000 in the foreign-owned non-pharma-chem industrial sector in 2011.

<sup>32</sup> Forfás (2013) Annual Business Survey of Economic Impact 2011

### g. Geographical destination of exports

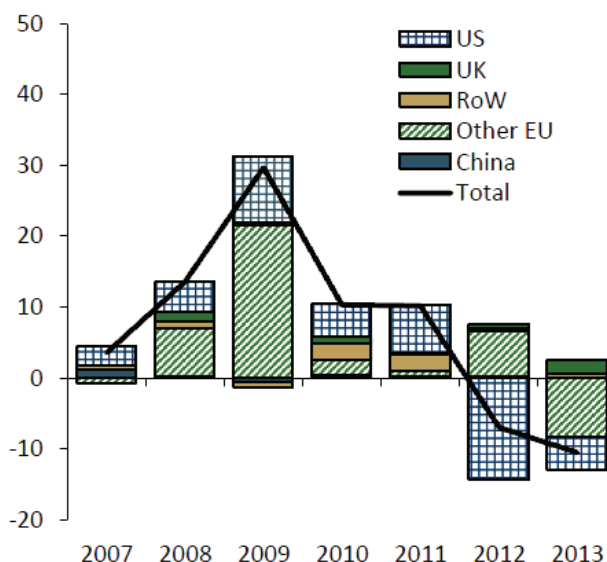
Pharmaceutical exports from Ireland are highly concentrated with North America and Europe accounting for approximately 85 per cent of exports. Exports of pharma-chem products by destination has shown a marked compositional shift since the start of 2012 (see Figures 12 and 13). Exports to the US led the overall decline in 2012, and fell (though contributed less) to the fall in 2013, with exports to other EU accounting for the bulk of the decline. Exports of organic chemicals (51) although not presented are not showing as pronounced a geographical trend.

**Figure 12. Pharma-chem exports by destination (54), 2012**



Source: CSO

**Figure 13. 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.

### h. 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'<sup>33</sup>, 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 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

<sup>33</sup> [http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2009/supplyuse\\_2009.pdf](http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2009/supplyuse_2009.pdf)

capital (depreciation) and taxes less subsidies. Of relevance for this exercise are chemicals and chemical products (20) and pharmaceutical products and preparations (21). Table 4 sets out the main results of the tables in stylised form.

**Table 4. Main results supply and use tables – Ireland**

Industry		Chemicals and Chemical Products (20)		Basic pharmaceutical products (21)		All pharma-chem (20 & 21)	
		€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
<b>Total intermediate consumption (a+b)</b>	<b>(c)</b>	<b>1290</b>	<b>56.9</b>	<b>21182</b>	<b>60.7</b>	<b>22472</b>	<b>60.5</b>
<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
<b>Gross value added at basic prices (d+e+f+g)</b>	<b>(h)</b>	<b>976</b>	<b>43.1</b>	<b>13705</b>	<b>39.3</b>	<b>14681</b>	<b>39.5</b>
<b>Output at basic prices (c+h)</b>		<b>2266</b>	<b>100.0</b>	<b>34887</b>	<b>100.0</b>	<b>37153</b>	<b>100.0</b>

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 available.<sup>34</sup>

An import share of 50 per cent suggests import elasticity to GDP of about one half,<sup>35</sup> 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.

<sup>34</sup> [http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2005/inputoutput\\_2005.pdf](http://www.cso.ie/en/media/csoie/releasespublications/documents/economy/2005/inputoutput_2005.pdf)

<sup>35</sup> 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.

### i. 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 shift<sup>36</sup> 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 2016.<sup>37</sup> 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.

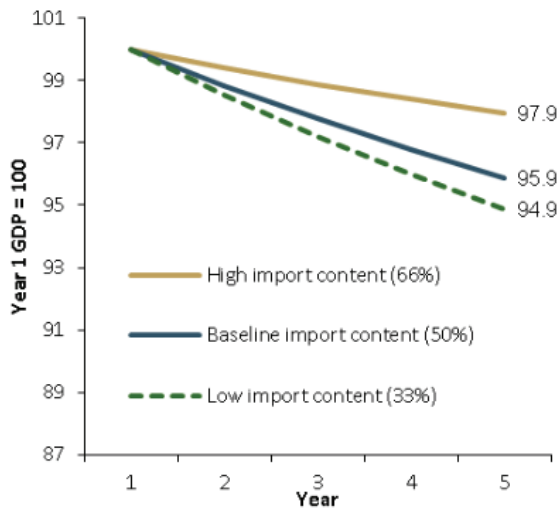
**Table 5. Simulations of output decline**

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

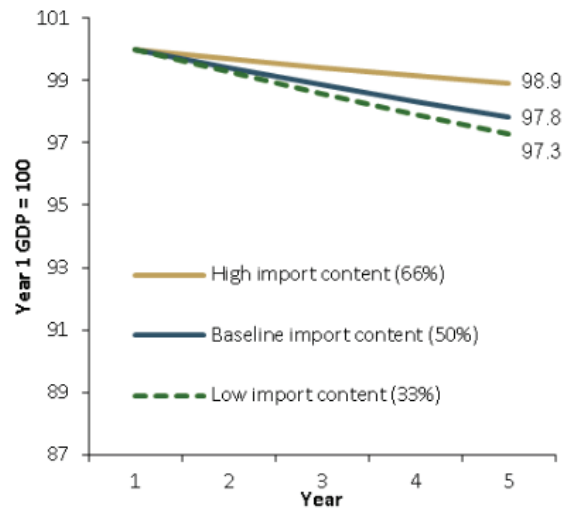
<sup>36</sup> ESRI (2013) ‘The Effect on Major National Accounting Aggregates of the Ending of Pharmaceutical Patents’ in Quarterly Economic Commentary, Autumn 2013.

<sup>37</sup> [http://www.imshealth.com.Medicines\\_Outlook\\_Through\\_2016\\_Report.pdf](http://www.imshealth.com.Medicines_Outlook_Through_2016_Report.pdf) see slide 24

**Figure 14. Large output decline**



**Figure 15. 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.
- However, given the high GVA per worker in the sector, any shrinkage in pharma-chem output as a share of output would likely depress measured productivity, particularly if non-multinational sectors experience a return to sustained growth. This could lead to an unwinding of some of the measured ULC-based REER improvements of recent years which (in any case) were potentially overstated due to the considerable change in the sectoral composition of output between 2007 and 2011.

#### **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 2013.<sup>38</sup> 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 focused 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.

### **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 protection.<sup>39</sup>
- 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 products.<sup>40</sup>
- 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 biopharmaceuticals<sup>41</sup> 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 whole.<sup>42</sup> Ireland now has over ten large-scale biopharmaceutical facilities.<sup>43</sup>

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.

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<sup>38</sup> <http://www.irishstatutebook.ie/2013/en/act/pub/0014/index.html>

<sup>39</sup> Davy (2012) Ireland and the Pharma Patent Cliff

<sup>40</sup> Van Egeraat (2012) The State of the Irish pharmaceutical industry in Future Science

<sup>41</sup> Biopharmaceuticals are defined as pharmaceuticals manufactured by biotechnology methods, with the products having biological sources, usually involving live organisms or their active components.

<sup>42</sup> European Biopharmaceutical Enterprises [http://www.ebe-biopharma.org/index.php?option=com\\_content&task=view&id=26&Itemid=102](http://www.ebe-biopharma.org/index.php?option=com_content&task=view&id=26&Itemid=102) Van Egeraat (2012) The State of the Irish pharmaceutical industry in Future Science

<sup>43</sup> 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 2013.<sup>44</sup> 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 2016.<sup>45</sup>

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 brands.<sup>46</sup>

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 the growth in innovative delivery mechanisms, companion diagnostics, niche busters and a shift toward biologics - which at the same time is seeing consolidation in the market.<sup>47</sup> 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 2016.<sup>48</sup>

## 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 (early-2014) 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 known to be 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 2016.<sup>49</sup>

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.

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<sup>44</sup> [http://www.moody.com/research/Moodys-Stable-outlook-for-global-pharmaceutical-industry-due-to-return--PR\\_271447](http://www.moody.com/research/Moodys-Stable-outlook-for-global-pharmaceutical-industry-due-to-return--PR_271447)

<sup>45</sup> Accenture (2012) Beyond the Patent Cliff – Signs of Recovery on Biopharma's New Normal

<sup>46</sup> IMS Institute (2012) The Global Use of Medicines: Outlook Through 2016

<sup>47</sup> Forfás (2013) Making it in Ireland: Manufacturing 2020

<sup>48</sup> IMS Institute (2012) The Global Use of Medicines: Outlook Through 2016

<sup>49</sup> Davy (2012) Ireland and the Pharma Patent Cliff

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

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.



**FIRST VOTE OF THANKS PROPOSED BY CHRIS VAN EGERAAT,  
NATIONAL UNIVERSITY OF IRELAND, MAYNOOTH**

Thank you for inviting me to discuss this paper. In the five year period since my initial research identifying the impending patent cliff and its significance to the economy of Ireland, there has been quite a bit of back-of-the-envelope estimation of the actual size of this impact on the Irish Economy. Estimates of the impact of the patent cliff on Irish exports, GDP and employment have varied widely. I therefore welcome this study by Shane Enright and Mary Dalton on the impact of the patent cliff on pharma-chem output in Ireland. It provides a detailed and thorough analysis of the state of the industry, comprehensive simulation of the impact of the patent cliff on Irish GDP, as well as some reflections on the impact on Irish employment. In my response I will discuss three issues: 1) the level of uncertainty related to estimating the impact of the patent cliff 2) the timeframe of the impact of the patent cliff and 3) the impact on employment.

First of all, any estimate of the impact of the patent cliff on Irish GDP must come with a strong health warning - there are great uncertainties involved in such an estimation. Most estimates are partly based on an analysis of the specific products losing patent protection and their global revenues. Relatively good data on patent expiry dates and global revenues is publically available. This data can then be linked to the companies operating in Ireland. Based on primary interview data and newspaper analysis, one can get a fair idea about which of the blockbuster drugs coming off patent are at least partially produced in Ireland. This allows us to get some idea as the size of the impact of the patent cliff on exports and GDP.

There are, however, a number of uncertainties:

- 1) Although we have good data on when blockbuster drugs are *due to* come off patent, not all of these drugs actually lose patent protection on the due date. Drug companies do what they can to protect their valuable intellectual property. Most will try to obtain an extension of their patent and some are successful. The granting of one or two patent extensions can seriously alter the impact of the patent cliff on a particular country.
- 2) Even greater uncertainties are involved in estimating Ireland's share in the global production of a particular drug. Pharmaceutical companies typically operate multiple sites for the production of active pharmaceutical ingredients and drug products. In some cases nearly 100% of the global supply is produced in Ireland, but in most cases we have no information about what share of production is accounted for by plants in Ireland. In most cases the only information we have is that part of the global production takes place in plants in Ireland.
- 3) Finally, there are uncertainties related to the location of the intellectual property (IP). Most products were developed at the research facilities of the multinational companies, typically located outside Ireland. But a number of companies have employed cost-sharing arrangements as a vehicle to locate part of the IP in Ireland. This influences the impact of the patent cliff on Ireland but the extent of the practice is unclear.

My second comment relates to the timeframe of the impact of the patent cliff on Irish GDP. Enright and Dalton, in their simulations of the impact of the patent cliff, make an assumption of a four-year loss period with reference to industry estimates of patent loss occurring mainly between 2012 and 2016. I believe that the greatest impact will have occurred in the period from 2012 to 2014. I base this on a simple inspection of the expiration data related to blockbuster drugs produced by multinational companies which have Irish plants.

Table 1 presents the blockbuster patent expirations relevant to Irish plants during the period from 2011 to 2016 (data on the involvement of Irish plants is based on interviews and internet search). The methodology provides no guarantee that all involvement of Irish plants is identified. However the pattern is clear enough to support my main argument

**Table 1. Blockbusters coming off patent\* and involvement of Irish plants**

Year	Drug	Company	Est. global sales (\$bn)	Irish plants involved?	
2011	Lipitor	Pfizer	11.8	Yes	
2011	Zyprexa	Lilly	4.9	Yes	
2012	Enbrel	Pfizer	7.4	Yes	(received patent extension USA)
2012	Actos	Takeda	4.5	Yes	
2012	Singulair	MSD	4.9	Yes	
2012	Diovan	Novartis	6.1	Yes	
2012	Lexapro	Forest	2.8	Yes	
2013	Cymbalta	Lilly	5.0	No evidence	
2013	Niaspan	Abbott	1.2	No evidence	
2014	Nasonex	MSD	1.3	No evidence	
2014	Actonel	W.C.	1.6	No evidence	
2015	Namenda	Forest	1.4	Yes	
2015	Lovaza	GSK	1.3	No evidence	
2015	Gleevec	Novartis	4.7	No evidence	
2016	Zetia	MSD	2.3	No evidence	
2016	Humira	Abbott	6.5	Most likely Puerto Rico	

Source: Medco; Global Market Review and corporate websites

\* For 2011 and 2012 the table only present blockbusters that are partly produced in Ireland

The data clearly show that patent expirations relevant to Ireland were concentrated in the period 2011-2012. Six blockbuster drugs whose patents expired, with a global sales value of \$35bn, were at least partly produced in Ireland (Enbrel's patent for the USA was extended). Because of the six-month 'exclusivity period', during which only one generics company is allowed to enter the market, the full effect on output will only be felt a half year after the expiration date. In addition, the table presents the expiration dates for the USA. In other markets, the drugs developed by US companies tend to come off patent somewhat later. This phenomenon is clearly illustrated in Table 2 which shows that the full effect of the Lipitor patent expiration in the US at the end of 2011, is only reflected in the 2013 global export figures of Ireland. I therefore suggest that the effect of the 2011-2012 cohort (in Table 1) will be fully expressed in the 2012-2014 export and output data.

The blockbusters that are losing patent protection in the 2013 to 2014 period have far smaller combined global sales (\$25bn over the three year period) and, crucially, the data suggest that few of these drugs are manufactured in Ireland. I could only find evidence for one drug, *Namenda*, a relatively small blockbuster with \$1.4bn global sales, coming off patent in 2015. These data suggest that in 2014 we will have passed the peak of the direct impact of the patent cliff on the Irish economy.

**Table 2. Pharmaceutical Exports (SITC 51 and 54)**

	E.U.	Rest of World	U.K.	U.S.A.	total
2010	20,418,977	6,149,925	4,124,219	12,988,420	43,681,542
2011	20,826,234	6,721,870	3,859,718	14,954,471	46,362,293
2012	21,597,988	8,066,232	4,076,762	10,863,300	44,604,281
2013	18,087,394	7,812,356	2,997,385	11,010,923	39,908,057
% Change 2010-11	2.0	9.3	-6.4	15.1	6.1
% Change 2011-12	3.7	20.0	5.6	-27.4	-3.8
% Change 2012-13	-16.3	-3.1	-26.5	1.4	-10.5

Source: CSO

My final comment relates to the impact of the patent cliff on Irish employment. In relation to this I first would like to point to the inconsistencies in employment statistics for this sector. According to the CSO QNHS, the pharmaceutical sector (NACE 20 and 21) employed 35,200 workers in 2011. The CSO Census of Industrial Production provides a figure of 21,200. Although the patent cliff has a substantial impact on GDP and exports, the impact on employment has been limited. There are several reasons why we can expect the direct impact on employment to be relatively limited. Blockbuster drugs are produced by a relatively small share of the workers employed in the pharmaceutical sector. In addition, the product may continue to be produced in Ireland (either by the originator company or by a generics company). However, it is likely that Ireland will experience further indirect collateral damage where originator companies are restructuring their global operations in reaction to the adverse impact of the patent cliff on their global revenues.

**SECOND VOTE OF THANKS, MICHAEL CONNOLLY, CENTRAL STATISTICS OFFICE**

I really enjoyed reading this paper. It is well laid out, the graphs are easy to interpret and generally the presentation is of a very high standard. The authors provide a clear explanation of the structure of the pharmaceutical industry and its impact on economic activity in Ireland. A very substantial body of evidence is introduced to substantiate the arguments in the paper. I'm sure the Society is very happy to facilitate the delivery of a paper of this standard.

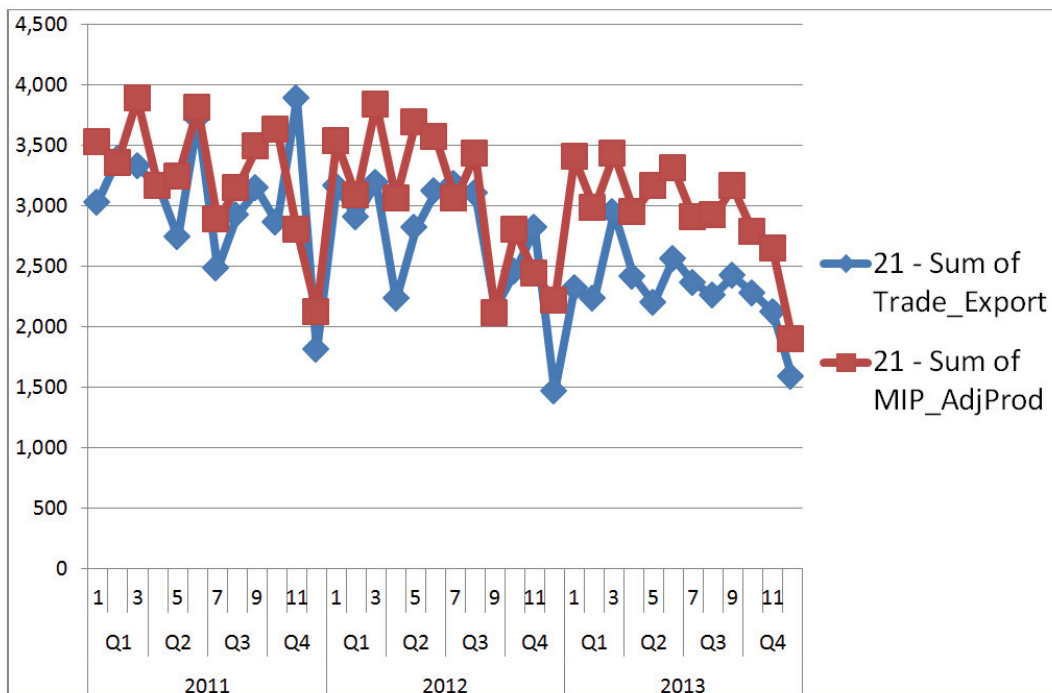
The paper explores the impact of the pharma cliff on the three methods of estimating GDP; the expenditure, income and output methods. On the expenditure side the focus is on exports of finished pharmaceutical products and imports of royalties and other services. On the income side the profits earned by pharmaceutical companies and the wages and salaries of employees are most relevant together with depreciation of plant and machinery. On the output side the authors point to the production of these pharma products and the intermediate consumption i.e. inputs used in the production consisting of base chemicals, royalties, business services etc. and the value added generated.

In fact the reader is taken through the various short term and structural statistical products that are produced mainly by CSO to review the impact of the patent cliff - i.e. how this phenomenon is reflected in the various official statistics. One particularly interesting feature is that the percentage of intermediate consumption in the Irish pharmaceutical industry explained by imports is almost ninety percent - the highest for any sector in the economy.

The analytical approach followed by the authors is not unlike the analysis carried out by the Large Cases Unit (LCU) in CSO. While in CSO we are going from micro (company level data) to macro whereas in the paper clearly greater levels of detail are not necessarily available to the authors. In the LCU we deal with all of the data in relation to a select group of key multinational corporations (MNEs). The objective is to ensure that the data reported by these MNEs used in calculating the various macroeconomic aggregates presents a consistent view of the economy. In fact in the light of the discussions in the paper it should come as no surprise that LCU companies explain substantial elements or a majority of the macroeconomic statistical aggregates produced in CSO.

**Specific issues**

The trend in monthly production by the pharmaceutical sector in Figure 8 in the paper seems at variance with the trend in the actual data (see below). Perhaps this is explained by the moving average smoothing of the data but it is difficult to reconcile the very different results.



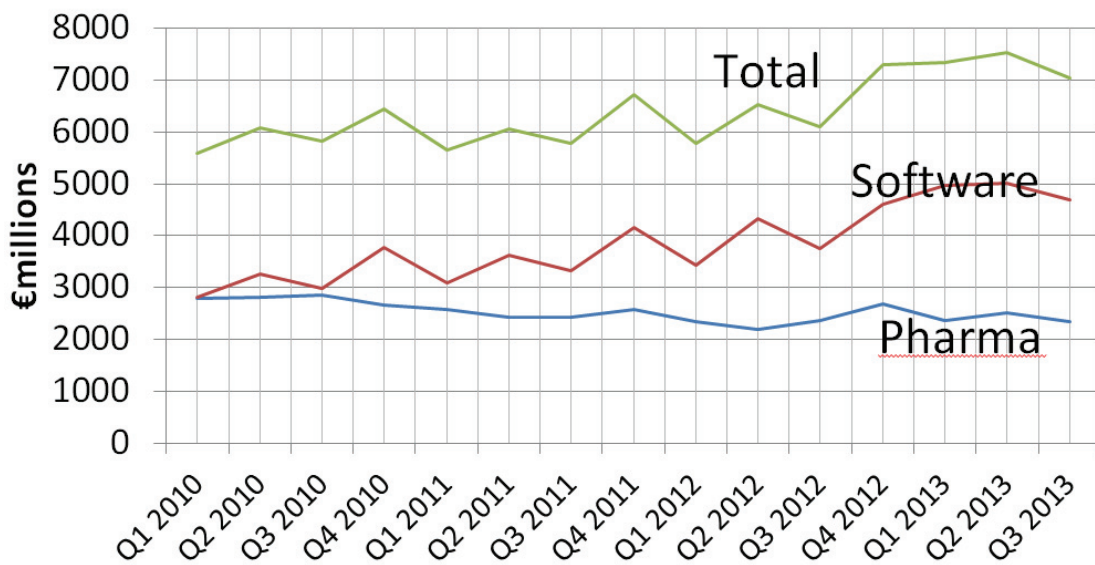
The paper raises the question about how the pharma data is impacted by the patent cliff. Is there evidence of a fall off in royalty payments with profits remaining at similar levels as before? Or, are royalties remaining the same and instead are the profits being earned falling due to the patent cliff effect? My analysis when exports are correlated against profits, interest paid, imports of royalties, imports of other business services is as follows:

**Table 1 Correlation between exports of Pharmaceuticals and Royalties, Profits Interest etc.**

Item	Correlation coefficient with exports
Profits	0.706
Royalty imports	0.096
Business Services imports	0.151
Goods imports	0.038
Interest paid	-0.479

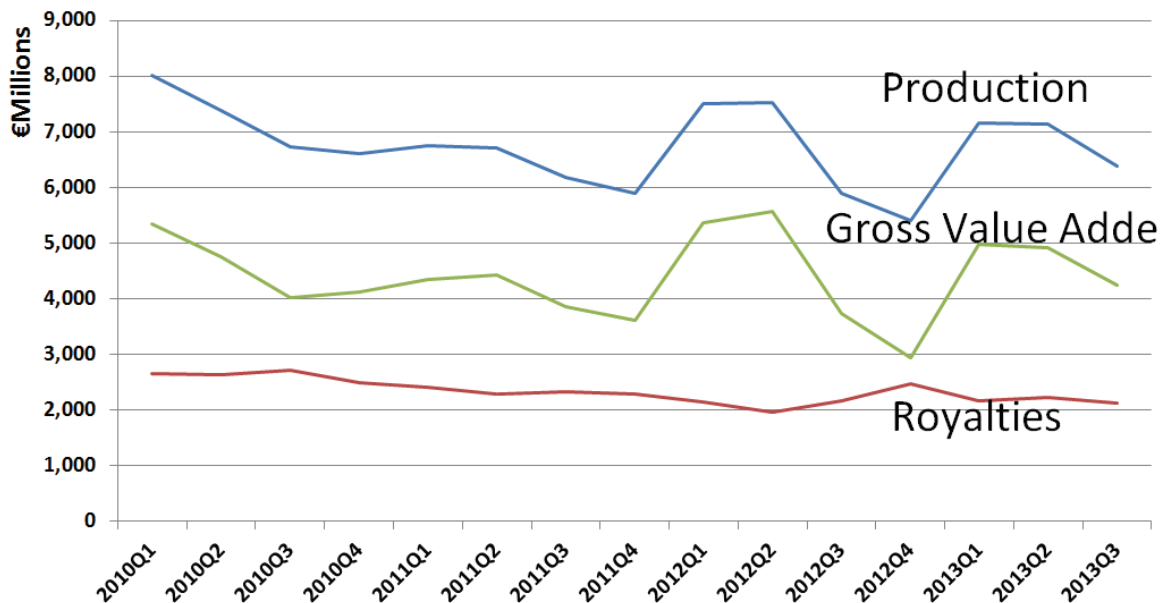
In Table 1 it can be seen that profits are closely correlated to exports (correlation = 0.76) and it can be concluded that the impact of the pharma cliff is most directly leading to reduced profits rather than reduced royalties (correlation = 0.096). In fact the correlation between exports and royalty imports is not particularly significant at almost 10%. In fact in previous years' prices the trend in royalty imports is practically flat. As illustrated below in the comparison of the trend in royalty payments related to pharmaceutical production and also related to software production:

**Royalties – Pharma & Software  
PYP Q1 2010-Q3 2013**



A further chart illustrates the composition of pharmaceutical output and value added, also in previous years' prices.

**Pharma Production – Royalties and Value Added  
PYP 2013-2013**



In this case it is clearly seen that value added is directly impacted by changes in production rather than intermediate consumption and in particular royalties. The chart also reveals the volatile nature of pharmaceutical production in Ireland. Overall, the picture that emerges is not uniquely an industry suffering serious declines and cliff like in nature. Instead, what is seen is a slow downward trend being offset by a period of increased production in turn offset by further reductions. In fact, there is a portfolio effect where some companies are increasing their production while others are suffering the negative impact of the expiry of patents. The impact varies from period to period with one or other impact dominating.

There is also the increasing impact of global production chains on the output of Irish pharmaceutical producers. In such cases the Irish MNE acts as a principal in a global production chain and engages contract manufacturers abroad to carry out production on its behalf. These foreign contractors are paid a fee for providing manufacturing services but the output is owned by the Irish MNE until it is sold to the customer (in practically all cases) abroad. In these scenarios, exports that do not cross the Irish border but when sold do in fact reflect a change in ownership of pharmaceutical products owned by foreign owned Irish MNEs. Identifying these transactions pose serious difficulties for National Statistical Institutes such as CSO because the standard source of export data is not available from the Customs. In fact, the new statistical standards ESA2010 (SNA 2008), being implemented by CSO in the near future, lay a greater emphasis on recording this change in economic ownership in the accounts of the principal.

Finally, I would like to congratulate Mary and Shane for an excellent paper. The extensive use of data is particularly effective in supporting the authors' arguments. I have tried to give a sense of how the CSO deals with these data challenges and how the pharma companies themselves appear to be managing the negative impact of the expiry of such a large number of patents on key products. The positive impact that global production chain activities can have on the performance of these MNEs has also been outlined briefly.

#### DISCUSSION

**Kevin Timoney:** There appears to be broad consensus on the view that the real-economy impact of the patent cliff is less severe than was previously feared. However, one lasting impact is on the value of GDP, which may be on a permanently lower trajectory following the patent cliff. Firstly, is this a relevant extension topic for further study as regards debt sustainability analysis (e.g. for the path of the Debt/Nominal GDP ratio, and the ability to meet fiscal targets in the medium term)? Secondly, has the patent cliff affected potential GDP and the structural budget calculations, and could there be further study done in this regard?

**David Jacobsen:** Having an interest in industrial economics, and sector-specific studies in particular, I welcome this paper and the fact that research of this kind is being undertaken in the Department of Finance. I also find very interesting the comments of Dr Chris van Egeraat, who proposed the second vote of thanks. Dr van Egeraat points out that the numbers employed in the sector vary enormously depending on the source of the data. This relates to the short section on labour market impact; however it does not affect Enright and Dalton's main findings which are on exports, output and turnover. There is another data issue that does impact on their main findings; this is the question of how the profit switching transfer pricing (PSTP) behaviour of multinational companies (MNCs) affects both sectoral and national statistics. Dr Jim Stewart showed, in a paper published many years ago<sup>1</sup> that MNCs in the pharmaceutical industry do indeed switch profits, through transfer pricing, from higher corporate tax areas to Ireland. His conclusion was that this not only distorts economic statistics, it also draws critical attention on the Irish fiscal regime. More recently, he has provided evidence that the effective tax rate for some of the major MNCs in Ireland is substantially lower even than the 12.5 per cent nominal rate that aims to attract new subsidiaries to – and keep old ones in – Ireland.<sup>2</sup> Although active, producing, employing labour and even paying some taxes (e.g. VAT) in Ireland, they are able to declare corporate profits for tax purposes abroad (in tax havens with zero tax rates). This all gives support to the argument that the extent to which Ireland's industrial policy rests upon its fiscal regime is extremely dangerous. It calls into question the findings of such careful analyses as those of Enright and Dalton and, more importantly, leaves Ireland vulnerable to the possibility that changes in fiscal regulations in the United States – and other OECD countries – will reduce the attractiveness of Ireland to MNCs and have serious repercussions for jobs.

I find convincing the arguments that Jim Stewart has drawn from the huge amount of research that he has done on this subject over the years and continue to be amazed at how little attention it draws from economists in

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<sup>1</sup> Stewart, J.C. (1989) "Transfer Pricing: Some Empirical Evidence from Ireland", *Journal of Economic Studies*, Vol. 16, No. 3, pp.40 - 56.

<sup>2</sup> Stewart, Jim (2013) "Corporation Tax: How Important is the 12.5% Corporate Tax Rate in Ireland?" in David Jacobson (ed.) *The Nuts and Bolts of Innovation: New Perspectives on Irish Industrial Policy*, Glasnevin Publishing, Dublin.

Ireland. This has driven me to pen the following polemic in rhyming verses: Industrial Policy? Profit switching transfer pricing/Mean multinationals are slicing/Tax revenues that we could get/Forcing underpaid into the net./So Ireland to win the day/Must call a stop and loudly say/All companies pay the same/Level play for a fairer game./We depend too much on the USA/If they change the rules their firms won't stay/And unemployment will be even worse/Than this attempt at rhyming verse./The message is that we should aim/To encourage local firms the same/As what we've done for all the rest/For Ireland's future, that's the best.

**Pat McArdle:** Many thanks to the authors for a timely and interesting paper. I would, however, have liked to see a greater focus on GNP given that GDP and related measures such as productivity have long been distorted by the activities of the multinationals. In the past, this distortion was upwards, more recently, the opposite has been the case. About 10 years ago, I produced a note based on stylised assumptions about the multinational sector. I found that, assuming all profits are repatriated, changes in output greatly affect GDP but have zero impact on GNP as long as there is no change in their domestic inputs. Given that the pharma cliff has been associated with declines in output but little change in employment that appears to be a reasonable description of the current situation. For as long as this persists, the fall off in pharma output will be a significant drag on GDP but GNP will be largely unaffected.

**Louis Brennan:** The paper presented tonight addresses the first order impact of drugs going off-patent for the pharmaceutical sector in Ireland i.e. the closure of the site producing the drug in Ireland. However, we need to appreciate that there can also be higher order impacts from this phenomenon. Corporations operating globally regularly assess the global configuration of their assets. For firms in the pharmaceutical sector, a trigger for such an assessment may be a drug going-off patent. While the drug going off-patent may not have been in production at the corporation's Irish site, the ensuing reconfiguration of their global assets may impact their Irish operations. Thus, the strategies pursued by corporations as they relate to the global configuration of their activities are an important consideration in any assessment of the likely trajectory of the Irish pharmaceutical sector. Understanding the determinants of such strategies in terms of such factors as changing product characteristics constraints and knowledge requirements is critical in the context of ongoing formulation of national industrial policy and its implementation.

**Martin O'Brien:** I welcome the Enright and Dalton paper, and note the reference made to corporation taxes, and how no effect from the patent cliff was evident in corporation tax trends. The very useful contribution from Michael Connolly on the sector specific value added, imports and profit trends highlights that profits had been reducing in line with the reduction in measured output. This was also consistent with the aggregate National Accounts and Balance of Payments data, where we have seen net factor outflows related to equity income reduce through 2013. It would be very useful to have tax data to allow a more comprehensive analysis of the contribution of the sector, particularly in the light of the variability of profits arising from the patent cliff.

**Brendan P. Ryan:** I also welcome this paper and congratulate the authors on it. I just have one or two questions. I wonder if the authors have tried to calculate the price elasticity of demand for pharma products. First, the ending of patent protection should lead to a reduction in price and consequently a rise in demand for the products. Thus the net negative impact on the volume of output of the product arising from patent expiry may be small. Second, it would be interesting to know the price elasticity of supply. When the patent expires one would expect the replacement or substitution of the patented product by a generic product containing the same active ingredient. To what extent do other producers enter the market delivering the same active ingredient at lower prices than the original patented product? Finally a comment: like others I wonder about the price deflators being used to estimate the impact of patent expiry on the volume of GNP.

**John FitzGerald:** This paper is extremely useful and it raises a number of important issues. The authors are correct in pointing out how the patent cliff is distorting the standard measures of productivity – defined as GDP per person employed, either at the level of the economy or at the level of manufacturing. It highlights the problems in using unit wage cost data to consider competitiveness. As a result, it is more appropriate to use relative labour costs in comparing the cost of labour in Ireland with competing countries.

It would be interesting to consider the factors that affect the price an incumbent should charge for its drug when it loses its patent. Because of the high cost of a plant to produce the drug and the cost of obtaining FDA approval there are barriers to entry. This should allow incumbents to charge a price for the generic which prevents entry but still delivers a continuing significant profit for the firm. However, this issue goes beyond the scope of this valuable paper.

The advent of the large cases unit in the CSO is very important. Because it tracks everything that goes into and out of a substantial number of very large companies it provides very important reassurance that we know what is happening in the current account. The absence of such an approach in the early 1980s meant that a large “black hole” developed in the balance of payments and this, in turn, contributed to major policy failures. This cannot happen today given the oversight provided by the large cases unit.

It would be helpful if, in future, the Revenue Commissioners published the breakdown of corporation tax by sector using the latest NACE classification. Also, it would be helpful if they could provide the breakdown at NACE two digit level matching the presentation in CSO National income and Expenditure Tables 31 and 32. The response by Michael Connolly was very useful in showing that the movement in the value added was correlated with movements in the value of exports but the imports of patents were not correlated. This suggests that the bulk of the effect of the ending of patents was felt on profits earned in Ireland, not on imports of patent royalties.

If the bulk of the effect of the ending of the patents was felt on profits of multinationals it will also have impacted on GDP. However, because there was little change in the wage bill the only effect on GNP will be the potential loss of corporation tax on the profits.

Using the numbers in Figure 11 of the paper a crude estimate can be made of the change in the impact of the sector on GNP between 2006 and 2011 when the GVA of the pharmaceutical sector rose from around 7% of the economy to peak at 12%. Over that period the wage bill appears to have been fairly stable at around 1.7% of GVA. Thus the profit margin rose from around 4.3% of GVA to around 10.3% of GVA, an increase of around 2.6 percentage points. However, even if all of that profit were taxable, the related increase in GNP would have been only 0.3 percentage points. Thus the fall in profits as a result of the ending of the patents will also probably have a pretty small impact on GNP. There is a danger that the effects on GDP/GVA and on profits will provide a distorted and exaggerated impact of the importance of the ending of the patents for the real Irish economy.