Estimated biologic drug P-quad (Production Plus Profit Pricing) prices and resulting net discounts

Mark R. Trusheim, MSc, Peter B. Bach, MD, MAPP, Nancy L. Yu, MBA

March 15, 2021

Overview

Bach and Trusheim have proposed "Production Plus Profit Pricing" (or P-quad) for biologic drugs in the US once those drugs are beyond their FDA 12-year market exclusivity. P-quad prices would be based on "fully loaded" company-reported manufacturing costs (so as to include capital costs and depreciation), reported distribution expenses, and a profit substantial enough to make continued investment in production and distribution appealing for the firm.

In order to estimate the potential financial impact of P-quad, we estimated the prices that the P-quad reporting-based approach would generate using two approaches. Then, we converted these prices into discounts from current net prices and constructed a conservative range: a 65% to 75% discount from net price. This range is intended to provide an overall sense of potential net price changes that could occur as a result of P-quad.

Method 1: Income statements of established biotech companies (Table 1):

Costs of production were estimated from 2019 annual financial reporting of 'costs of goods sold' (COGS) for established public companies that derive most of their revenues from biologic drugs. For each company, we abstracted the COGS, added to it a distribution cost that we estimated to be half of the reported SG&A, and then added either a 10% or 20% profit. We took this to be the P-quad price and evaluated it with respect to company revenue to determine what the 'discount' from net price would be.

Table 1: Income statement approach, the average discount from net price ranged from 74.0%–76.2 %

Company	Discount from current net price	
	Profit 10%	Profit 20%
AbbVie[1]	69.6%	66.8%
Amgen[2]	73.5%	71.1%
Biogen[3]	76.1%	73.8%
Regeneron[4]	85.7%	84.4%
Average	**76.2%**	**74.0%**

Method 2: 'Bottom up' approach from industry reports of cost of production (Table 2):

For three exemplar biologic drugs—Herceptin, Remicade and Xolair—we estimated the cost of manufacturing their Active Pharmaceutical Ingredient (API) based on reports of per gram costs from industry sources.[5,6] We doubled formulation of drug product to account for fill and finish, added a 30% shipping and distribution cost, and a lower (10%) and upper (20%) bound profit margin (Appendix, Table 2A-3B). These constituted the P-quad prices that we compared against the Average Sales Price (ASP) for the drug in the first quarter of 2021.[7] (Table 2)

Table 2A: 'Bottom up' approach, the average discount from net price ranged from 79.9% to 92.2%

Drug	Discount from current net price			
	Lower estimate of production cost*		Higher estimate of production cost**	
	Profit 10%	Profit 20%	Profit 10%	Profit 20%
Herceptin	94.6%	94.4%	86.4%	86.1%
Remicade	88.2%	87.9%	70.4%	69.7%
Xolair	92.9%	92.7%	82.2%	81.8%
Average	**92.2%**	**91.9%**	**80.3%**	**79.9%**

**Based on $200 per gram*
***Based on $500 per gram*

Conservative nature of calculations: We aimed to be conservative in our modeling, and so in both the calculation of P-quad prices and the range selection of the discount from net prices we favored decisions that would lessen the anticipated savings. These decisions included the following:

a. Rounded down the lower bound – 66.8% to 65% (Table 1) – of the 65% to 75% range of discounts we calculated – By doing so we compensated for the fact that we focused on large biotech companies for our income statement method, while smaller biologic companies may have less favorable margin structures. In addition, we round down the lower bound to account for potentially underestimated costs.
b. Used worldwide revenue from income statements, which are based on lower average unit prices than US revenue alone – By applying a discount to that worldwide number in Method 1 we underestimated the discount P-quad would constitute from US net prices.
c. Included subset of high volume biologics exhibiting low pricing pressure – Pricing variability exists among biologic products and across therapeutic areas. We included biologics that qualified as high-volume products and products that have yet to see effects of pricing pressure.
d. Applied 20% profit margin – The upper end profit margin we applied of 20% is greater than the profit margins of most industries, including the originating drug industry itself (Table 3).

Table 3: Average profit margins by industry

	Net Margin (Annual TTM)
Total Market	7.8%
Major Drugs	13.9%
Tobacco	9.4%
Medical Equipment & Supplies	11.3%
Steel Industry	0.9%
Aluminum	0.8%
Electric Utilities	8.2%
Natural Gas Utilities	10.5%
Water Utilities	15.7%
Chemical Manufacturing	7.0%
Chemicals plastics & rubber	1.9%
Paper and Paper Products	5.7%
Semiconductors	19.6%
Oil & Gas Production	4.0%
Aerospace	6.1%

For Q4 2019, adapted from:
https://csimarket.com/Industry/industry_Profitability_Ratios.php

e. Our estimated discount range of 65% to 75% from US net prices under P-quad pricing is less than 80%+ discounts seen in a handful of European markets for specific products following biosimilar entry. These larger discounts, off lower European starting prices, implies that firms can be profitable at prices lower than our modeled 65% discount off of current US net prices.[8-10]

Appendix.

Table 1. COGS-Based Estimates, per gram

COGS Based Estimates, per gram and Sources	
Gutierrez Thesis[5]	**$200**
Merck Millipore Graph in Tufts Report[6]	
Low	$100
Mid	$250
High	**$500**

Lower Bound 10%-Profit Margin Scenario

Table 2A. COGS Based Target Price Estimate, 10% Profit Margin

COGS Based Target Price Estimate	Lower Production – Gutierrez	Higher Production – Merck, High
API cost per g	**$200**	**$500**
Drug Product and Fill and Finish, 100%	$200	$500
Product COGS	$400	$1,000
Shipping, 30% of COGS	$120	$300
Total cost	$520	$1,300
10% Profit, as % of Cost	$52	$130
Target Price per gram	**$572**	**$1,430**

Upper Bound 20%-Profit Margin Scenario

Table 2B. COGS Based Target Price Estimate, 20% Profit Margin

COGS Based Target Price Estimate	Lower Production – Gutierrez	Higher Production – Merck, High
API cost per g	**$200**	**$500**
Drug Product and Fill and Finish, 100%	$200	$500
Product COGS	$400	$1,000
Shipping, 30% of COGS	$120	$300
Total cost	$520	$1,300
20% Profit as % of Cost	**$104**	**$260**
Target Price per gram	**$624**	**$1,560**

Lower Bound 10%-Profit Margin Scenario

Upper Bound 20%- Profit Margin Scenario

HERCEPTIN

Average mg per dose, 10 mg

Indicated for RA, Psoriatic Arthritis

Table 3A. Herceptin Discount Calculation with 10% Profit

	Lower Production	Higher Production
Calculated Target Price per 10 mg dose	$5.72	$14.30
2021 ASP per dose	$97.92	$97.92
Target Price as % of 2021 ASP	6%	15%
Discount from 2021 Price	**94.2%**	**85.4%**

Table 3B. Herceptin Discount Calculation with 20% Profit

	Lower Production	Higher Production
Calculated Target Price per 10 mg dose	$6.24	$15.60
2021 ASP per dose	$97.92	$97.92
Target Price as % of 2021 ASP	6%	16%
Discount from 2021 Price	**93.6%**	**84.1%**

REMICADE

Average mg per dose, 10 mg

Indicated for RA, Psoriatic Arthritis

Table 4A. Remicade Discount Calculation with 10% Profit

	Lower Production	Higher Production
Calculated Target Price per 10 mg dose	$5.72	$14.30
2021 ASP per dose	$44.90	$44.90
Target Price as % of 2021 ASP	13%	32%
Discount from 2021 Price	**87.3%**	**68.2%**

Table 4B. Remicade Discount Calculation with 20% Profit

	Lower Production	Higher Production
Calculated Target Price per 10 mg dose	$6.24	$15.60
2021 ASP per dose	$44.90	$44.90
Target Price as % of 2021 ASP	14%	35%
Discount from 2021 Price	**86.1%**	**65.3%**

XOLAIR

Average mg per dose, 5 mg

Indicated for RA, Psoriatic Arthritis

Table 5A. Xolair Discount Calculation with 10% Profit

	Lower Production	Higher Production
Calculated Target Price per 5 mg dose	$2.86	$7.15
2021 ASP per dose	$37.42	$37.42
Target Price as % of 2021 ASP	8%	19%
Discount from 2021 Price	**92.4%**	**80.9%**

Table 5B. Xolair Discount Calculation with 20% Profit

	Lower Production	Higher Production
Calculated Target Price per 5 mg dose	$3.12	$7.80
2021 ASP per dose	$37.42	$37.42
Target Price as % of 2021 ASP	8%	21%
Discount from 2021 Price	**91.7%**	**79.2%**

References

1. AbbVie Inc. 2019 Annual Report on Form 10-K. 2020. Accessed from https://investors.abbvie.com/static-files/71f9318f-9a32-42ee-92ee-a34975edcd19
2. Amgen Inc. 2019 Letter to Shareholders. 2020. Accessed from https://investors.amgen.com/static-files/d45cb739-9637-4e13-856c-e2fc29571032.
3. Biogen Inc. 2019 Annual Report. 2020. Accessed from https://investors.biogen.com/static-files/f86236ee-b489-461e-bb28-b7b4ccc4aeea.
4. Regeneron Inc. 2019 Annual Report. 2020. Accessed from https://investor.regeneron.com/static-files/cbebda5b-c02d-466b-8be9-e0d8a4052cf8.
5. Gutierrez, BJ. Financial Analysis of Biosimilar Development Candidates: A Case Study on the US Biosimilar Business. (Master's thesis, Harvard Extension School). 2015. Accessed from http://nrs.harvard.edu/urn-3:HUL.InstRepos:24078352.
6. Baaj A, Kaitin K, Serebrov M. Manufacturing Strategy for Diverse Biologic Pipelines of the Future. White Paper, Tufts Center for the Study of Drug Development. 2017. Accessed from https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5aa2ff8953450a815ebf3377/1520631693367/Manufacturing-WP-2017.pdf.
7. Center for Medicare and Medicaid Services. Medicare Part B Drug Spending Dashboard. Accessed on January 16, 2021. Accessed from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.
8. Sagonowsky E. AbbVie offers up 80% Humira discount in EU tender market to hold off biosimilars: report. FiercePharma. Accessed January 15, 2021. Accessed from https://www.fiercepharma.com/pharma/abbvie-offers-up-80-humira-discount-eu-tender-market-to-hold-off-biosims-report.
9. Silverman E. AbbVie offers a 'huge' discount on Humira to fend off European rivals. STAT News. 2018. Accessed January 15, 2021. Accessed from https://www.statnews.com/pharmalot/2018/11/01/abbvie-humira-biosimilars-prices/.
10. Gal A. Biosimilars (December update): US B&B market for oncolytics launch; EU pricing in 3Q (-70%); Herceptin vs Rituxan SC. Bernstein Analyst Report. 2019. Accessed on January 15, 2021.