

DAMBOIS Denis (GROW)

From: DOMANICO Fabio (EMPL)
Sent: jeudi 17 janvier 2019 10:50
To: DAMBOIS Denis (GROW)
Subject: FW: Case Studies _ IP incentives _ EuropaBio
Attachments: Case studies_IP Incentives_EuropaBio.docx

From: [REDACTED] <[REDACTED]@europabio.org>
Sent: Monday, August 7, 2017 11:03 AM
To: DOMANICO Fabio (GROW) <[REDACTED]@ec.europa.eu>
Cc: Donald Legar <[REDACTED]@europabio.org>; David Marchi <[REDACTED]@europabio.org>
Subject: Case Studies _ IP incentives _ EuropaBio

Dear Mr. Domani,

As requested, please find in attachment several case studies of pharmaceuticals whose research and development have benefitted from the available set of IP incentives in the EU.

We would also like to note that molecules are patented early in the development process, when no one can tell whether a medicine will eventually show to work in humans and be safe or be more efficacious than the existing medicines. As it takes at least 10-15 years to bring a new discovery through clinical trials and marketing to authorisation, the effective term of protection is much less than 20 years from the filing of the patent. Additional schemes, such as SPCs, are therefore crucial to incentivise companies (and investors in general) to bring these medicines to market via all the expensive regulatory compliance trials.

It is noteworthy, that for case studies 3 and 4, the existing set of IP incentives was not sufficient to bring these European discoveries to market (neither BioVex nor Micromet succeeded in getting sufficient funding to bring these first-in-class molecules to market, even with the current set of incentives). Consequently, if the current set of incentives are insufficient, then reducing them will only constrain and limit further medicines development in the EU.

At EuropaBio, we are convinced that the reduction or 'recalibration' of IP incentives, including SPCs, would damage the overall model encouraging the investment in R&D for pharmaceuticals. The patented inventions of today pay for the research and development of the new medicines of tomorrow. If, by "access to medicines" we include access to future medicines, to medicines yet to be invented, proved and developed, it is more than dangerous to interfere with the major source of funding for these future medicines.

We remain at your disposal should you have further questions regarding the case studies in attachment.

Best regards,

[REDACTED]



EuropaBio - The European Association for Bioindustries

Avenue de l'Armée 6, 1040 Brussels

+32 2 719 11 70 | +32 2 719 30 30

www.europabio.org