

BEYOND INTERNATIONAL PRICING INDEX MODEL IN THE UNITED STATES – IMPACT TO GLOBAL PRICING STRATEGIES & ACCESS TO INNOVATIVE MEDICINES

AUTHORS

Svitil P¹, Milosic R¹, Paris M¹, Mlcoch T², Dolezal T²

¹ COGVIO, Prague, Czech Republic,

² VALUE OUTCOMES, Prague, Czech Republic

Background

International Pricing Index (IPI) model has been proposed in the United States (US) with the aim to reduce Medicare Part B medicines expenditures. IPI model may introduce the external reference pricing (ERP) mechanism to the US market during 2020.

The proposed IPI model reference basket (RB) from October 2018 consists of 14 countries (AT, BE, CA, CZ, DE, DK, FI, FR, GR, IE, IT, JP, NL, UK). The final price would be determined based on the ratio between spending under the US Average Sales Prices (ASP) and the average of medicine prices from the IPI basket. [1]

IPI model countries frequently use ERP mechanism to regulate prices, i.e. referencing to other IPI or "non-IPI" countries and thus creating an interconnected ERP environment.

Objectives

To create a model of a new ERP environment with the following objectives:

- Analyze the average price ratio between the US and IPI model countries
- Analyze the potential indirect impact of price drops in the non-IPI countries to the average price in the US via the IPI model
- Describe the potential US price erosion mechanism

NOTE: The criticism of the IPI model from the US conservative groups side in terms of negative impact on medicine innovations in the US was out of the scope of this work. [2]

Methodology

Price ratio

A sample of 25 active molecules was defined for the analysis based on the following rules:

- set of Medicare Plan B medicines with the highest sales price per unit in 2018 [3]
- AND medicine is authorized in Europe [4], Japan [5] and Canada [6]

Ex-factory package level prices were extracted in **Cogvio Price Monitor** in March 2019 (aggregated database covering EU publicly available sources of medicinal product prices – MoHs, NCAs and other). Subsequently, the ratio of **US price to average unit price from the IPI basket** was calculated. Analysis of prices was performed in EUR (exchange rates – March 2019). The potential bias of biosimilarisation/generification of markets was neglected as the model should represent the potential real situation at the time of the IPI model implementation.

IPI ERP model

A model of the new ERP environment has been developed. The model encompassed:

- Countries
 - The US, also called the "master" country
 - Primary countries, i.e. IPI model basket countries
 - Secondary countries, i.e. all countries referenced by primary countries
- ERP Rules
 - US IPI model – an average of prices from the proposed IPI basket countries
 - Rules for IPI model countries – a systematic search for national regulations was performed in March 2019 and the model was created based on the results (Note: the simplified model did not consider the difference in frequency of price revisions for each country)

Price drop simulation

The following simulation was performed using the created ERP model:

- An equal initial price was set for a virtual medicine in all countries included in the model
- Drops from -10% to -90% (with 10% increments) in ex-factory price of the medicine were simulated in each secondary country individually
- External price referencing was performed for all of the primary countries
- The US referenced the countries in its IPI reference basket
- The impact of price drops in countries was measured as a change in the original US price in percents

Results

Price ratio

25 active substances with 54 unique packages were included in the analysis. Figure 1 shows the price ratio between the US and average

IPI basket package prices per active substance ranged from 1.0 (daptomycin and idarucizumab) to 4.6 (adalimumab) with average 2.3 for the US (i.e. 2.3-higher prices than in the IPI basket).

IPI ERP model

IPI basket countries (12 EU countries + Canada + Japan = 14) reference to a pool of 18 non-IPI countries, all of them inside the EU geographical region. The interconnected ERP environment of IPI and non-IPI countries is visualized in the matrix in Figure 2. The rightmost column represents the total number of countries in the basket. The bottom row represents the total number of times each country is referenced by other countries.

A network representation of the IPI countries baskets is shown in Figure 3-A. 5 IPI countries do not have any non-IPI countries in their basket (or they do not use the ERP system, such as value-based pricing countries – UK, DE, SE). The leftmost nodes in the network represent all non-IPI countries referenced by the IPI basket. The number of times each country is referenced is marked on the left of the nodes.

Figure 3-B shows the interconnectedness of countries inside the IPI basket. The numbers attached to the nodes represent the number of times each IPI country is referenced by other IPI countries.

Price drop simulation

Figure 4 shows the relationship between the price drop size in a secondary country individually (in percent) and the US price after referencing. The simulation showed that from the EU countries not included in the US IPI proposal, Spain and Sweden had the greatest impact on the US price at all levels of price drops. Norway and Switzerland were omitted from the figure since they had less than 1% impact on the US price across all levels of price drops.

Discussion

Pharmaceutical companies may adjust their global pricing strategies to maximize revenues due to the interconnected ERP environment. Experience shows larger and economically stronger markets to be of higher priorities for access. [8] [9] As a consequence, traditional "low priority markets" in EU which are frequently referenced by the IPI model reference countries may experience additional delayed patient access to innovative medicines if they represent a potential "harm" to global revenues.

11 out of 14 IPI countries come from the top 15 EU region countries ranked by GDP per capita in PPP (Int\$). Sweden and Spain are the only two non-IPI countries from the top 10 EU countries by GDP per capita in PPP (Int\$), not included in the proposed model. At the same time, Spain has the highest population size from non-IPI countries, which makes it less likely to experience an additional delay, despite the finding of our analysis. On the other hand, Sweden has the highest GDP PPP (Int\$) from non-IPI countries, however, it's population size is almost 5-times smaller than that of Spain.

Conclusions

The measured ratio of the US to the average IPI basket price on the selected sample showed medicines to be 2.3-times more expensive in the US – results are consistent with other available analysis [7]. The IPI proposal intends to curb the ratio and alleviate the spending on expensive medicines in the US. The IPI model is designed to be rolled out in 5 years, each year increasing the reliance on the IPI calculated price [1].

Our model of the interconnected ERP environment and subsequent simulation proved and quantified the impact of non-IPI countries (those referenced by the proposed IPI model countries) to US prices. Spain (the only EU5 country not listed in the IPI model) and Sweden have the biggest potential to indirectly impact the US in our simplified model. 7 other countries with potential impact are Portugal, Hungary, Slovakia, Lithuania, Poland, Latvia and Slovenia (referenced by 5 IPI basket countries).

Pharmaceutical companies may adjust their global pricing strategies with a consequent delayed patient access to innovative medicines both in IPI and non-IPI countries.

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Figure 1 – Ratio for the US to average IPI basket prices for analyzed 25 active substances

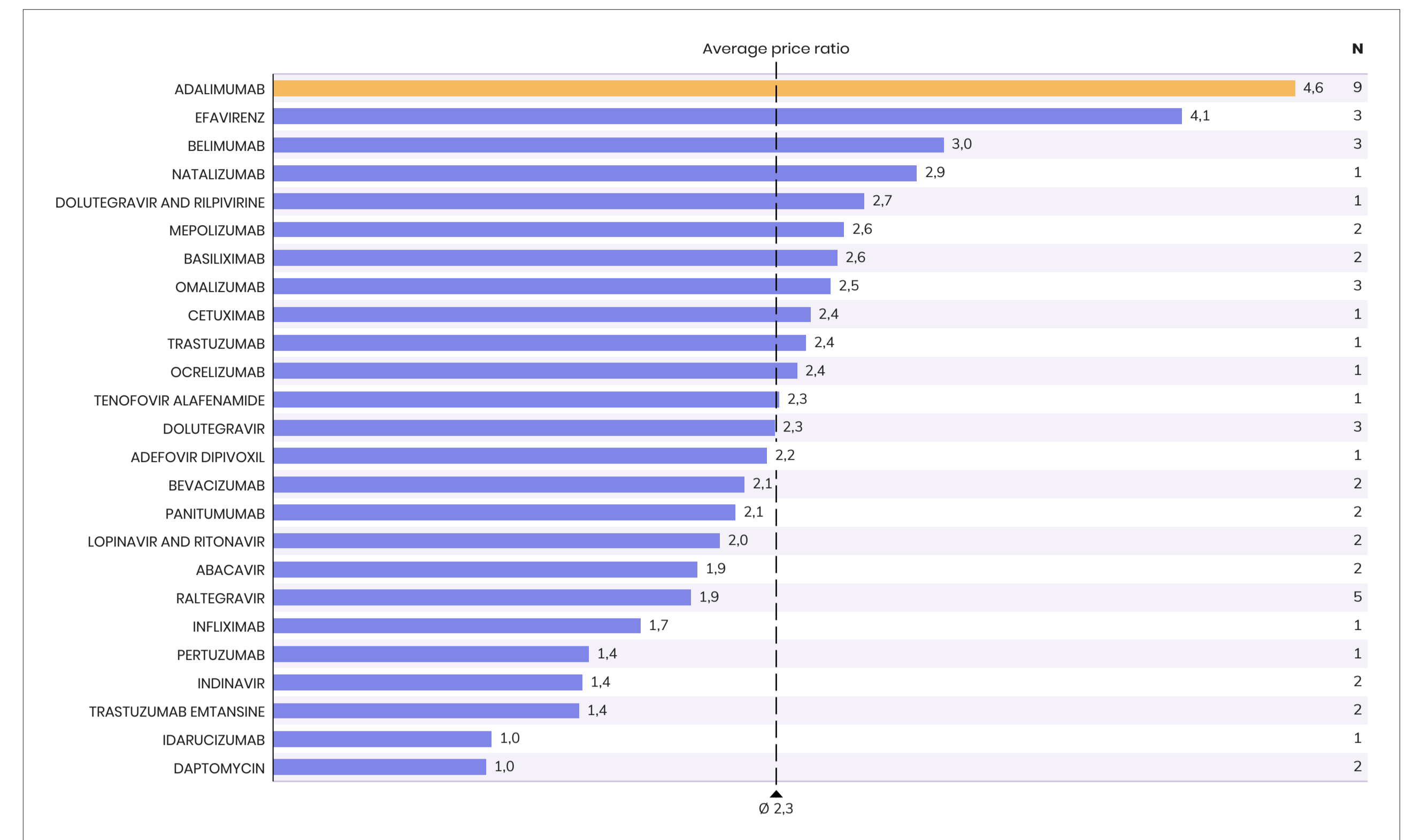


Figure 2 – Basket matrix for the US, IPI and non-IPI model countries

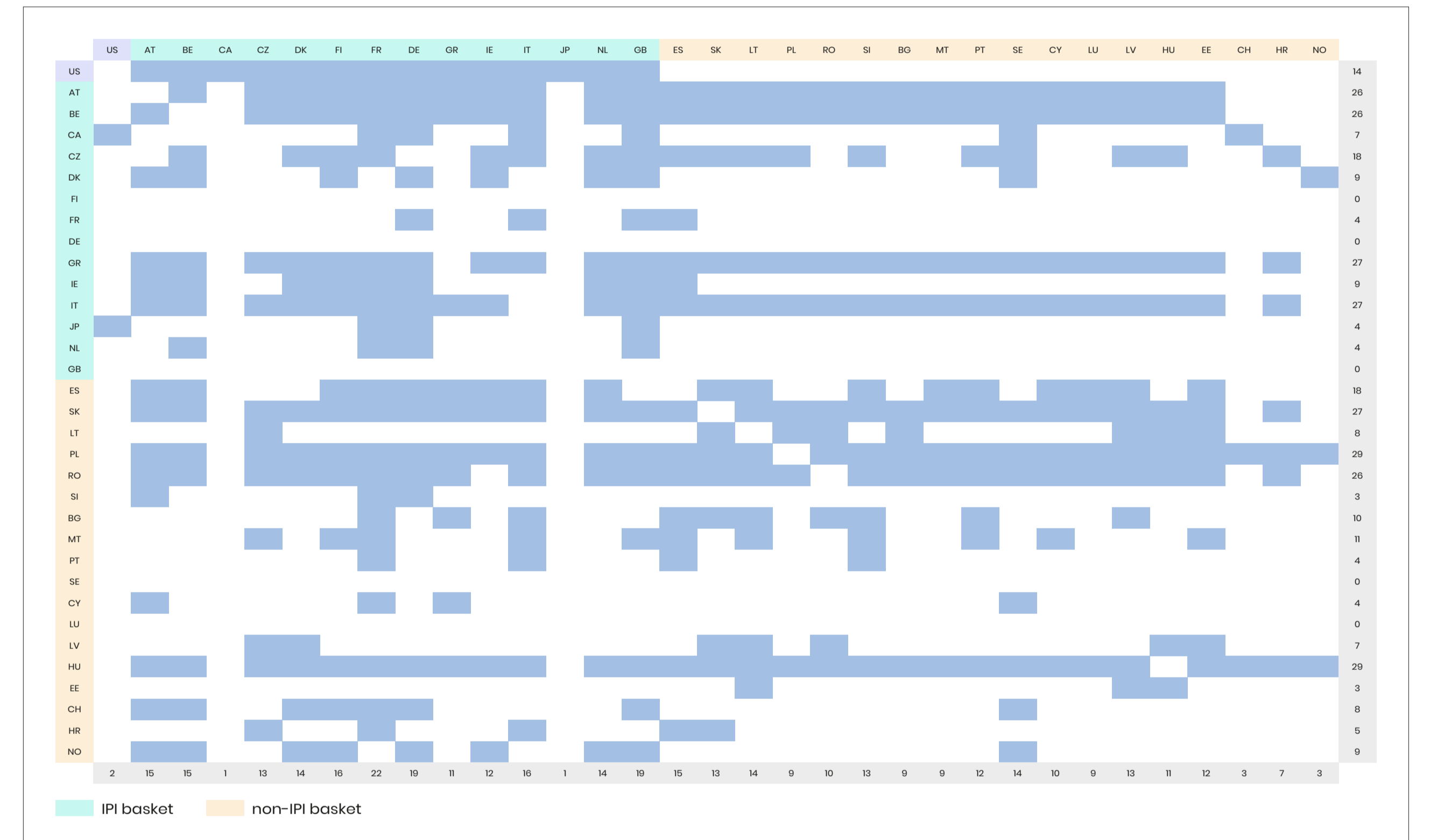


Figure 3 – IPI model network analysis

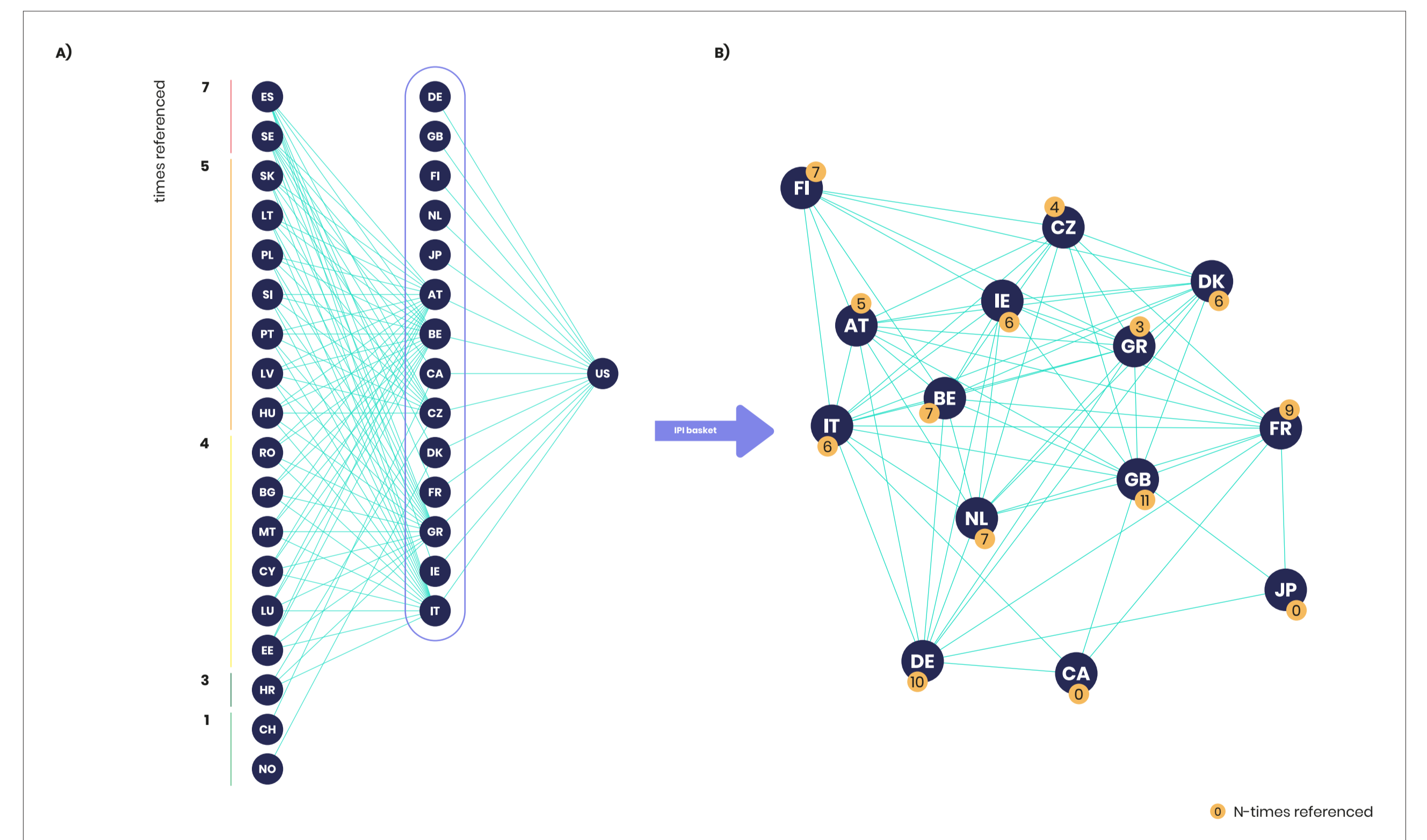


Figure 4 – Impact of a price drop in non-IPI countries on the US price

