

Value of IP for health and growth

The economic benefits of strengthening the innovation environment in South Korea

MAY 2023



KEY FINDINGS

Executive summary

BACKGROUND AND OBJECTIVES

INTERPAT asked Charles River Associates (CRA) to identify and quantify the economic benefits from strengthening the environment for innovation in South Korea.

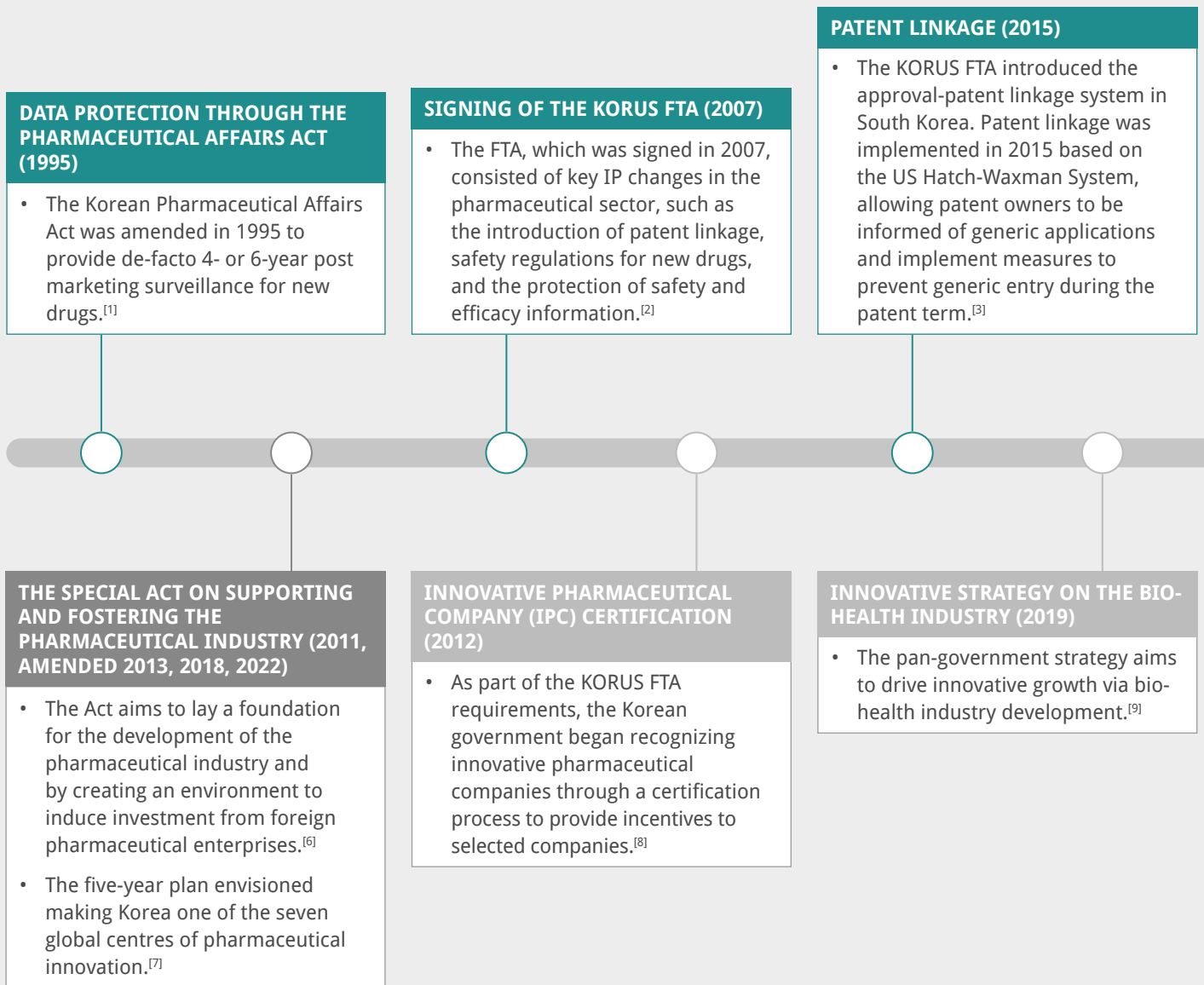
The objective of the study is to:

1. Set out the policy **framework** for supporting innovation in South Korea and the current state of innovative activity
2. Undertake a **case study analysis** on countries with potential lessons from other countries which may represent an opportunity for South Korea
3. Develop **scenarios** as to how innovative activity could change in South Korea, if policies adopted in other countries were pursued

The approach builds on a similar analysis applied to countries in Latin America (Argentina in 2018, Brazil in 2019, Mexico in 2020, Colombia in 2021) and in China in 2022/2023

POLICY ENVIRONMENT SUMMARY: LEGISLATION TIMELINE

CHANGES IN THE IP REGIME



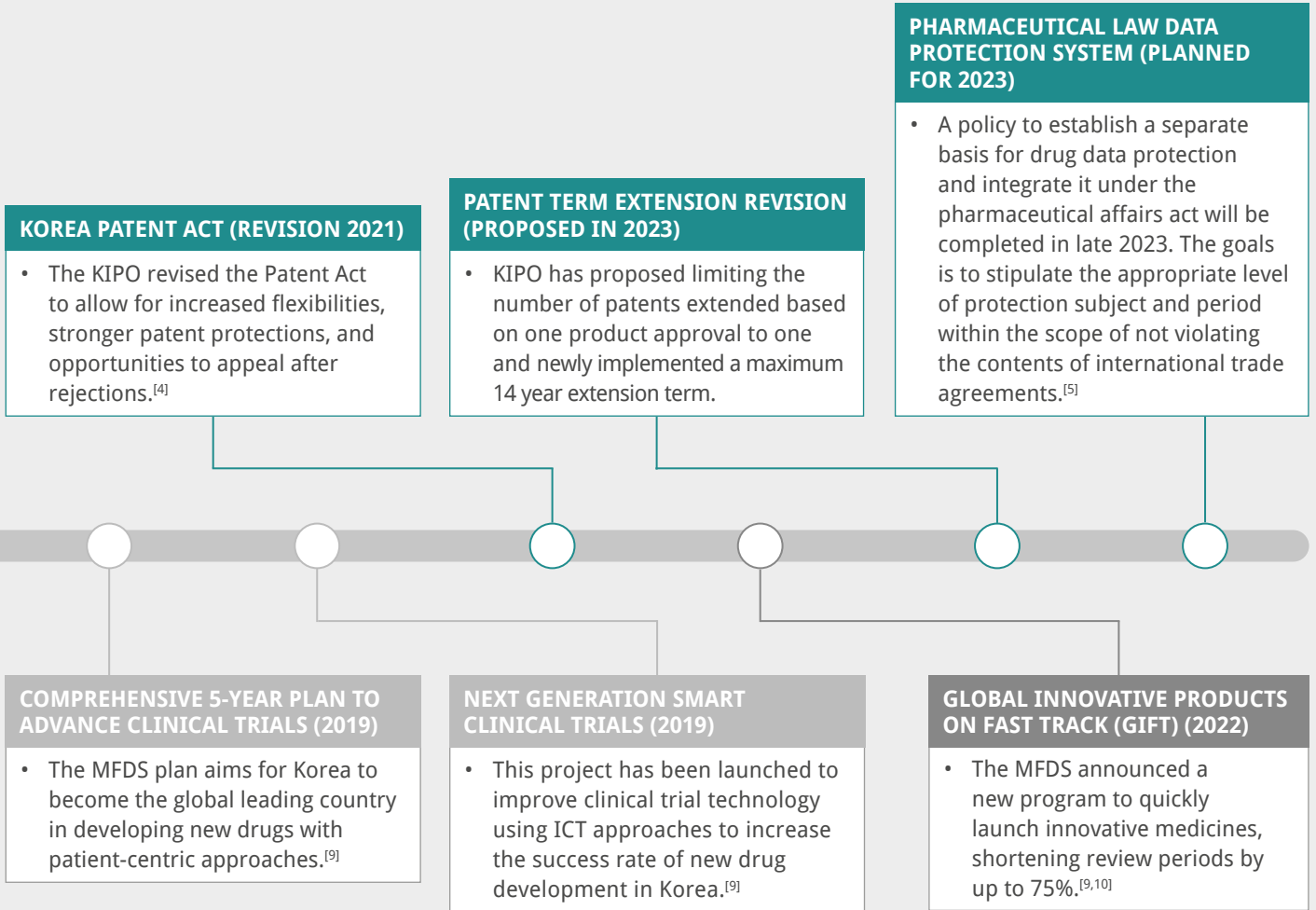
CHANGES IN INNOVATION POLICY

^[1] KLRI (2016). PHARMACEUTICAL AFFAIRS ACT. Available at: https://elaw.klri.re.kr/eng_service/lawView.do?hseq=40196&lang=ENG

^[2] Thomson Reuters Practical Law (2011). "Impact of the South Korea-US Free Trade Agreement on the Korean pharmaceutical industry". Available at: [https://content.next.westlaw.com/0-518-2090?_lrTS=20210901050417924&transitionType=Default&contextData=\(sc.Default\)&firstPage=true](https://content.next.westlaw.com/0-518-2090?_lrTS=20210901050417924&transitionType=Default&contextData=(sc.Default)&firstPage=true)

^[3] PhRMA (2021) Special 301 Submission 2021. Available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2021-Special-301_Review_Comment-1.pdf [Accessed November 2022]

^[4] Lexology (2022). "Revisions to South Korean Patent Act in effect from April 2022". Available at: <https://www.lexology.com/commentary/intellectual-property/south-korea/nam-nam/revisions-to-south-korean-patent-act-in-effect-from-april-2022#:~:text=The%20revisions%20were%20promulgated%20on,opportunities%20to%20acquire%20IP%20rights>



^[5] Han, SG. (2022). 자료보호 제도 도입, 약사법서 모두 관리... 내년 상반기 완료 목표. https://www.medipana.com/article/view.php?page=6&sch_menu=1&sch_cate=A&news_idx=305852

^[6] Korea Law (2013). "SPECIAL ACT ON FOSTERING AND SUPPORT OF PHARMACEUTICAL INDUSTRY". Available at: https://elaw.klri.re.kr/eng_service/lawView.do?hseq=29562&lang=ENG

^[7] Kim, D., McGuire, A., & Kyle, M. (2015). Korean pharmaceutical industry policy: lessons for Korea.

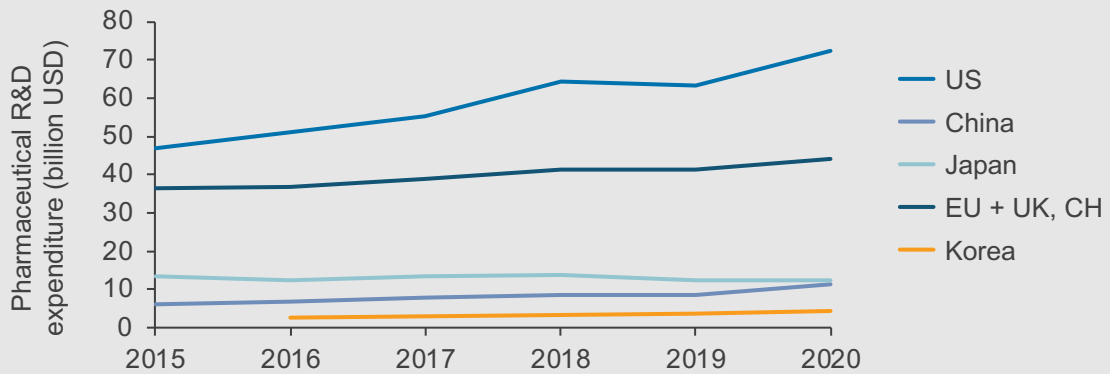
^[8] 온라인 중앙일보 (2015). "혁신형 제약 인증 실패기업 살펴보니". Available at: <https://www.joongang.co.kr/article/18127405#home>

^[9] Ministry of Health and Welfare (2022). "Start with Korea". Available at: https://www.konect.or.kr/_img/en/Brochure_09_final.pdf

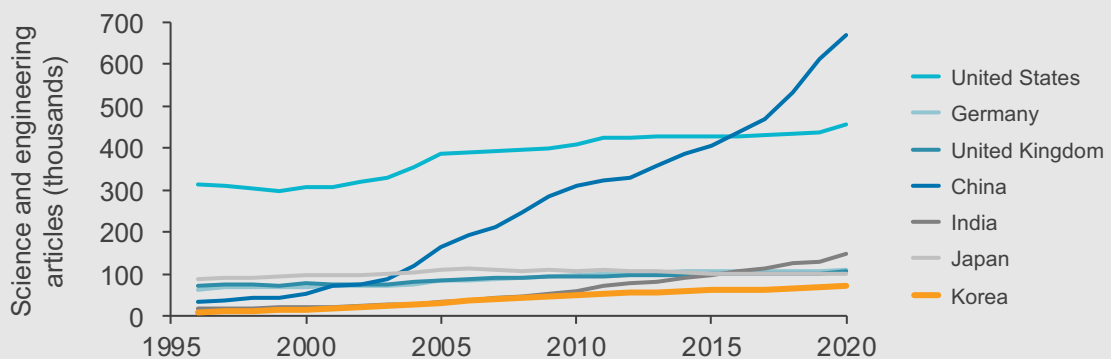
^[10] Seo (2023). 대응제약, 신속심사 성공사례 '엔블로정' 발표. <https://www.sentv.co.kr/news/view/644246>

IMPROVEMENTS IN THE INNOVATION ENVIRONMENT HAVE LED TO SUBSTANTIAL AND RAPID GROWTH IN INNOVATIVE AND ECONOMIC ACTIVITIES

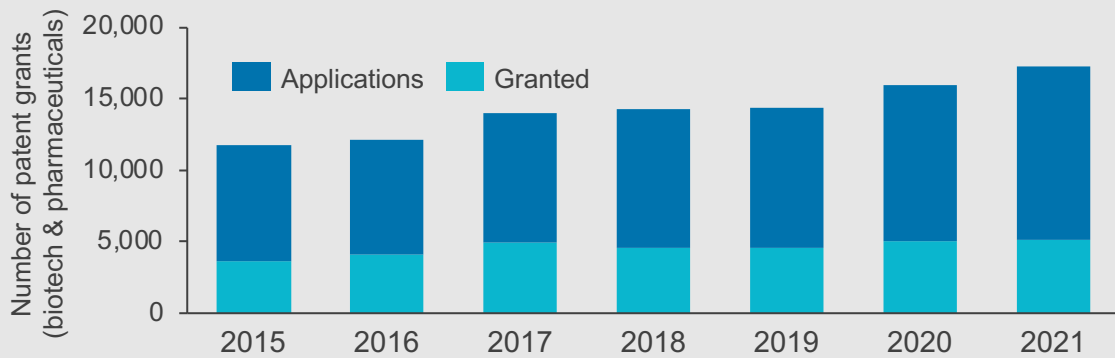
International innovative pharmaceutical companies in South Korea are driving the R&D pharmaceutical activity in the country



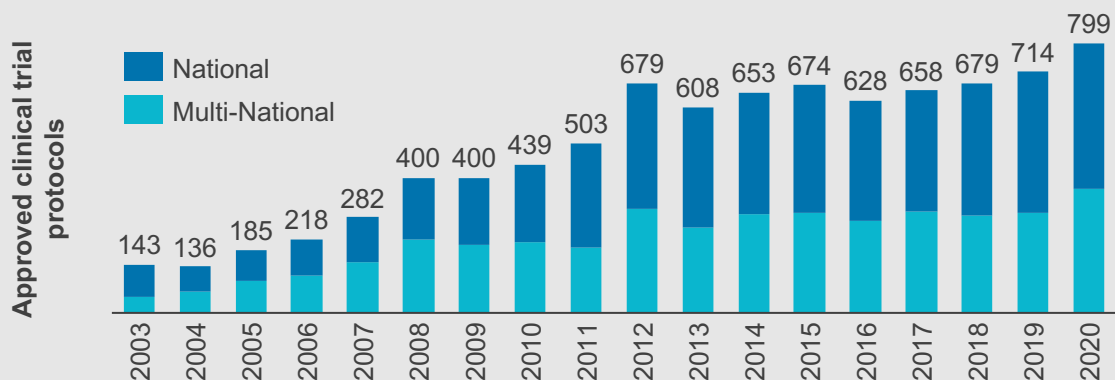
South Korea has had strong academic R&D output in recent years and the fostering of cross-sectoral moves between the industry and academia



Through the strengthening of the patent system, international pharmaceutical companies filed more patents in Korea, whilst domestic companies started increasing their innovative capabilities

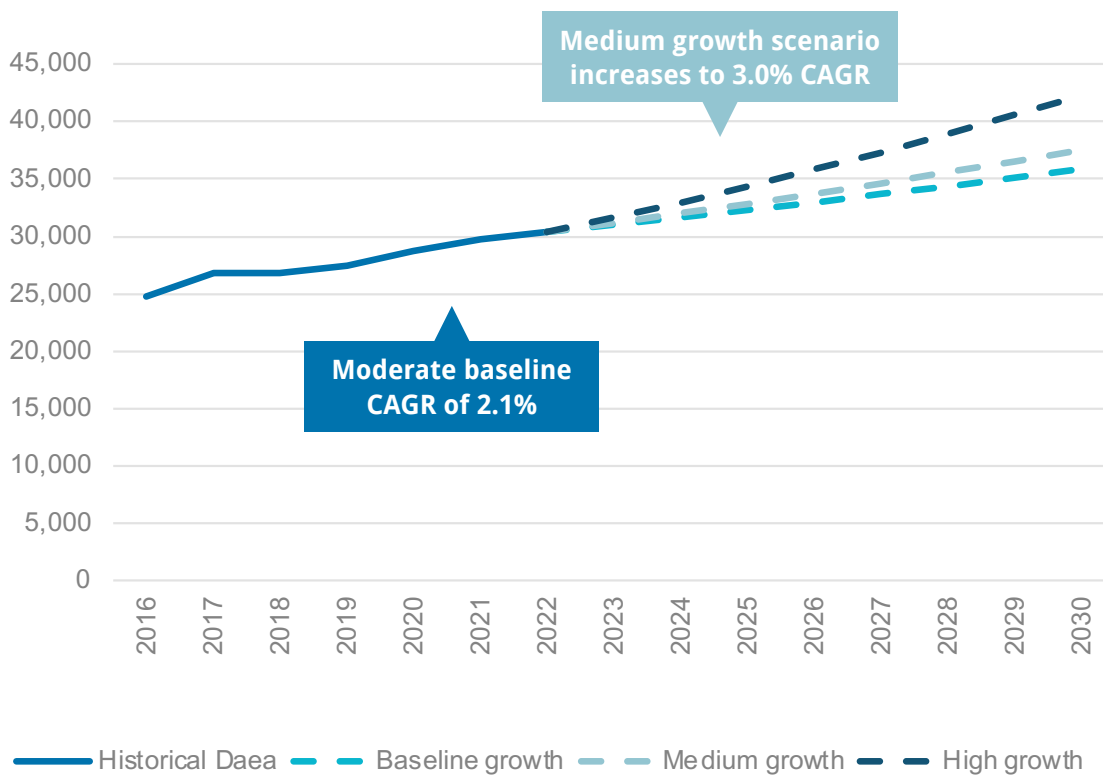


Companies have invested more funds in new drug R&D, which is reflected in an increase in clinical trial activity



GROWTH SCENARIOS FOR INNOVATIVE ACTIVITIES IN KOREA WERE ANALYSED BASED ON CASE STUDY COUNTRIES US, EU, JAPAN, AND CHINA

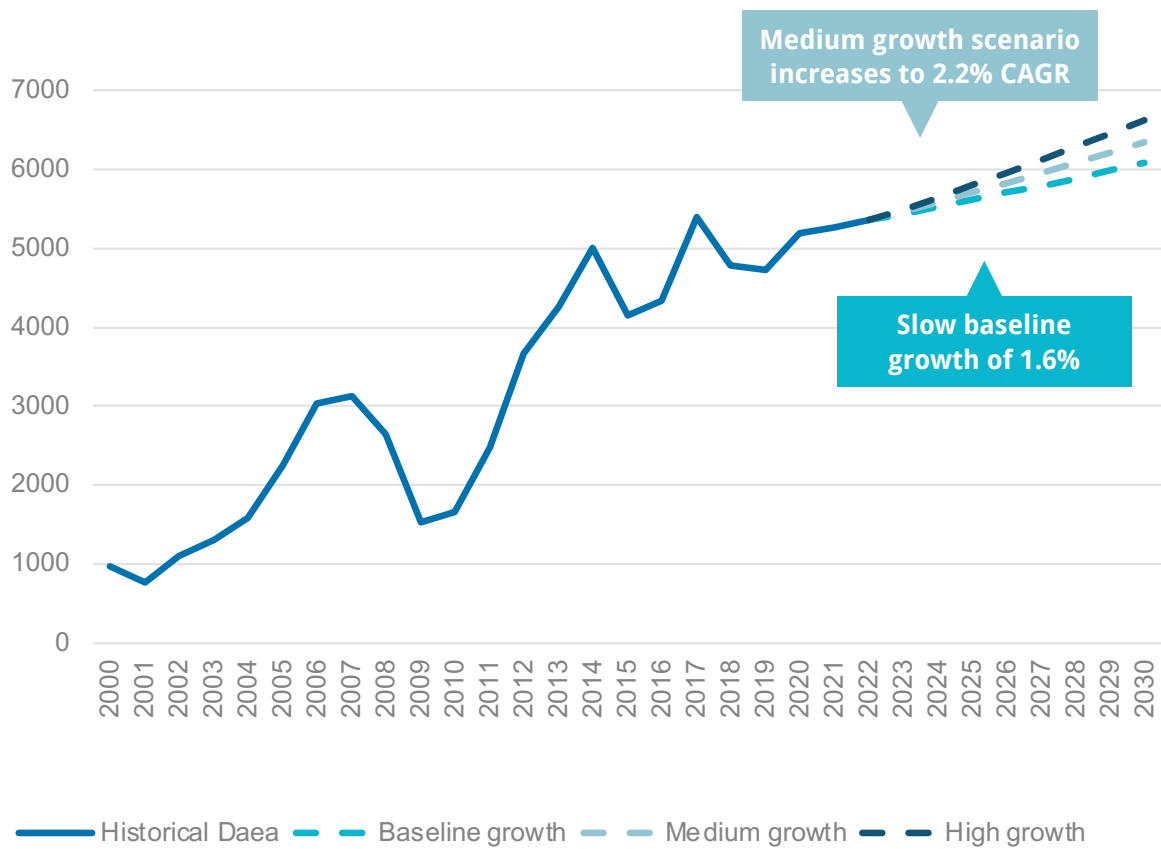
PHARMACEUTICAL R&D EMPLOYMENT GAINS



- In recent years there has been moderate growth in South Korea’s pharmaceutical R&D employment
- The medium and high growth scenarios suggest that there certainly could be further improvements in South Korea’s growth if the innovation ecosystem were to be strengthened

Abbreviations: CAGR = Compound annual growth rate

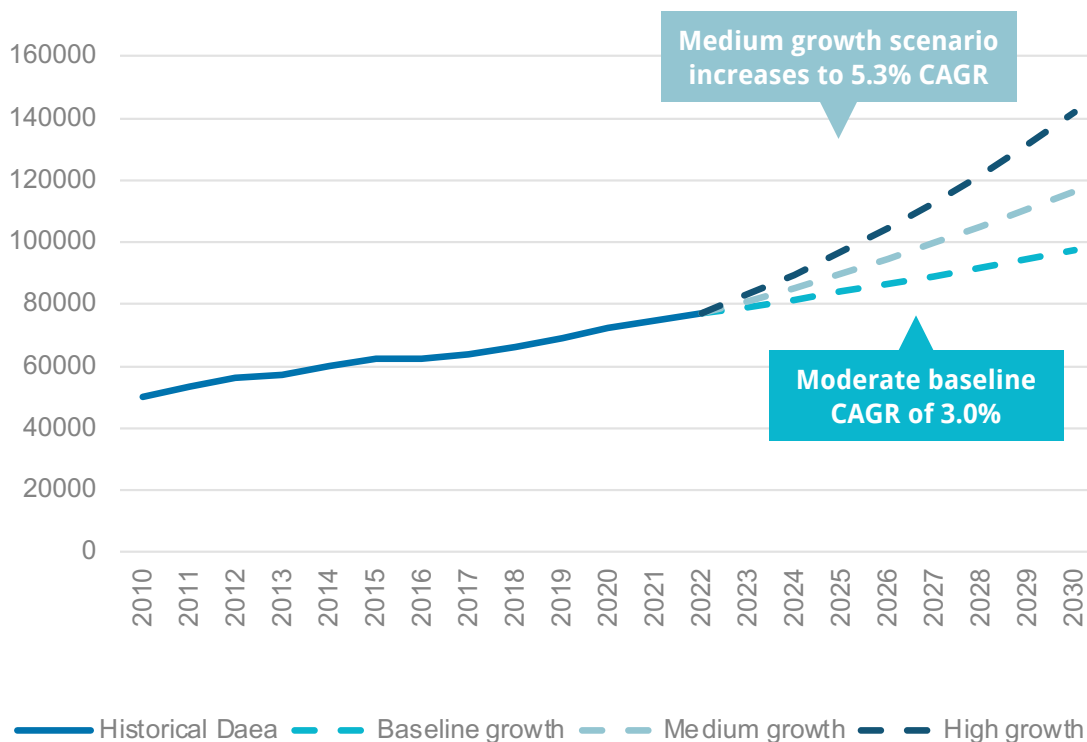
PATENT GRANT GAINS



- In recent years there has been a slow growth in South Korea's patent grant gains
- However, the medium and high growth scenarios suggest that there certainly could be improvements with a stronger IP framework

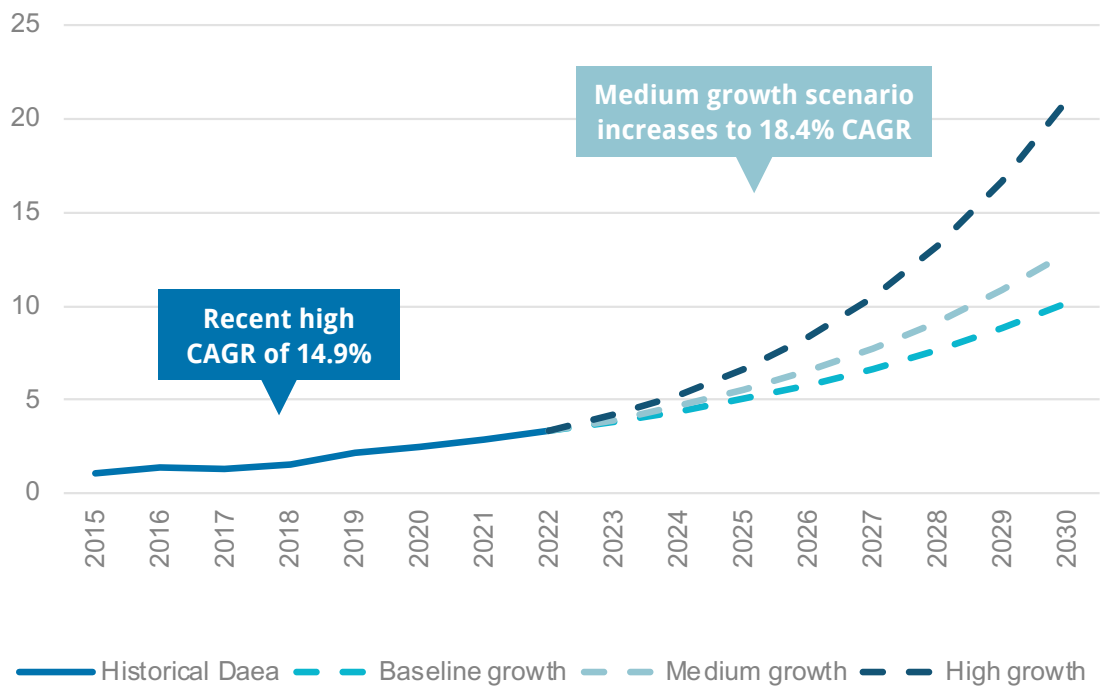
BASED ON THE GROWTH SCENARIOS, POTENTIAL GAINS FROM IMPROVEMENT IN THE INNOVATION ENVIRONMENT COULD BE SIGNIFICANT FOR R&D EXPENDITURE GAINS

BASIC RESEARCH GAINS (IN S&E PUBLICATIONS)



- Previous growth in the number of Science and Engineering publications has been relatively moderate in South Korea
- The medium and high growth scenarios suggest that there certainly could be significant improvements with a stronger IP and innovation ecosystem

PHARMACEUTICAL R&D EXPENDITURE GAINS (BN USD)



- Pharmaceutical R&D expenditure in South Korea is already rapidly growing, so further changes based on alternative markets make it appear that growth in South Korea would increase much faster

CONCLUSIONS

1. THE SCALE OF SOUTH KOREA'S PROGRESS TO DATE

South Korea has become a more favourable environment for supporting biopharmaceutical innovation

- Historically, South Korea has had a strong domestic generic industry. Increasingly, the environment has also become much more favourable towards innovation and the development of new innovative medicines.
- Several national innovation plans and amendments to the IP regime – including but not limited to the introduction of post-marketing surveillance, signing of the KORUS FTA, the Special Act on Supporting and Fostering the Pharmaceutical Industry, and the improvements to the IP regime these key policies enabled – have been a major contributor to these improvements.

Improvements in the innovation environment have led to growth in innovative and economic activities

- Across several metrics in innovative and economic activity, South Korea has demonstrated notable growth in previous years, despite the nascent stage of development of innovative domestic companies. This is evident through the steady increase in R&D investments made by pharmaceutical companies, growth of successful bio-clusters, and a gradual increase in clinical trial activity.
- Whilst Korea narrowed the gap with other regions – now nearing levels of innovative activity in Japan in some metrics – it remains behind the global leaders in innovation, such as the US, Europe and China. In these regions, following positive reforms to innovation policy and strengthening of the overall innovation ecosystem, there have been significant economic and societal benefits. This suggests the potential for South Korea to achieve comparable growth if a pro-innovation mindset is adopted and delivered in terms of policy.

2. REMAINING GAPS IN THE INNOVATION ENVIRONMENT

There remain some notable shortcomings to the innovation environment in South Korea

- Although South Korea has made substantial progress in terms of the innovation environment and resulting innovative and economic activities, there are still some significant areas for further improvement.
- This remains the case with regards to the IP regime, and innovative activity could be further stimulated if the South Korean IP regime was improved in line with the US, Europe, and Japan.

The most significant gaps include concerns around differences in patentability and the wider innovation ecosystem

- The introduction of innovative policies such as data protection, patent linkage, and patent term extensions (PTE) were key milestones in supporting and incentivising innovation, but issues remain with their criteria and implementation that leave IP protections lagging behind those in other regions.
- Although implementation of these policies have been one of several steps forward, comparison with other regions also indicates Korea still favours a genericized market and lacks a well-functioning “innovation ecosystem”, supported by a coherent and targeted set of innovation policies and appropriate pricing and reimbursement policies.

Some recent proposals suggest a possible backwards trend, carrying implications for Korea’s future progress

- Bill 2121189, introduced in April 2023, suggests Korea is moving further away from international best practices related to PTE. The innovative industry share concerns that this proposal represents a missed opportunity for fostering a stronger innovation environment.
- With revision of the pharmaceutical data protection system also expected in 2023, it is critical to consider whether these changes are contributing to or detracting from the strength of the innovation environment.

CONCLUSIONS

3. THE BENEFITS OF FURTHER IMPROVEMENTS

Addressing the remaining gaps in the innovation environment would lead to substantial benefits for South Korea

- If the innovation policy environment was improved in a way that addresses the remaining barriers, the impact would be to encourage innovation from both domestic and international pharmaceutical companies and attract and foster local and international talent.
- This would deliver benefits across the innovation pathway, from early innovative activity around scientific publications and basic research, through to investment in R&D and employment of researchers, and ultimately leading to more clinical trials, patent applications, and new innovative therapies for patients.

Based on the experience of other countries, further improvements could lead to an acceleration in innovative and economic activity

- In order to assess potential gains from an improvement in the enablers of innovation, we applied the change in growth rates from case study countries where positive changes in the IP and innovation regime were introduced to South Korea's current baseline growth rate.
- While there are some challenges with this methodology, it nevertheless illustrated that the potential gains to be had from future innovation policy improvements in South Korea could be substantial for key metrics including pharmaceutical R&D expenditure and biopharma patent grants.

4. KEY POLICY IMPLICATIONS

Strengthening the IP regime could lead to further progress in South Korea

- South Korea already has moved towards a more supportive environment for biopharmaceutical innovation. To ensure that this positive trajectory is maintained there are a number of specific policy implications for how further progress in South Korea could be brought about:

A patent regime to match South Korea's aspirations for world-leading innovation

- South Korea started to move up the international rankings in life sciences innovation, including the observed growth in R&D spend, clinical trials and patent grants. Moving towards a patent regime that is as supportive of innovation as in the EU, US, and Japan will likely be necessary if South Korea is to meet its objectives of becoming one of the seven global centres of pharmaceuticals and growing the number of world-leading Korean pharmaceutical companies.

Seizing opportunities to become a leader in Asia and then globally

- Given that many of the key enablers of innovation are already present in Korea, industry leaders see that there is an opportunity for Korea to set a new standard in the Asia-Pacific region by aligning with international best practices in terms of IP protections and support for innovation.
- Achieving this will require engaging in productive dialogue with the domestic and multinational pharmaceutical industry to identify opportunities for encouraging local innovation and foreign investment in a way that fosters growth and benefits Korea's economy and society.
- This could be underpinned by adopting a more long-term strategy to foster growth of innovative activity in Korea.

CRA Charles River
Associates

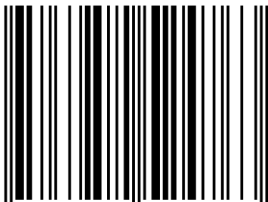
 **Interpat**

CRA International
8 Finsbury Circus
London, EC2M 7EA
United Kingdom

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