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Econometric Analysis of Biopharmaceutical Transfer Pricing

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> In this world nothing can be said to be certain, except death and taxes.
>
> Benjamin Franklin
>
> *A Founding Father of the United States, diplomat, scientist, inventor, writer*

Introduction

Interestingly, the above quote by Benjamin Franklin epitomizes in many respects the significant daily challenges faced by biopharmaceutical companies – to lengthen and improve the quality of life, while always facing the mortality of patients against increasingly challenging diseases, and at the same time engaged in pursuing this noble endeavor in a prudent economic fashion. This white paper goes outside the traditional boundaries of biopharmaceutical commercial analytics to explore a topic noted in the second part of Benjamin Franklin's quote – taxes. In particular, this white paper will explore the application of econometric analysis of biopharmaceutical transfer pricing, a direct result of differentials in cross-country corporate income tax rates. Given disparities in the US corporate income tax rate relative to other developed countries with major biopharmaceutical operations, this is a white paper that deserves your attention, and will guarantee not to "tax" you (pun intended).

Differentials in Country Corporate Income Tax Rates

British PM Theresa May recently came out with a plan to reduce the main UK corporate income tax rate to 17% by 2020 from its current rate of 20%.[1] The proposed reduction in the tax rate, in response to the Brexit vote and a policy effort to retain and attract corporate capital investment, will likely produce if enacted, greater tax rate competition among developed countries. Similarly, President-elect Donald Trump has made the US corporate income tax rate, the highest among OECD (Organisation for Economic Co-operation and Development) countries,[2] an economic policy issue. He has vowed to reform the corporate income tax structure that would encourage the repatriation of trillions of dollars of corporate profits being held by US company subsidiaries overseas due to the current tax liability that would be imposed if those profits were brought back to the US. Significant disparities exist in the combined statutory corporate income tax rate (the effective corporate income tax rate, the rate that is ultimately paid by companies, could be very different), by selected OECD countries (see **Table 1**).[2]

Table 1: Combined statutory corporate income tax rate by selected OECD countries in 2016 ranked in order from highest to lowest

Country	Tax rate (%)
United States	38.9
France	34.4
Italy	31.3
Germany	30.2
Australia	30.0
Japan	30.0
Canada	26.7
Israel	25.0
Netherlands	25.0
Spain	25.0
Sweden	22.0
Switzerland	21.2
United Kingdom	20.0
Ireland	12.5

Note: Tax rate rounded to one decimal point.

Source: OECD (Organisation for Economic Co-operation and Development).[2]

The question this white paper explores is the role that econometric analysis can play in understanding the degree of "transfer pricing" or tax shifting between countries that biopharmaceutical multinational companies (MNCs) can undertake to lower their tax liability. A subtheme demonstrated here and to be shown in future white papers is the expanding application of biopharmaceutical commercial analytics to a wider range of issues beyond sales, marketing, and market access areas as traditionally and currently practiced.

For biopharmaceutical MNCs, especially those that have their R&D operations outside the US and thus create intangible assets such as intellectual property, significant disparities in the corporate income tax rate have implications on the degree of transfer pricing engaged by firms. Simply stated, transfer pricing is applying tax laws that allow a portion of corporate net income from a country to be shifted to another location if it can be empirically shown that the source of that income portion was really produced outside the taxing country. For a simple example, say a biopharmaceutical company has R&D facilities in the UK responsible for the intellectual property (IP) product attributes of a drug sold in the US, and where those attributes are primarily responsible for drug financial success. There is then a significant economic incentive for the company to shift that portion of the US corporate income attributed to those IP attributes from the 38.9% US tax rate to the 20.0% UK tax rate, directly affecting the bottom line of the company. The issue then becomes an empirical study on measuring what portion of US corporate income is caused by IP attributes produced outside the US versus activities done domestically such as sales and marketing that may also contribute to drug financial returns.

Evidence and Importance of Biopharmaceutical Transfer Pricing

Is biopharmaceutical transfer pricing a significant issue worth studying? The answer is definitely yes, especially given the amount of financial returns achieved in the US on new drug launches and significant differences in cross-country corporate income tax rates as shown in **Table 1**. What does the literature and actual practice of tax law suggest? A general study of 286 publicly listed US MNCs from the 2006-2012 period found among an array of results that companies with multinational operations, tax haven utilization, and intangible assets engaged in significant transfer pricing aggressiveness.[3] A 2013 working paper empirically found

that European MNCs engaged tax shifting behavior and that changes in national country laws designed to limit transfer pricing reduced profit shifting activity.[4] The authors suggest such an outcome may be socially desirable, however that conclusion takes a myopic view of the consequences of tax rule changes. For biopharmaceutical firms, this conclusion does not take into account the broader implications of limiting transfer pricing and its impact on reducing financial returns used for R&D, subsequent adverse effects on product innovation, and thus future negative effects on health outcomes and cost effectiveness as previously reported in this white paper series. A 2016 empirical study on resource shifting behavior of US pharmaceutical firms found the following: 1) firms engaged in resource shifting behavior, 2) companies producing biologic drugs were less likely than other manufacturers to practice resource shifting to international affiliates, and 3) found no evidence that firms with intangible assets composed more on IP were more or less likely to engage in resource shifting.[5] The second and third conclusions may be the result of some US companies seeing the domestic R&D environment as more dynamic for the creation of biologic specialty medicines (as previously reported in this white paper series), thereby reducing the need to have R&D facilities outside the US and thus decreasing the incidence of resource tax shifting.

GSK in 2006 agreed to pay the IRS $3.4 billion in the largest transfer pricing dispute dating back to the tax years 1989 through 2005.[6] Other biopharma companies have found themselves entangled in transfer pricing disputes with the IRS over the years. The biopharmaceutical industry is increasingly focused on R&D efforts and new product launches towards specialty medicines as documented in this white paper series.[7] This means the commercialization of product attributes mainly due to IP on new novel drug therapies will likely increase, especially as companies focus on sales, marketing, and market access strategies geared toward disseminating scientific evidence of health/economic outcome benefits. The result will be biopharmaceutical MNCs increasingly focused on the tax treatment of intangible assets and navigation through the complexity of transfer pricing regulations in the future.[8] Governments looking to raise tax revenue will also be at odds with biopharmaceutical MNCs in believing that the proportion of net income caused by externally generated product attributes via research-based IP is far less than domestically-led activities such as traditional sales and marketing. The preceding discussion leads to addressing the main question, focusing on the US with the highest corporate income tax rate among developed countries and having the single largest biopharmaceutical market by value. How can econometric analysis help

biopharmaceutical MNCs with transfer pricing and provide defensible empirical evidence on what proportion of net income is subject to the US corporate income tax rate, with the other portion tax-shifted to the country where the IP was generated?

Econometric Analysis of Biopharmaceutical Transfer Pricing

The analytical approach taken to address this question is to develop a product-level market share model by therapy class among drugs seen as competing with one another using a panel data (pooled time-series and cross-sectional data) econometric design.[9] Biopharmaceutical panel data models are commonly applied in traditional commercial analytics and health economic outcomes research (HEOR). Whether it be for example, analyzing respectively a cross section of physician Rx activity, patient outcomes, or product performance each over time, panel data models are extremely rich in the insights they can afford the researcher for business policy. Another benefit, the total number of observations in a perfectly balanced set of panel data would be the number of cross section elements multiplied by the number of time elements (e.g., 12 would equal monthly data analysis). Therefore, the total regression model degrees of freedom become far less of an issue than strictly time-series or cross-section models, making the occurrence of small sample bias another less likely issue in panel data models. Also, statistical issues of multicollinearity or near-multicollinearity become less prevalent in such models since such patterns are less likely to exist between variables varying both over cross-section and time-series. Lastly, and on the other side, greater care must be undertaken to estimate panel data models given their complexity and statistical issues plaguing the analysis of either time-series and cross-section models that can now both exist in panel data models.

Given the preceding pros and cons of panel data models, the intent is to measure ultimately the effect of product-level attributes (those generated by IP) on market share relative to domestically generated sales, marketing, and market access activities. The measured proportions of product (drug) market shares attributed to IP versus non-IP factors would be the estimated percent of corporate net income that is tax shifted outside the US versus what is applied to the US tax rate respectively. The applications of the panel models explained here are significant for biopharmaceutical companies that derive US revenue from drugs where the development of intangible IP assets are developed outside the US in countries with a substantially lower corporate income tax rate.

Three econometric model designs can be applied to address this problem. Method (1) is a general biopharma panel data model that explicitly specifies variables that vary by cross-sectional and time-series elements. The goal here is to model directly those variables that are connected to varying drug IP-generated attributes, such as quantity and quality of FDA indications, side effect profile, dosing administration, pharmacokinetic and pharmacodynamic properties, etc. Method (2), specifically called a Covariance Model,[10] uses dummy variables to account for all cross-sectional and time-series variation that in turn will affect the intercept term. Method (3), specifically called an Error–Component Model,[11] is an extension of method (2) as a starting point that then addresses model (2) limitations where the error terms in the pooled data model may be correlated across time and individual product units. Below is the outline of the general econometric design for each approach.

General Biopharma Panel Data Model

(1) $Y_{pt} = \alpha_{pt} + \beta A_{pt} + \lambda B_{pt} + \gamma C_{pt} + \theta D_{pt} + \delta X_{pt} + \varepsilon_{pt}$

where,

Y = vector of product market shares

A = vector of product-level IP-generated attribute variables

B = vector of personal promotion (sales) variables

C = vector of non-personal promotion marketing variables

D = vector of market access-oriented variables

X = vector of other exogenous explanatory variables

p = product (cross-sectional) dimension

t = time (time-series) dimension (typically a month)

α = intercept term

$\beta, \lambda, \gamma, \theta, \delta$ = vector of non-stochastic parameters

ε = error term

Covariance Model

(2) $Y_{pt} = \alpha + \beta X_{pt} + \gamma_2 W_{2t} + \gamma_3 W_{3t} + \ldots + \gamma_N W_{Nt}$

$+ \delta_2 Z_{p2} + \delta_3 Z_{p3} + \ldots + \delta_T Z_{pT} + \varepsilon_{pt}$

where,

Y = vector of product market shares

X = vector of exogenous explanatory variables

W = vector of cross-sectional dummy variables

W_{pt} = 1 for the *p*th product, p = 2, . . . , N (N being the number of drugs in the therapy class)

0 otherwise

Z = vector of time-series dummy variables

Z_{pt} = 1 for the *t*th time period, t = 2, . . . , T (if monthly, T = 12)

0 otherwise

p = product (cross-sectional) dimension

t = time (time-series) dimension (typically a month)

α = intercept term

β, γ, δ = vector of non-stochastic parameters

ε = error term

Error–Component Model

(3) $Y_{pt} = \alpha + \beta X_{pt} + \varepsilon_{pt}$

$\varepsilon_{pt} = u_p + v_t + w_{pt}$

where,

Y = vector of product market shares

X = vector of exogenous explanatory variables

p = product (cross-sectional) dimension

t = time (time-series) dimension (typically a month)

α = intercept term

β = vector of non-stochastic parameters

ε = error term

$u_p \sim N(0, \sigma_u^2)$ = cross-section error component

$v_t \sim N(0, \sigma_v^2)$ = time-series error component

$w_{pt} \sim N(0, \sigma_w^2)$= combined error component

Econometric models (1) - (3) have varying pros and cons in their development and execution. The general biopharma model design (1) has the main advantage of understanding how specific cross-sectional product attributes and time-series elements affect market share. Thus the empirical results speak to an underlying theoretical causal structure of relationships. Potential disadvantages of this general modeling approach are as follows, though each issue can be significantly mitigated with proper care in following the right methodology:

- Assumes all key measures accounting for systematic variations in explaining product market shares by cross-section and time-series are available and well-defined. Since the US biopharma market is data rich in relevant variables captured through secondary data audits, this potential issue can be significantly mitigated. Product attribute measures can also be constructed from a variety of available sources.

- Requires the outlining of an empirical model based on *a priori* causal relationships developed from a theoretical structure, otherwise issues of specification error can occur. Again, this potential issue can be significantly mitigated given the wealth of published academic research papers and internally produced commercial studies on modeling the determinants of variations in biopharmaceutical product market share.

The Covariance Model design (2) requires less variable specification, however, there is a lumping of all effects at the cross-sectional and time-series levels into the respective set of product and time dummy variables. Thus the use of each set of dummy variables, though convenient, represents a lower causal understanding about the model. The application of dummy variables prevents the identification of what causes the regression line to shift over time and across products. So, the ease of estimation and less demands on variable measures and model specification comes at the cost of less key insights that may be important from a transfer pricing standpoint. There may also be some strictly cross-sectional elements, like for example, order-of-entry, that is not related to IP-generated product attributes. In addition, the specification of monthly time and product dummy variables uses a significant number of degrees of freedom (N+T–2) given the previous model outline. If for example, a therapy class have 8 products being studied by month, the degrees of

freedom taken away would be 18 (8+12-2), before including the set of exogenous explanatory variables.

The Error–Component design (3) allows for greater flexibility in assumptions about the error structure. Relative to the Covariance Model, an Error–Component design will generate unbiased and consistent parameter estimates, though the latter design is estimated using a form of generalized least-squares (GLS) regression and produces more efficient estimates than the Covariance Model process.[10] However, given that the error–component variance are not known in advance, a two-stage estimation process is required:[10]

- the first stage applies ordinary least-squares (OLS) regression is run on the entire pooled sample.
- OLS regression residuals are used to generate the sample estimates of the variance components.
- the second stage uses the estimated variances where GLS parameter estimates are obtained.

Finally, it is possible that the assumption in the general biopharma panel data model (1) of fixed-slope parameter estimates across products, time, or both combined can be relaxed. This development requires estimation using what is called random coefficient regression (RCR) models where the slope parameters are given a stochastic process.[12] The useful applications of these RCR econometric models to biopharmaceutical topics are left to a future white paper.

Conclusions

The shift to commercializing specialty medicines, where market performance will be predicated on the demonstration and delivery of scientific evidence, will mean the importance of intangible assets like IP will be fundamental to future biopharmaceutical financial success. The global nature and internal structure of biopharmaceutical MNCs means that the location of commercialization is often different from where IP-generated product attributes are developed. Therefore, understanding the financial implications of transfer pricing caused by differentials in cross-country corporate income tax rates can legally and significantly minimize individual country tax liabilities. The econometric analysis outlined here can also help generate greater drug financial returns that can be used to plow back into R&D, the future lifeblood of any biopharmaceutical company, especially given the increasing cost and risk of R&D for specialty medicines.[13] This white paper also demonstrates a different area not traditionally thought of where commercial analytics can be successfully applied for biopharmaceutical companies. Future white papers will explore other areas to expand the application of commercial analytics beyond traditional boundaries given changes in the biopharmaceutical external environment.

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George A. Chressanthis, Ph.D.
Principal Scientist
Axtria Inc.
300 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
Email: george.chressanthis@axtria.com

Contact Us

+1-877-9AXTRIA
info@axtria.com

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