Memo

On Pharmaceutical Industry Competitiveness

Nov 2023

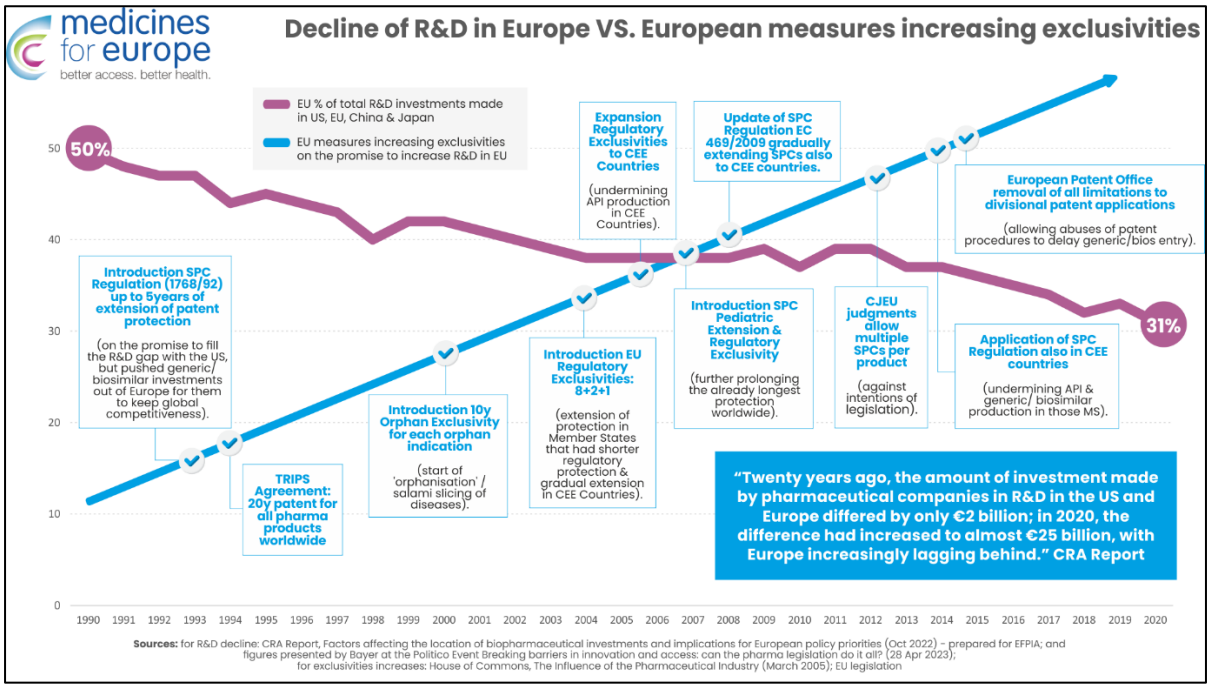
The impact of Intellectual Property and regulatory protections on R&D industry

There is no doubt on the fact that the EU pharmaceutical legislation reform, including the parts on exclusivity protections, will not necessarily undermine the competitiveness of the EU pharmaceutical industry. This is widely recognised by all independent studies and by the European Commission itself.

The decline in global competitiveness of the European pharmaceutical sector in R&D is not related to intellectual property erosion since, as demonstrated in the graph below (Table 1), **the EU has consistently increased regulatory incentive and IP monopolies since the 1990s. Each new IP or regulatory protection** (product patents under TRIPs, SPCs, the world's longest regulatory and market exclusivities, orphan exclusivity, paediatric exclusivity and SPC extension, etc.) **was introduced with the stated objective to make Europe the world leader in R&D innovation.**

Yet this ratcheting up of monopoly protections corresponds *exactly* with Europe's relative R&D decline compared to China and the US. This shows that **the claim '*more monopoly leads to more R&D*' is false**.

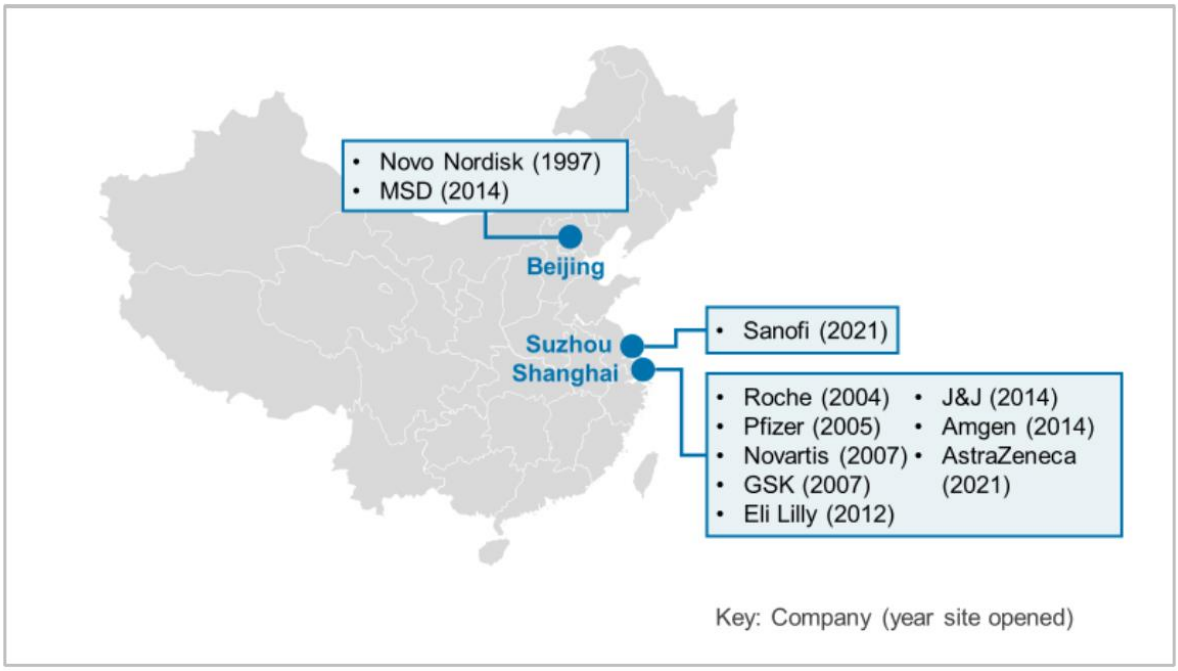
Table 1: *Decline of R&D in Europe VS. European measures increasing exclusivities*



Indeed, a Charles River Associates (CRA) Report of 2022 (commissioned by EFPIA and from which the declining line of R&D investments in Table 1 derives) also shows the **investments made by originator pharmaceutical companies in China since 1997**, *ie*. the period of the implementation of the strongest protection (*ie*. the Supplementary Protection Certificate) introduced in Europe on the promise of more R&D investments in the EU (see Table 2 below). It is worth underlining that **China, as denounced for decades by the originator industry, until a couple of years ago has been one of the countries with the lowest IP and regulatory protection system**. **This confirms that IP protection in a certain region has no influence on R&D investments in that region**.

Table 2: ***The R&D investments in China by the large multinational pharma companies***

Figure 11: The majority of large multinational pharmaceutical companies now have an R&D centre in China

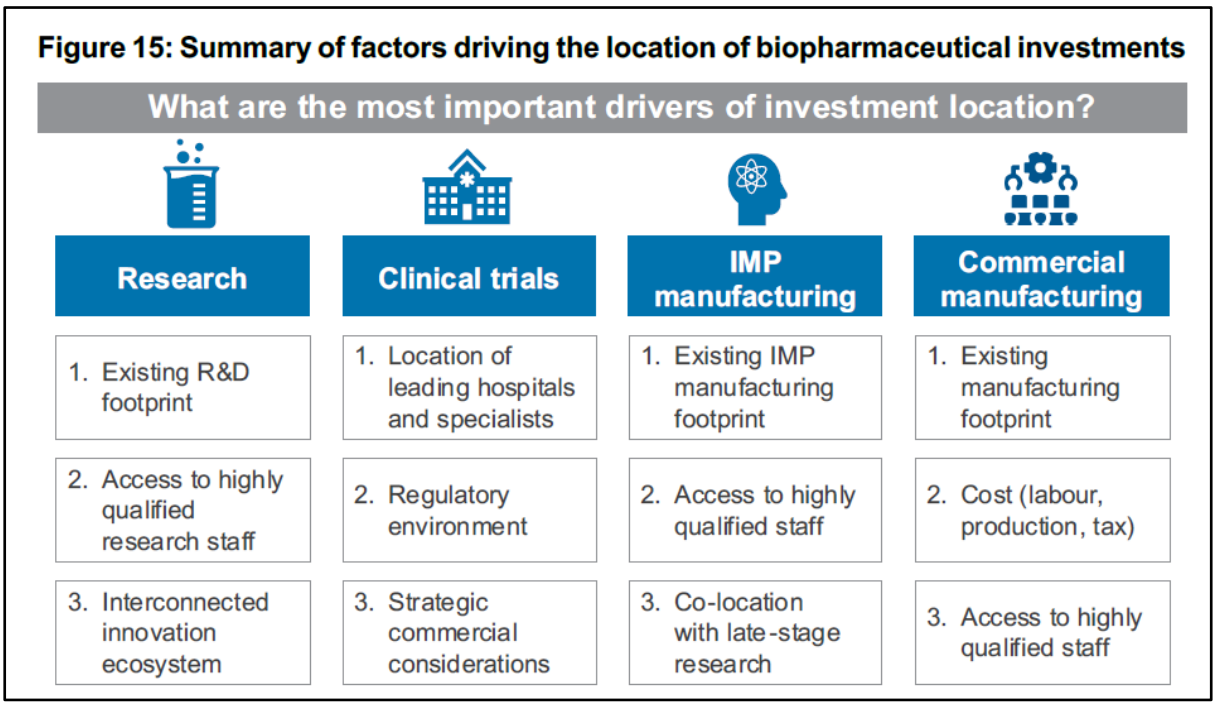


Sources: CRA Report, Factors affecting the location of biopharmaceutical investments and implications for European policy priorities (Oct 2022) - prepared for EFPIA

The same CRA Study even presents a table summarizing the factors driving localization of R&D investments, which obviously do not include intellectual property rights (see Table 3).

Table 3: *Summary of factors driving localization of R&D investments from CRA study prepared for Efpia (page 51)*

Figure 15: Summary of factors driving the location of biopharmaceutical investments



Very recently, a new study commissioned by EFPIA has underlined "*a trend which has already seen Europe lose a quarter of its global R&D investment in the last 20 years*", with ***"€2 billion in lost R&D investments each year***".

Such a forecast seems to be perfectly in line with the originator industry choice to invest out of Europe.

The impact on the generic and biosimilar medicines industry

To make matters worse, **these monopoly measures introduced in Europe since 1993 have directly contributed to the delocalisation of medicine manufacturing outside of Europe**, which explains the EU's efforts to correct this with reforms such as the SPC manufacturing waiver or the Bolar exemption. It is important to note that before such a forced delocalisation, Europe was a world leader in the development and production of Active Pharmaceutical Ingredients (API).

In contrast, **policy measures that have stimulated competition from the off-patent sector have fully delivered on their promise**.

Generic licencing rules have stimulated much needed competition, doubled access to medicines in Europe and reduced pressure on healthcare budgets.

Biosimilar licencing rules have made Europe the global leader in this technology and driven substantial investment in EU biologic manufacturing.

It is therefore imperative that the Pharmaceutical Strategy for Europe continues to foster this sector, which is employing all the efforts to actually invest in Europe.

The (independent) Competitiveness Check made by the European Commission

This European Commission Impact assessment of the pharmaceutical legislation underlines (page 43) that

> *"[a] direct link between EU incentives and EU competitiveness is hard to establish because* ***while the incentives make the EU markets more attractive, they are agnostic to the medicines' geographical origin****. Around 20% of new medicines authorised in the EU are from the EU, the others are mainly from US, UK, Switzerland and Japan that are equally eligible to all EU incentives. Equally EU based innovative companies can benefit from incentives elsewhere, if they sell their products there. In June 2016, the Council requested the Commission to conduct an evidence-based analysis of the impact of incentive mechanisms, notably SPCs. Two studies have been commissioned. One from Max Planck Institute[1] questions whether the availability of patent or SPC protection affects companies' decisions to locate research facilities in one jurisdiction or another,* ***emphasising that other factors are likely of greater importance****. The Copenhagen Economics study[2] argued that SPCs could play a role in attracting innovation to Europe,* ***pointing out that taxation, education, and other factors are probably more significant in that respect****." (Emphasis added)*

In relation to SMEs, the Impact assessment states: (page 60)

> *"In terms of effect on competitiveness,* ***the proposed incentives do not make a geographic distinction, they equally offer regulatory protection for products developed in the EU, or anywhere in the world*** *which ensures a level playing field between EU-based and third country-based companies. While the EU regulatory framework is attractive for developers,* ***competitiveness also depends on many other factors e.g. tax system and incentives; available grants, loans and other funding (e.g. the European Innovation Council Accelerator); pool of talents; proximity of top academia; clinical trials infrastructures; market size; security of supply chains; favourable reimbursement decisions****." (Emphasis added)*

[1] Max Planck Institute. Study on the legal aspects of supplementary protection certificates in the EU, 2018.
[2] Copenhagen Economics. Study of the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards, 2018.