Interpat

CRA Charles River Associates

Value of IP for health and growth

The economic benefits of strengthening the innovation environment in South Korea

MAY 2023

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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

DATA PROTECTION THROUGH THE PHARMACEUTICAL AFFAIRS ACT (1995)

- The Korean Pharmaceutical Affairs Act was amended in 1995 to provide de-facto 4- or 6-year post marketing surveillance for new drugs.[1]

SIGNING OF THE KORUS FTA (2007)

- The FTA, which was signed in 2007, consisted of key IP changes in the pharmaceutical sector, such as the introduction of patent linkage, safety regulations for new drugs, and the protection of safety and efficacy information.[2]

PATENT LINKAGE (2015)

- The KORUS FTA introduced the approval-patent linkage system in South Korea. Patent linkage was implemented in 2015 based on the US Hatch-Waxman System, allowing patent owners to be informed of generic applications and implement measures to prevent generic entry during the patent term.[3]

THE SPECIAL ACT ON SUPPORTING AND FOSTERING THE PHARMACEUTICAL INDUSTRY (2011, AMENDED 2013, 2018, 2022)

- The Act aims to lay a foundation for the development of the pharmaceutical industry and by creating an environment to induce investment from foreign pharmaceutical enterprises.[6]
- The five-year plan envisioned making Korea one of the seven global centres of pharmaceutical innovation.[7]

INNOVATIVE PHARMACEUTICAL COMPANY (IPC) CERTIFICATION (2012)

- As part of the KORUS FTA requirements, the Korean government began recognizing innovative pharmaceutical companies through a certification process to provide incentives to selected companies.[8]

INNOVATIVE STRATEGY ON THE BIO-HEALTH INDUSTRY (2019)

- The pan-government strategy aims to drive innovative growth via bio-health industry development.[9]

CHANGES IN INNOVATION POLICY

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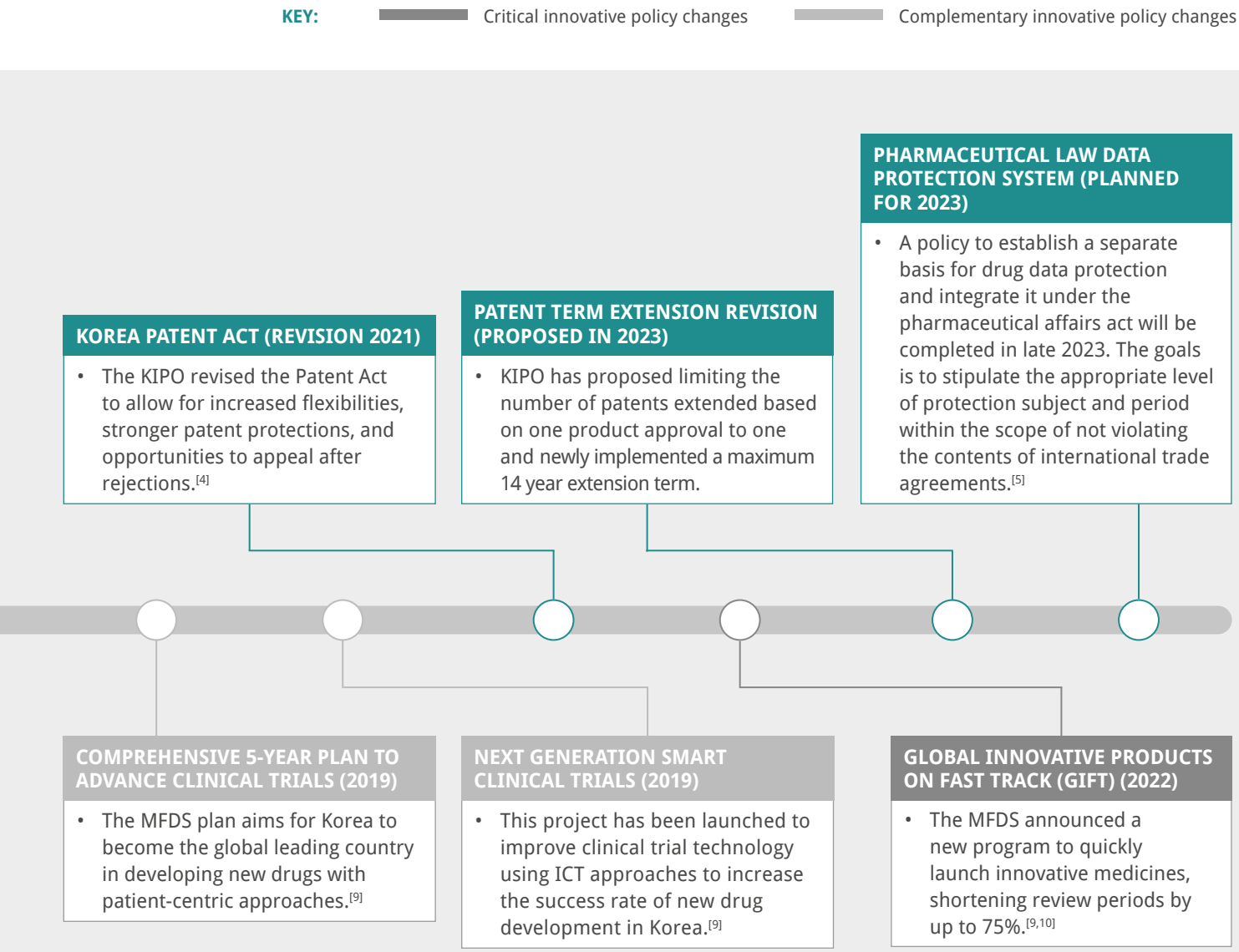
[3] PhRMA (2021) Special 301 Submission 2021. Available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2021-Special-301_Review_Comment-1.pdf [Accessed November 2022]
[4] Lexology (2022). "Revisions to South Korean Patent Act in effect from April 2022". Available at: https://www.lexology.com/commentary/intellectual-property/south-korea/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
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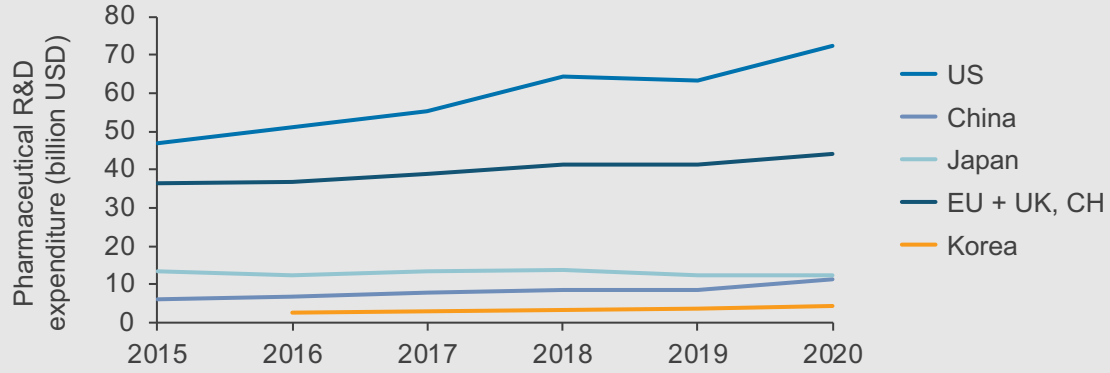
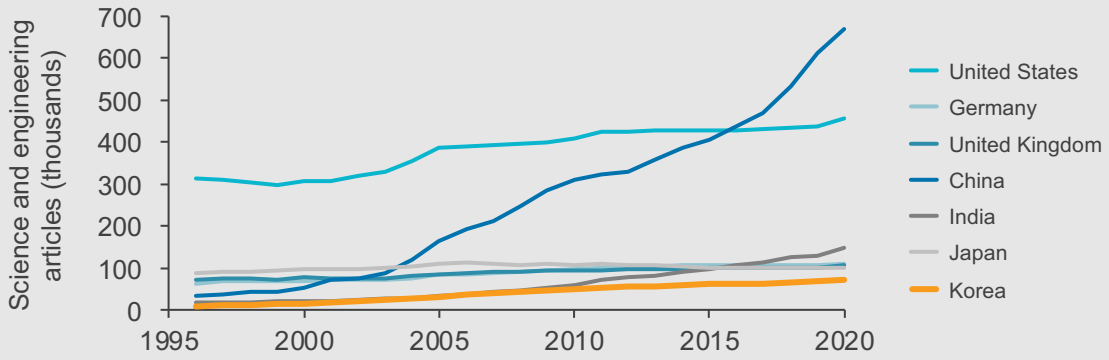
[9] Ministry of Health and Welfare (2022). "Start with Korea". Available at: https://www.konect.or.kr/_img/en/Brochure_09_final.pdf
[10] Seo (2023). 대웅제약, 신속심사 성공사례 '엔블로정' 발표. https://www.sentv.co.kr/news/view/644246

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

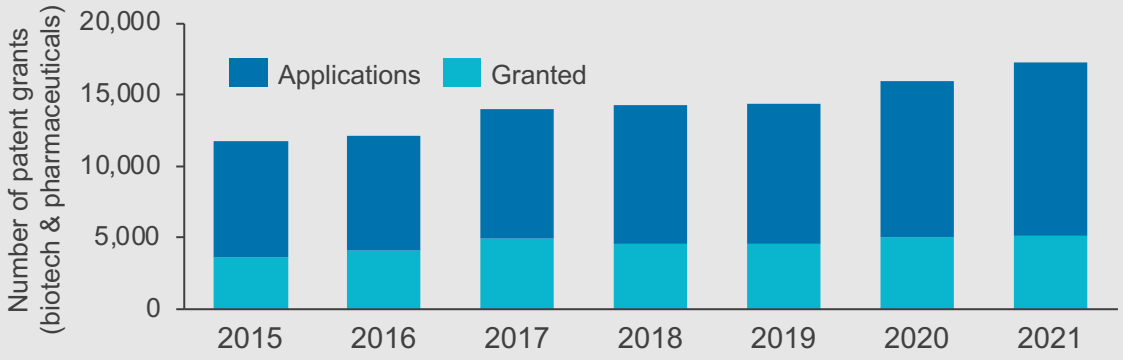
International innovative pharmaceutical companies in South Korea are driving the R&D pharmaceutical activity in the country



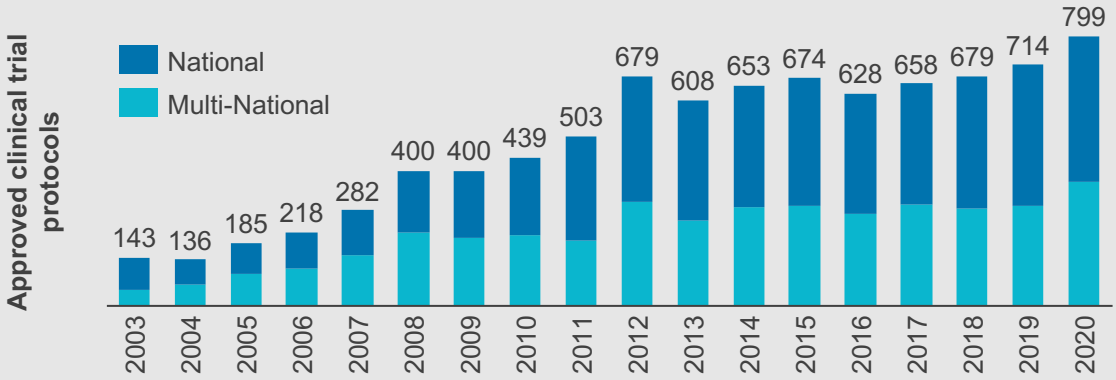
South Korea has had strong academic R&D output in recent years and the fostering of cross-sectoral moves between the industry and academia



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

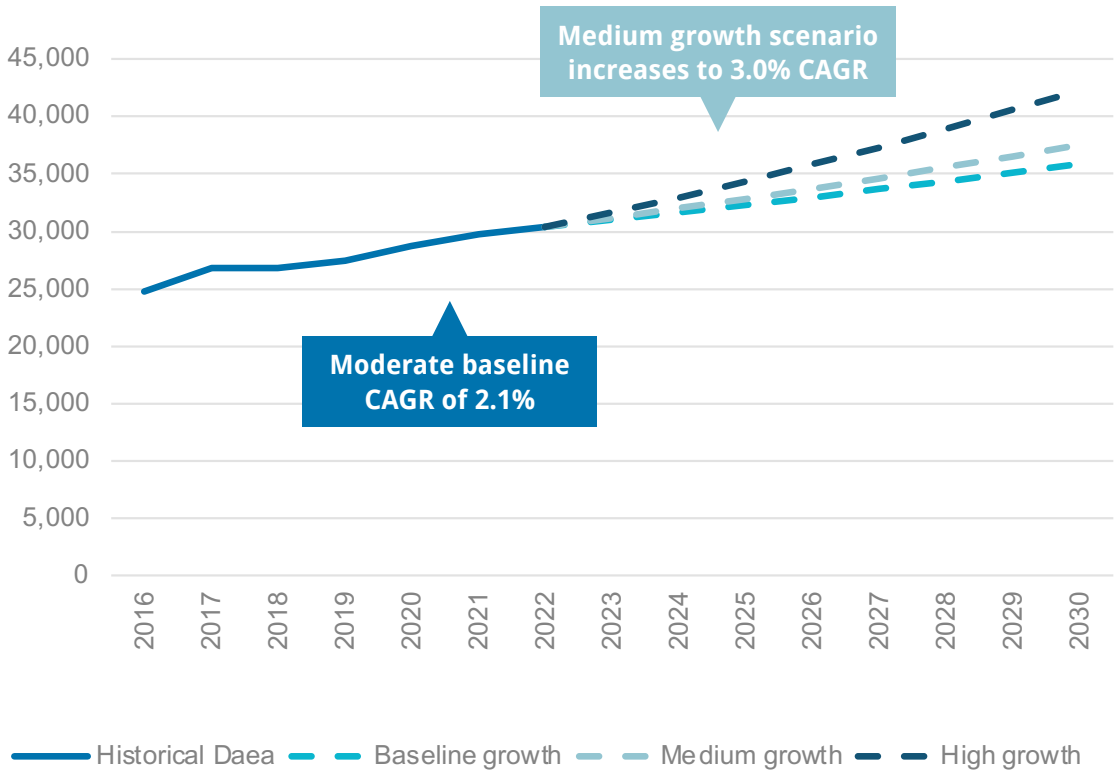


Companies have invested more funds in new drug R&D, which is reflected in an increase in clinical trial activity



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

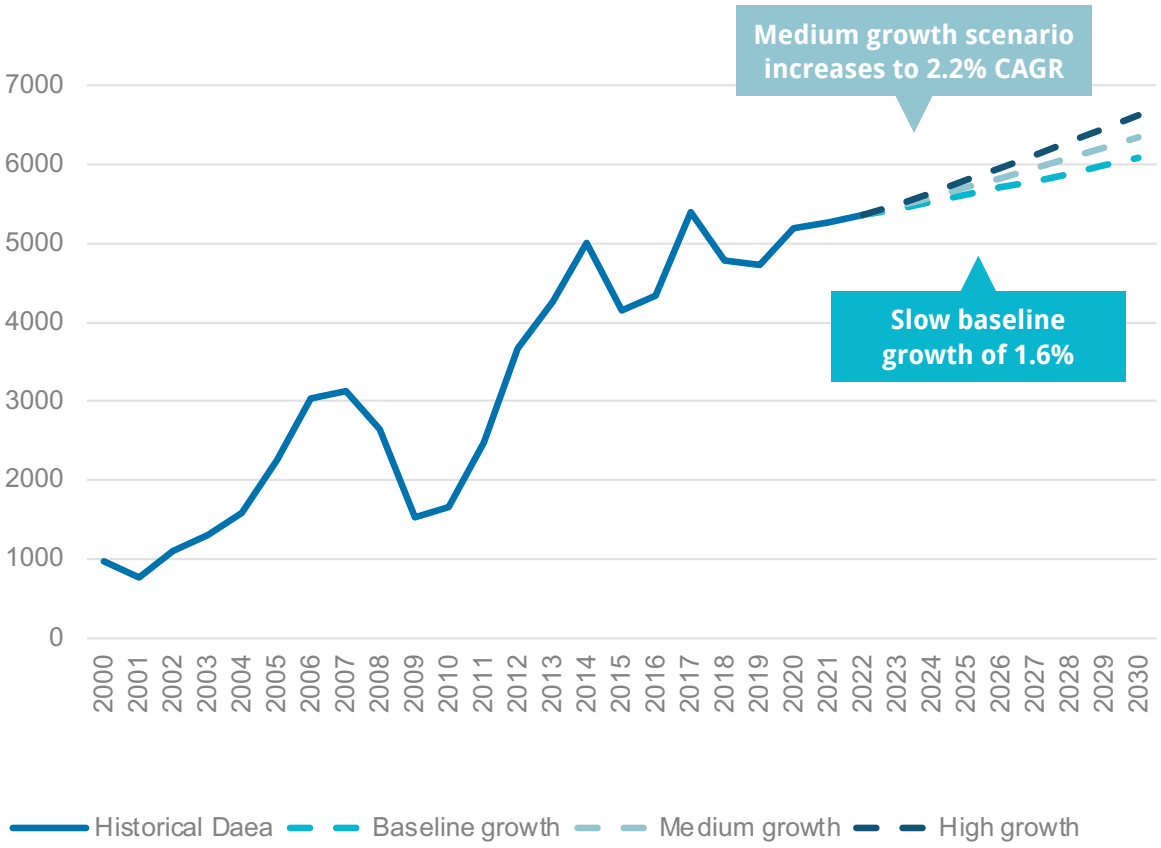
PHARMACEUTICAL R&D EMPLOYMENT GAINS



- 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

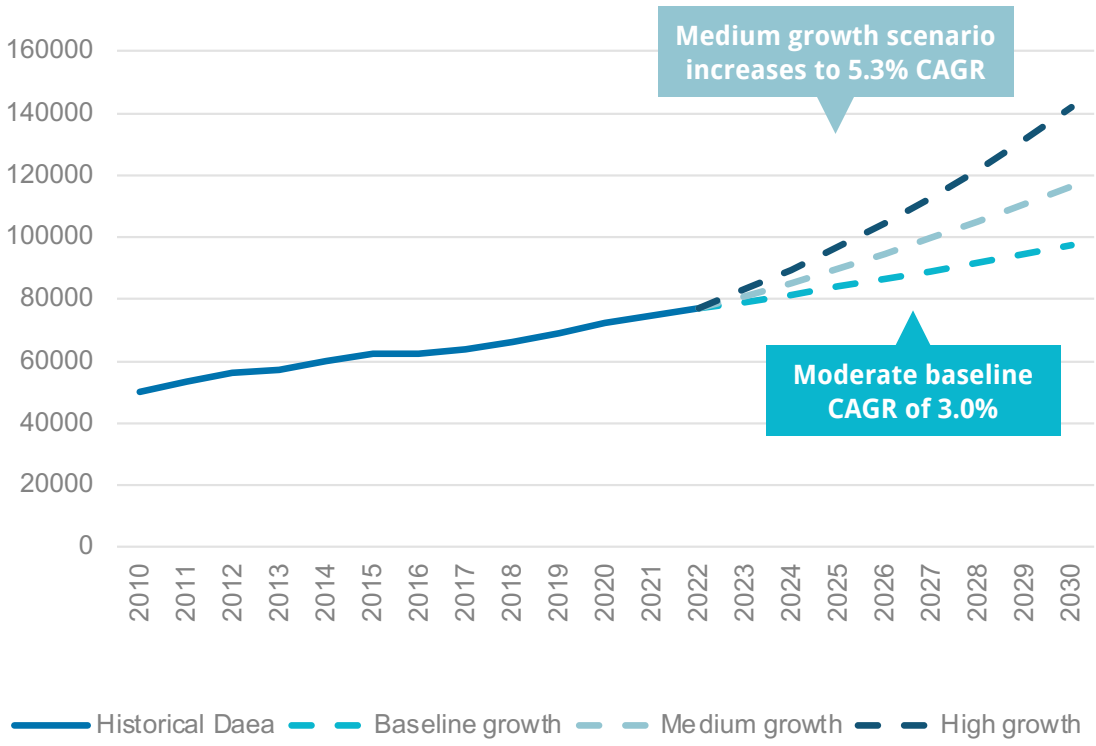
PATENT GRANT GAINS



- 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

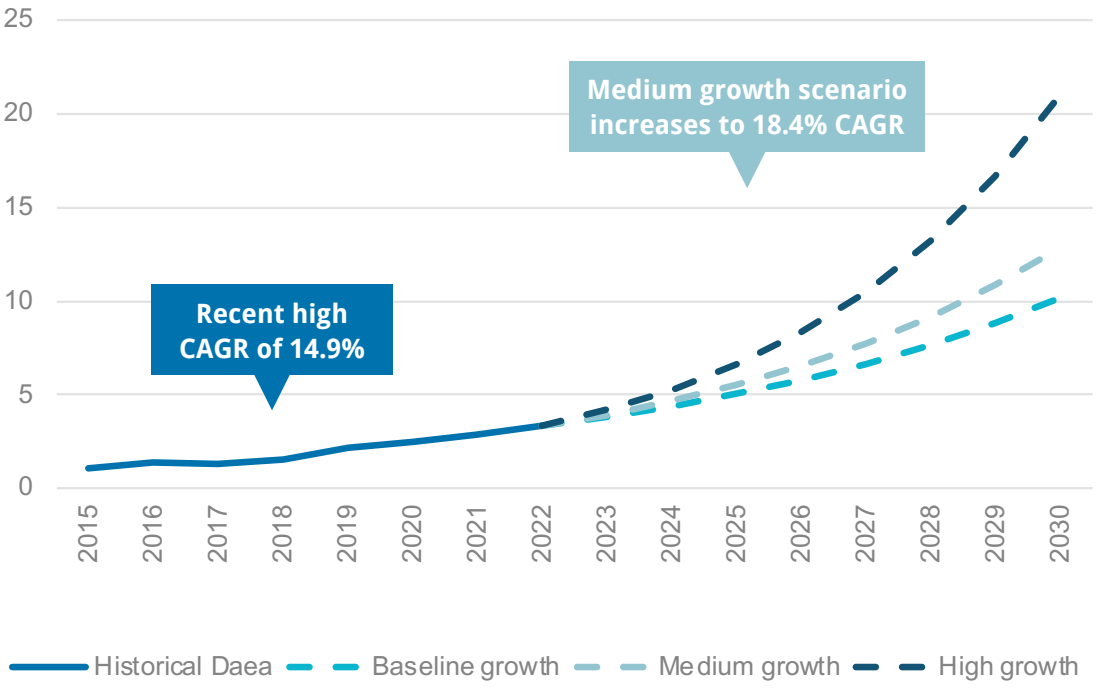
BASED ON THE GROWTH SCENARIOS, POTENTIAL GAINS FROM IMPROVEMENT IN THE INNOVATION ENVIRONMENT COULD BE SIGNIFICANT FOR R&D EXPENDITURE GAINS

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.

1. Project objectives and methodology

BACKGROUND AND OBJECTIVES

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THE PROJECT HAD FOUR STEPS

1 →

REVIEW OF THE INNOVATION ENVIRONMENT

Activities

- Review the current IP framework in South Korea
  - The current rules and regulations
  - Any recent changes
  - Academic, grey literature on how it works in practice
  - The existing policy debate
- Gather quantitative data to describe the impact of key policy developments

Deliverables

- Description of the current innovation environment including challenges and opportunities

2 →

GATHER STAKEHOLDER PERSPECTIVES

Activities

- Interview N=20 experts to validate findings and gather diverse perspectives:
  - Policymakers
  - Industry (domestic and multinational)
  - IP experts (lawyers and judges)
  - Academics
- Summarise findings

Deliverables

- Consolidated feedback from interview programme

3 →

DEVELOPMENT OF THE REPORT

Activities

- Integrate findings from literature review, data analysis and interviews
- Develop a report, presentation and external publication of findings
- Review draft with INTERPAT and any agreed co-authors of the report

Deliverables

- Draft report

4 →

DEVELOPMENT OF PEER REVIEWED PAPER

Activities

- Finalise report and translate into Korean
- Develop external version of the report
- Launch report in Seoul at the INTERPAT Korean General Assembly (13 and 14th June 2023)

Deliverables

- Final report with policy implications (English and Korean)

RESEARCH ON THE INNOVATION AND IP ENVIRONMENT WAS CONDUCTED THROUGH A REVIEW OF INTERNATIONAL AND LOCAL SOURCES IN SOUTH KOREA

- We used more than 50 international and local publications and databases in both English and Korean language on the current innovation environment as well as the challenges in the IP regime in the South Korean pharmaceutical industry:

ACADEMIC PUBLICATIONS AND GREY LITERATURE

- International and local academic literature, including Um et al. (2022), Choi and Lee (2022), and Chung, Eum and Lee (2019)
- Literature found through targeted Google searches, including online media articles, reviews and op-eds, from local and international sources including industry trade associations

KOREAN AND INTERNATIONAL DATABASES

- Data analysis and comparisons leveraged sources including official national statistics databases, the Organisation for Economic Co-operation and Development and the World Bank

WE GATHERED A BROAD RANGE OF PERSPECTIVES THROUGH THE INTERVIEW PROGRAMME

THE PHARMACEUTICAL INDUSTRY

- **Interviews with 7 internal experts** (INTERPAT members) were used to understand the innovative industry's view of strengths and remaining key gaps:
  - Astellas
  - Bristol Myers Squibb
  - Eli Lilly and Company
  - Johnson & Johnson
  - Novo Nordisk
  - Pfizer
  - Sanofi
- **Interviews with 2 domestic companies** were used to understand the domestic industry's view
- **Interviews with 3 local trade associations** provided a broader perspective on these issues:
  - Korean Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA)
  - Korean Research-based Pharmaceutical Industry Association (KRPIA)
  - Bio Korea

THE BROADER INNOVATION ECOSYSTEM

- **8 external interviews** were conducted with former policymakers and advisors for the Ministry of Food and Drug Safety and Ministry of Health and Wellness, academics, regulatory experts, law firms and former High Court judges to develop understanding of the broader innovation policy in South Korea
- The majority of input was collected via interviews but some stakeholders also provided their perspectives in written form
- Interviews with experts from other relevant stakeholders were also requested

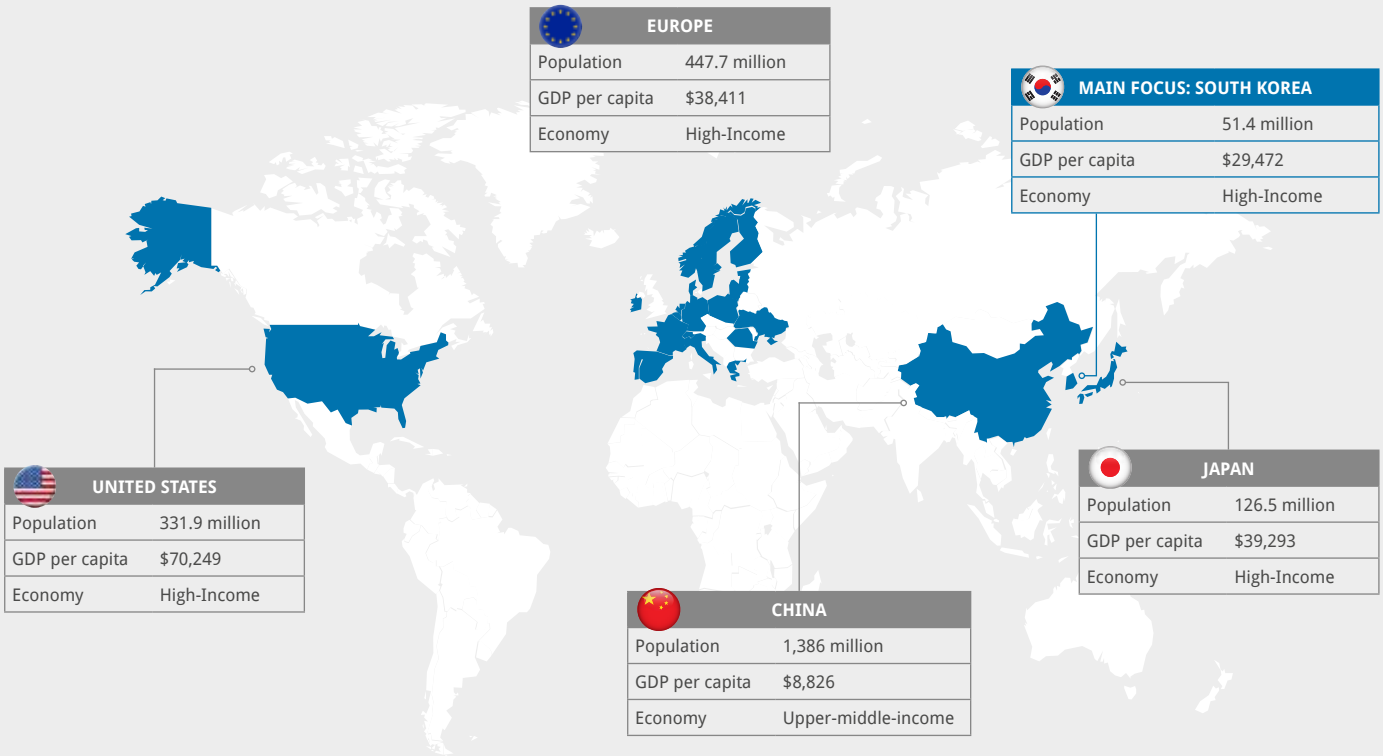
CASE STUDIES WERE USED TO ILLUSTRATE BENEFITS OF INNOVATION AND DRAW LESSONS FOR SOUTH KOREA

THE OBJECTIVES OF A CASE STUDY APPROACH ARE TO:

- Quantify the impact of policies to strengthen innovation environment
- Develop understanding of the context, to better understand the success of innovation policy change
- Understand the possible scenarios for how biopharma innovation could evolve in South Korea

THE SELECTION CRITERIA FOR OUR CASE STUDY MARKETS AND EXPERT ADVICE SUGGEST SEVERAL MARKETS TO INVESTIGATE:

1. Have shown a focus on strengthening the innovative environment, particularly the IP protection
2. Placed broadly in the same income, size and development category as South Korea
3. Show an observable impact on innovative activity



2.

The benefits of changes to the life sciences innovation environment in Korea

WE USED A FRAMEWORK TO SUPPORT AN ASSESSMENT OF THE INNOVATION AND IP POLICY ENVIRONMENT AND THE BENEFITS OF THIS

POLICY ENVIRONMENT → RESOURCES FOR INNOVATION

OVERALL INNOVATION SUPPORT

- National innovation plans
- Targeted initiatives

RULES FOR INNOVATION PROTECTION

- IP rules and patentability criteria
- Patent filing and granting process
- Regulatory data protection
- Preliminary injunction process
- Free Trade Agreements

INCENTIVES FOR INNOVATION

- R&D tax credits
- Pricing and reimbursement

FUNDING FOR INNOVATION

- Public and private funding for research
- Foreign Direct Investment

EXPERTISE AND INFRASTRUCTURE

- University quality and education attainment
- Care: Hospital infrastructure and physician availability
- Collaboration and clusters

HEALTH SYSTEM STRENGTH

- Care provision indicators

INNOVATIVE ACTIVITIES → ECONOMIC ACTIVITIES → PATIENT IMPACT

EARLY AND BASIC RESEARCH

- Publications
- Public private collaborations

PRODUCT DEVELOPMENT

- Clinical trials by phase, type and funder

OUTPUTS OF INNOVATION

- Number of patents filed, granted both domestic and international

EMPLOYMENT

- Researchers employed in pharma
- Types (roles) of employees in pharma in the country.
- Compensation levels

TRADE

- Imports vs exports in pharma and biotech.

ACCESS TO MEDICINES

- Approval of innovative drugs

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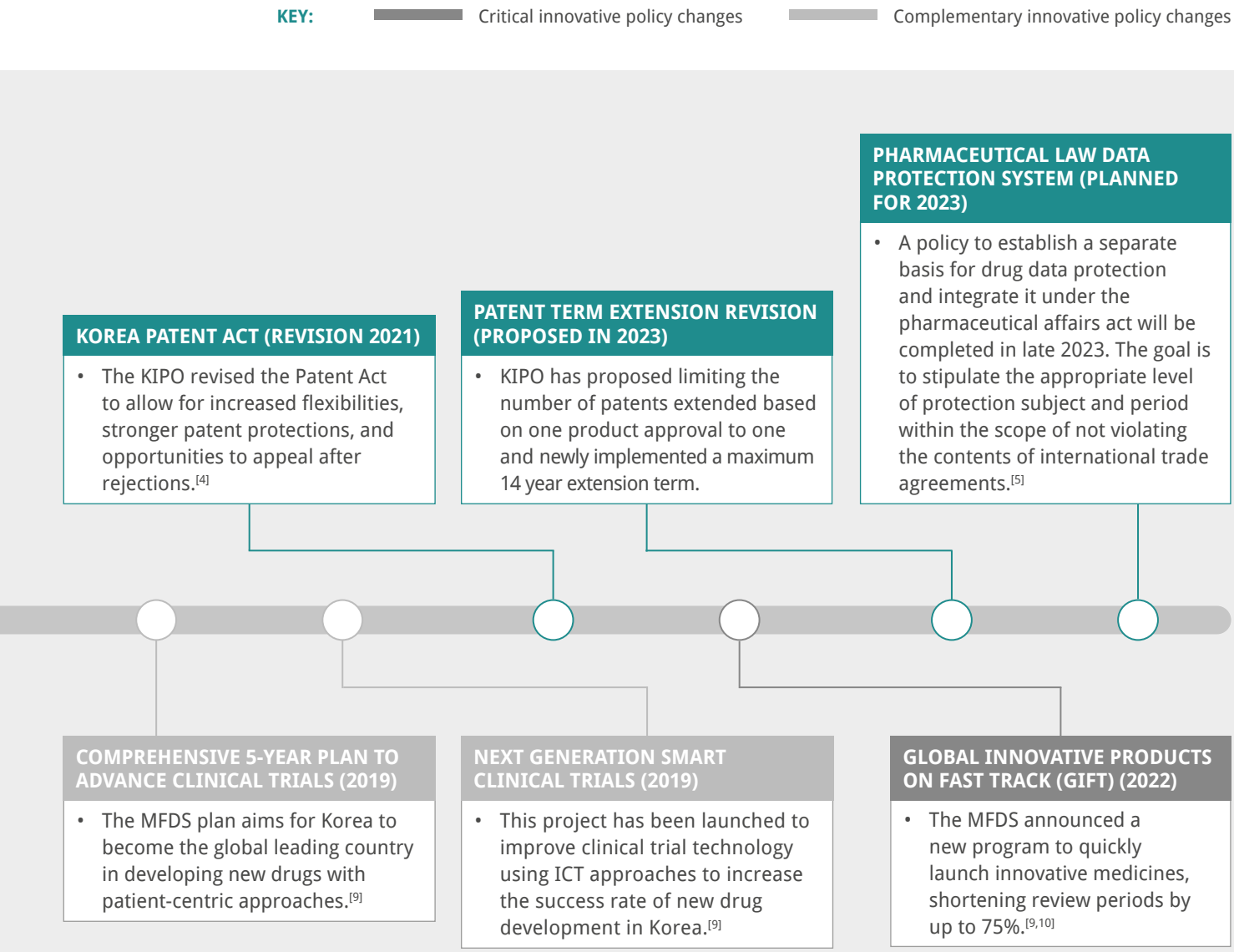
[3] PhRMA (2021) Special 301 Submission 2021. Available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2021-Special-301_Review_Comment-1.pdf [Accessed November 2022]
[4] Lexology (2022). "Revisions to South Korean Patent Act in effect from April 2022". Available at: https://www.lexology.com/commentary/intellectual-property/south-korea/nam-nam/revisions-to-south-korean-patent-act-in-effect-from-april-2022#:~:text=The%20revisions%20were%20promulgated%20on,opportunities%20to%20acquire%20IP%20rights



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[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). 대웅제약, 신속심사 성공사례 '엔블로정' 발표. https://www.sentv.co.kr/news/view/644246

OVERALL INNOVATION SUPPORT: VARIOUS POLICIES AND ACTIVITIES HAVE BEEN CREATED TO HELP KOREA ACHIEVE ITS AMBITIOUS INDUSTRY GOALS

KEY INNOVATION SUPPORT POLICIES

- In 2011, the National Assembly enacted **the Special Act on Supporting and Fostering the Pharmaceutical Industry** and released a series of five-year plans to raise public funds, develop specialized workforces, and provide strategic support for exports and developing cutting-edge industry clusters and other infrastructure.[1]
- Announced in 2022, the **GIFT (Global Innovative products on Fast Track) program** is expected to significantly increase innovation and boost pharmaceutical exports. The MFDS hopes it will shorten review periods by up to 75%. In addition to expedited review, innovative products will receive flexibilities for data submissions and technical briefings and consulting sessions.[2]

KEY INNOVATION SUPPORT ACTIVITIES

- As part of **the Special Act on Supporting and Fostering the Pharmaceutical Industry**, the MoHW began certifying companies that invest a certain amount or more in Korea on R&D of innovative drugs.[1]
- The current Yoon administration has made various pledges to foster the pharmaceutical bio-industry including the creation of a "Pharmaceutical Bio-innovation Committee".[3]
- KRPIA has been regularly collaborating with KOTRA to host Global innovation sessions, providing competency training programs with the aim of strengthening domestic start-ups and their entry into the global market.[4]

PHARMACEUTICAL INDUSTRY GOALS [1,3]

1. Making Korea one of the **seven global centers** of pharmaceuticals
2. Raising the value of its pharmaceutical **exports** from KRW 2.3 trillion in 2012 to KRW **25 trillion KRW** by 2027
3. Achieving **fifth place globally** in medical device exports
4. Developing **two blockbuster drugs** by 2027
5. Increasing **government investment** in R&D projects
6. Increasing the number of Korean companies **among the world's top 50** pharma companies

Abbreviations: MFDS: Ministry of Food and Drug Safety; MoHW: Ministry of Health and Welfare; R&D: research and development; KRPIA:Korean Research-based Pharmaceutical Industry Association; KOTRA: Korea Trade-Investment Promotion Agency

[1] Kim, D., McGuire, A., & Kyle, M. (2015). Korean pharmaceutical industry policy: lessons for Korea.
[2] Ministry of Food and Drug Safety (2022). About Gift. Available at: https://www.mfds.go.kr/wpge/m_1113/de080101l0001.do [Accessed January 2023]
[3] Lee (2023). 복지부, 글로벌 신약 2개 개발·제약바이오혁신위원회 추진. Available at: http://www.hitnews.co.kr/news/articleView.html?idxno=43221 [Accessed January 2023]
[4] KRPIA (2019). KRPIA-KOTRA, 글로벌 오픈이노베이션 코리아에서 설명회 및 파트너링 상담회 진행. Available at: https://www.krpia.or.kr/board/select/press/10041 [Accessed January 2023]

RULES FOR INNOVATION PROTECTION AND INNOVATION INCENTIVES: THERE ARE THREE MAIN PILLARS REQUIRED TO SUPPORT A HEALTHY LIFE SCIENCES INNOVATION ECOSYSTEM

POLICY ENVIRONMENT

Overall innovation support

- National innovation plans
- Targeted initiatives

Rules for innovation protection

- IP rules and patentability criteria
- Patent filing and granting process
- Regulatory data protection
- Preliminary injunction process
- Free Trade Agreements

Incentives for innovation

- R&D tax credits
- Pricing and reimbursement

INTELLECTUAL PROPERTY

Intellectual property protections supports biopharmaceutical R&D by encouraging innovation, fostering and securing industry investments and enabling cooperation and coordination.

PRICING & REIMBURSEMENT

Pricing and reimbursement structures with fair and appropriate pricing mechanisms for pharmaceuticals are required to ensure patient access and encourage industry investment.

REGULATORY STRUCTURES

Regulatory structures should be reliable and support manufacturers undergoing lengthy and rigorous regulatory processes to ensure a predictable environment

RULES FOR INNOVATION PROTECTION AND INNOVATION INCENTIVES: THESE PILLARS WORK IN TANDEM TO SUPPORT INNOVATION IN KOREA

INTELLECTUAL PROPERTY

Korea has few domestic companies dedicated to innovative products. In the past 20 years, Korean policy has expanded IP provisions to align with major markets such as the United States, Europe and Japan. This shift has created a more innovation-friendly environment, but remains comparatively restricted relative to these other markets.

PRICING & REIMBURSEMENT

The reimbursement status and prices of products in Korea's insurance system are highly regulated with a less favourable environment for innovative products than the US or EU. The pricing and reimbursement challenges are limiting patient access to novel therapies and innovative medicines.

REGULATORY STRUCTURES

Regulatory structures in Korea have improved considerably, but innovative companies still face some significant regulatory challenges in all steps of the product cycle. New policies and revisions of the existing Patent Act are making attempts to expedite these regulations and decrease administrative burden.

Although the three pillars work in tandem to support the innovation environment, this report will focus mostly on the impact of IP provisions to understand how IP policies can support the development of a stronger innovation environment in South Korea.

Abbreviations: IP: intellectual property

RULES FOR INNOVATION PROTECTION:
IN THE PAST DECADE, KOREA HAS DEVELOPED THE FOUNDATIONAL IP FRAMEWORK NEEDED TO BECOME AN INNOVATIVE MARKET

PATENTABILITY AND FILING

Korea has very strict patentability criteria and robust requirements for drug approvals.[1]

In the US-Korea FTA, the parties confirm "that patents shall be available for any new uses or methods of using a known product." However, given that the text of the treaty leaves some leeway at the national level to determine how such applications would need to be formulated, in practice patentees face difficulties in obtaining secondary patents.[1,2]

A 2021 Supreme Court decision shed hope that the standards for assessing secondary use patents will be loosened.[1]

PATENT ENFORCEMENT AND REGULATORY ENVIRONMENT

While patent applications have increased in the past 10 years, so have disputes. These disputes are diversifying from patent infringement lawsuits to trademark and design infringement lawsuits.[3]

The WIPO report has ranked Korea's overall regulatory environment as one of the weakest amongst its income group (high-income countries) due to low regulatory quality and the cost of redundancy dismissal.[4]

KEY IP PROVISIONS AND PROTECTIONS

Regulatory Data Protection

- The Korean Pharmaceutical Affairs Act was amended in 1995 to provide de-facto 4- or 6-year post-marketing surveillance for new drugs, where before expiry, no generic applicant can rely on the clinical trial data.[5]

Patent Term Extension

- Patent owners can extend the term of substances, processes, uses and compositions for a "new chemical entity" for a maximum of five years.[6]

KORUS Free Trade Agreement (FTA)

The KORUS FTA between Korea and the US entered into force in 2012 and stipulated a wide range of pharmaceutical industry changes.[7]

Patent Linkage

- Based on the Hatch-Waxman model, original patent owners were given the opportunity to suspend generic sales for up to nine months if their patents were listed in the "Green Book".

Innovative Pharmaceutical Company (IPC) Certification (2012)

- Certified innovative companies receive regulatory benefits

The actual implementation of IP protections in Korea differs from the US due to the differences in legal systems and the context in which they were adopted. While the US started increasing protections in the presence of already established multinational pharmaceutical firms, Korea was and still is a mostly generics market with no established multinational company.[4,8]

[1] Interview with multinational pharmaceutical company
[2] Adachi, K., 2022. The Patentability of Second and Subsequent Medical Uses in Asia's Patent Legislation. Asian Journal of Law and Economics. https://www.degruyter.com/document/doi/10.1515/ajle-2022-0091/html
[3] Jeong, C.W. (2004). 제약산업의 지적재산권 조명. Available at: http://www.bosa.co.kr/news/articleView.html?idxno=47457 [Accessed January 2023]
[4] WIPO (2022). "Global Innovation Index 2022 What is the future of innovation driven growth?". Available at: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-2000-2022-en-main-report-global-innovation-index-2022-15th-edition.pdf [Accessed January 2023]
[5] Interview with multinational pharmaceutical company
[6] Kasan Insight. Patent Term Extension (PTE) in Korea. Available at: http://koreaniplaw.blogspot.com/2017/09/patent-term-extension-pte-in-korea.html [Accessed February 2023]
[7] Shin, E. J., Kim, S., & Han, Y. (2022). The Pharmaceutical Intellectual Property and Competition Law Review: South Korea. In D. Kracov (Ed.), The Pharmaceutical Intellectual Property and Competition Law Review. Law Business Research Limited.
[8] Interview with IP lawyer

INCENTIVES FOR INNOVATION:
KOREA HAS LAUNCHED VARIOUS PROGRAMS AND INITIATIVES TO INCREASE ITS PRESENCE IN THE GLOBAL PHARMACEUTICAL INDUSTRY

NATIONAL INNOVATION PLANS AND PROGRAMMES

- Korea was ranked the **top innovation economy in Southeast Asia, East Asia, and Oceania region** by WIPO in the Global Innovation Index 2022 and 6th globally.[1]
- National innovation plans and programs from 1995 to present have **supported Korea's shift from a generics industry to a more pro-innovation environment:**
    - For example, in 2011, the National Assembly enacted the Special Act on Supporting and Fostering the Pharmaceutical Industry, and then in 2013 the Korean government announced its first five-year plan for advancing the pharmaceutical industry according to that Act.[2]
- In a similar light, in 2022, MFDS announced the new Global Innovative Products on Fast Track (GIFT) programme to **significantly increase innovation and boost pharmaceutical exports.**
    - Through the launch of this programme, MFDS guaranteed it will shorten its review period by up to 75%.[3]
    - In addition to expedited review, innovative products that qualify for the GIFT program will receive flexibility for data submissions and have opportunities to consistently communicate with reviewers and developers through technical briefings and consulting sessions.[3]

Abbreviations: WIPO: World Intellectual Property Organization; MFDS: Ministry of Food and Drug Safety; R&D: research and development; OECD: Organisation for Economic Co-operation and Development

[1] WIPO (2022). "Global Innovation Index 2022 What is the future of innovation driven growth?". Accessible from: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-2000-2022-en-main-report-global-innovation-index-2022-15th-edition.pdf [Accessed January 2023]

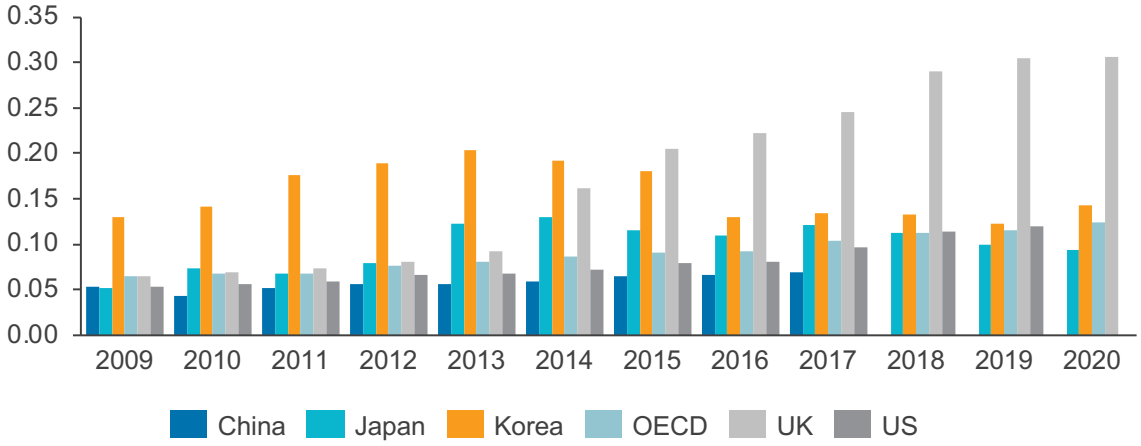
[2] Kim, D., McGuire, A., & Kyle, M. (2015). Korean pharmaceutical industry policy: lessons for Korea.

[3] Ministry of Food and Drug Safety (2022). About Gift. Available at: https://www.mfds.go.kr/wpge/m_1113/de080101l0001.do [Accessed January 2023]

R&D TAX CREDITS

- Korea provides **R&D tax relief** through a hybrid R&D tax credit and volume-based investment credit for machinery and equipment and buildings.[4]
- In 2019, Korea is placed among the OECD countries that provide the **largest level of total government support** to business R&D as a percentage of GDP, at a rate equivalent to 0.29% of GDP.[4]

Indirect government support through R&D tax incentives (% of GDP)[5]

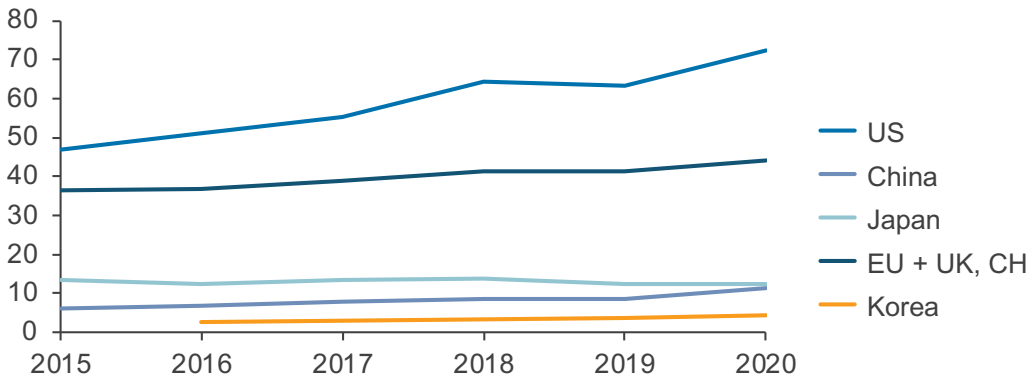


[4] OECD (2021). "R&D Tax Incentives: Korea, 2021". Available at: https://www.oecd.org/sti/rd-tax-stats-korea.pdf [Accessed January 2023]
[5] OECD (2020). "R&D tax expenditure and direct government funding of BERD". Available at: https://stats.oecd.org/Index.aspx?DataSetCode=RDTAX

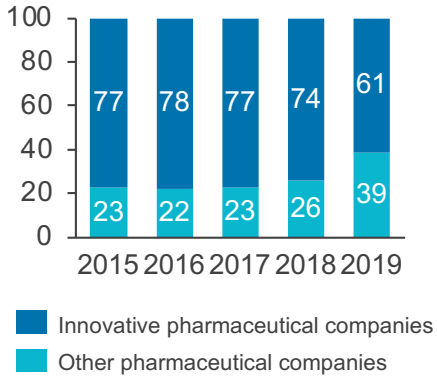
FUNDING FOR INNOVATION: R&D

INTERNATIONAL INNOVATIVE PHARMACEUTICAL COMPANIES IN SOUTH KOREA ARE DRIVING R&D PHARMACEUTICAL ACTIVITY IN THE COUNTRY, WHILST THE GOVERNMENT IS INCREASING PUBLIC SPENDING ON R&D WITH THE AIM TO FURTHER GROW THE BIOPHARMACEUTICAL INDUSTRY

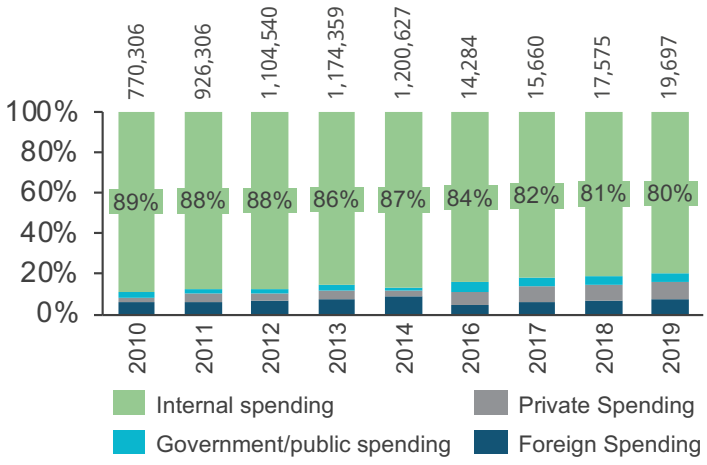
Total pharmaceutical R&D expenditure (billion USD)[1]



Split of R&D investment by Innovative/ Other Pharmaceutical Companies[2]



Total R&D expenditure by source of funding (100m KRW)[3]



[1] Various

[2] Korea Health Industry Development Institute. "Potential of the Pharmaceutical Industry in Korea". Available at: https://www.khidi.or.kr/board?menuId=MENU02288&siteId=SITE00032 [Accessed January 2023]

[3] 과학기술정보통신부·한국과학기술기획평가원, 연구개발활동조사, 각 년도. Available from: http://210.179.230.152:8083/statHtml/statHtml.do?orgId=358&tblId=DT_WER34&conn_path=I2 [Accessed January 2023]

FUNDING FOR RESEARCH

- In 2020, 27 South Korea pharmaceutical companies invested 5,902 KRW billion (4.41 USD billion) in R&D expenditure, an increase of 64% from the investment in 2016, the majority of which is by international innovative pharmaceutical companies, however, the share of domestic companies is increasing.[4]
- The Korean government's support for pharmaceutical R&D tends to be concentrated in universities and corporations, favouring the former over the latter.[5]
- Inclusion in the government's R&D support scheme often serves as a marker of the quality of a project, which enables researchers involved to receive additional investment from other investors with greater ease. Governmental support can also affect and shape corporations' R&D portfolios.[5]
- However, many have criticized the redundancy of investments made by multiple departments and agencies and the lack of interdepartmental cooperation.[5]
- The government plans to increase public spending on R&D for the biopharmaceutical industry to at least 4 trillion KRW by 2025 and is planning to directly invest 2 trillion KRW over the next 5 years.[6]
- A study by WIPO found that a key area for improvement for Korea is to increase venture capital opportunities.[7] However, KOTRA and KoreaBio are partnering with the aim to develop collaborative projects in areas such as bio-venture start-up mentorship.[8]

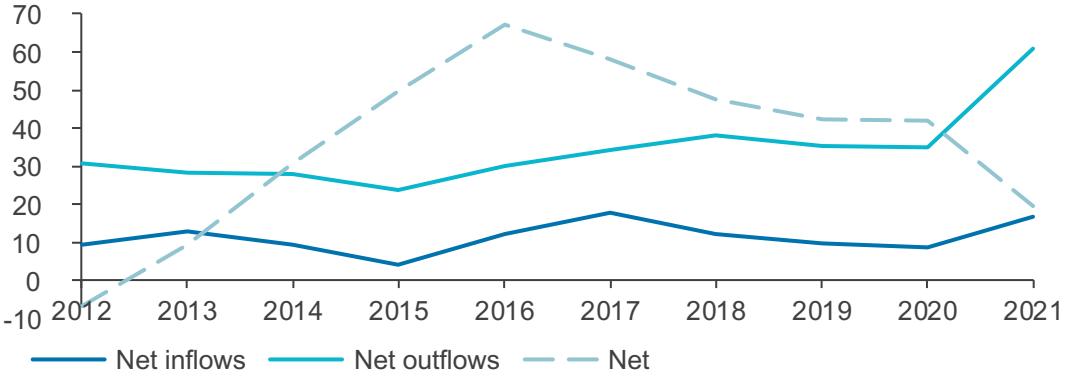
[4] KRPIA. "R&D Investment". Available at: https://www.krpia.or.kr/eng/contribute/investment [Accessed January 2023]
[5] Kim, D., McGuire, A., & Kyle, M. (2015). Korean pharmaceutical industry policy: lessons for Korea.
[6] Korea Institute of Intellectual Property (2020). A Study on Intellectual Property Issues and Responsive Strategies for Innovative Growth.
[7] WIPO (2022). "Global Innovation Index 2022 What is the future of innovation driven growth?". Accessible from: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-2000-2022-en-main-report-global-innovation-index-2022-15th-edition.pdf [Accessed January 2023]
[8] KRPIA (2022). "Korean Research-based Pharmaceutical Industry Association Annual Report 2022".

FUNDING FOR INNOVATION:
FOREIGN DIRECT INVESTMENT

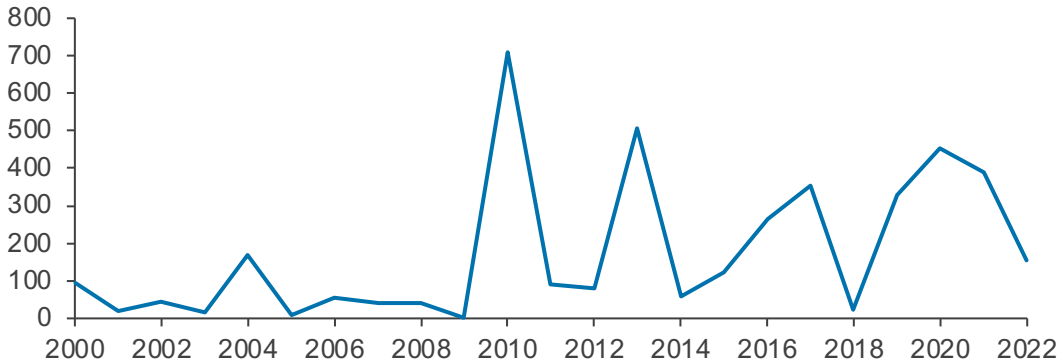
THE GOVERNMENT HAS TAKEN VARIOUS MEASURES TO ATTRACT FOREIGN INVESTMENT TO SOUTH KOREA, INCLUDING THE FOREIGN INVESTMENT

OMBUDSMAN WITHIN KOTRA AND ENACTED THE FOREIGN INVESTMENT PROMOTION ACT

Total Inflow/Outflow FDI (bn USD)[1]



FDI – Medicinal and pharmaceutical products (m USD)[2]



Abbreviations: FDI: foreign direct investment; WIPO: World Intellectual Property Organisation

[1] World Bank (2020). Foreign direct investment, net inflows (% of GDP) - Korea, Rep. Available at: https://data.worldbank.org/indicator/BX.KLT.DINV.WD.GD.ZS?locations=KR

[2] 산업통상자원부,「외국인직접투자통계」, 산업별 외국인 투자 유치 실적. Available from: https://kosis.kr/statHtml/statHtml.do?orgId=115&tblId=DT_115_2009_H3001_18_1&vw_cd=MT_ZTITLE&list_id=S2_14&scrId=&seqNo=&lang_mode=ko&obj_var_id=&itm_id=&conn_path=MT_ZTITLE&path=%252FstatisticsList%252FstatisticsListIndex.do [Accessed January 2023]

FOREIGN INVESTMENT

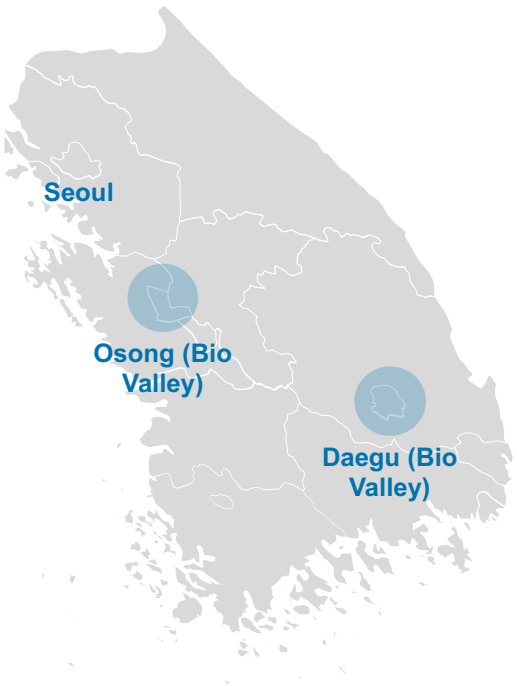
- Korea's FDI net inflows as percentage of GDP is only 0.6%, ranking Korea as 112/132 countries in the WIPO global innovation index.[3]
- The government has taken steps to address these issues over the last decade, notably with the establishment of a Foreign Investment Ombudsman inside the Korea Trade-Investment Promotion Agency (KOTRA) to address the concerns of foreign investors.[4]
- The Foreign Investment Promotion Act was enacted to support and facilitate efforts to attract foreign investment. Most of FDI incentives offered by the Korean government are provided via:[5]
    - Tax support (corporate tax and income tax reduction, acquisition tax and property tax reduction, exception from custom duties)
    - Cash grant (land purchase expense, lease expense, employment/education/training subsidy)
    - Industrial Site Support (location support, subsidy for difference of sale price, rent reduced-subsidized)
- Since the KORUS agreement, Korea has experienced an increase in FDI in the medicinal and pharmaceutical space, and some years since then (notably 2010) have experienced pronounced peaks in investment.[2]

[3] WIPO (2022). "Global Innovation Index 2022 What is the future of innovation driven growth?". Available at: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-2000-2022-en-main-report-global-innovation-index-2022-15th-edition.pdf [Accessed January 2023]
[4] U.S. Department of State (2022). "2022 Investment Climate Statements: South Korea". Available at: https://www.state.gov/reports/2022-investment-climate-statements/south-korea/ [Accessed January 2023]
[5] Santander (2023). "SOUTH KOREA: FOREIGN INVESTMENT". Available at: https://santandertrade.com/en/portal/establish-overseas/south-korea/foreign-investment [Accessed January 2023]

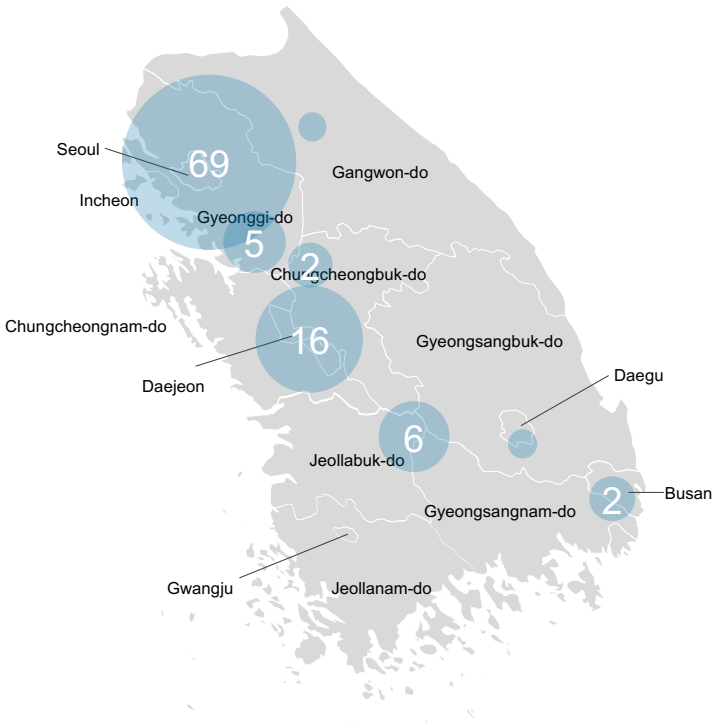
EXPERTISE AND INFRASTRUCTURE: CLUSTERS

THROUGH ITS BIO-CLUSTER POLICY, THE KOREAN GOVERNMENT HAS PROMOTED A BALANCED DEVELOPMENT OF THE BIO-INDUSTRY THROUGH THE GROWTH AND SUPPORT OF BIO-CLUSTERS BASED ON THE REGIONAL CHARACTERISTICS

Biomedical clusters [1]



CRO clusters [2]



FOREIGN INVESTMENT

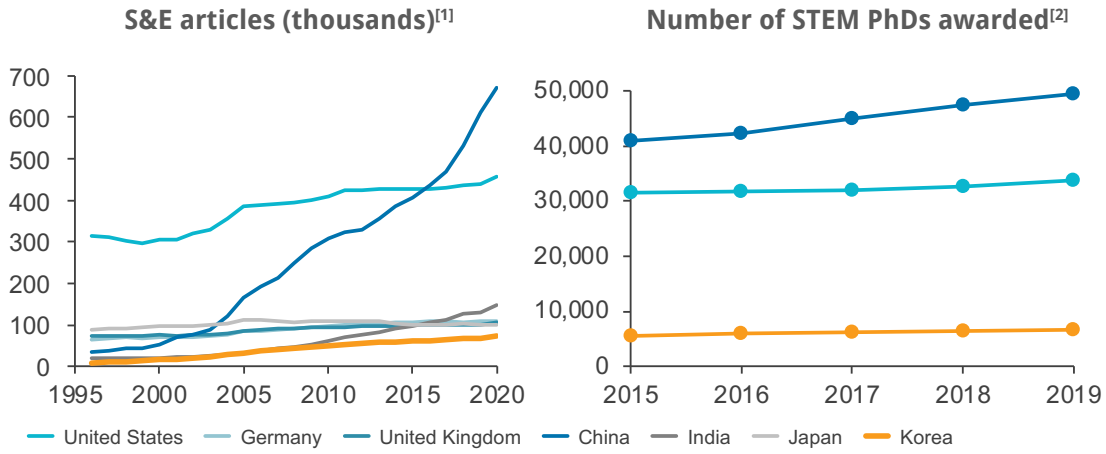
- Korea has 4 of the top 100 Science & Technology clusters in the world, outnumbered only by 4 countries (China, Germany, Japan, and the US).[3]
- The Korean government has been implementing its bio-cluster policy to establish regional innovation systems and to accomplish balanced national development through the construction of regional bioindustry complexes.[1]
- Also, by establishing Korea Bio-Hub as a central point of bio-clusters the activation of the domestic bioindustry has been promoted through human technology networking and industrialization support among domestic and foreign clusters.[1]
- Since the 2000s, it has invested extensively in developing the Osong Bio Valley, the Daegu Bio Valley, and other such bio-clusters, with the Osong project alone receiving almost KRW 7 trillion.[1]

Abbreviations: CRO: contract research organisation

[1] Kim, D., McGuire, A., & Kyle, M. (2015). Korean pharmaceutical industry policy: lessons for Korea.
[2] Contract Research Map. Available at: https://www.contractresearchmap.com/places/korea [Accessed January 2023]
[3] WIPO (2022). "Global Innovation Index 2022 What is the future of innovation driven growth?". Available at: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-2000-2022-en-main-report-global-innovation-index-2022-15th-edition.pdf [Accessed January 2023]

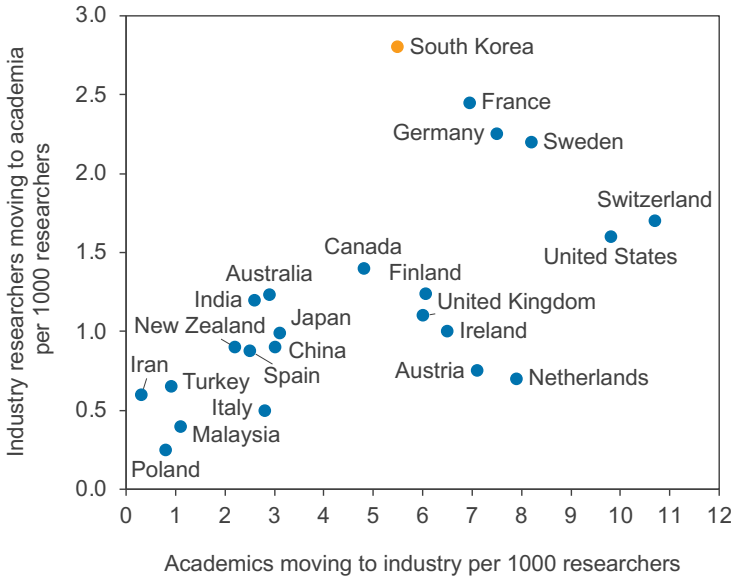
OUTPUTS OF INNOVATION: ACADEMIC ACTIVITY AND ACADEMIA-INDUSTRY COLLABORATION

SOUTH KOREA HAS HAD STRONG ACADEMIC R&D OUTPUT IN RECENT YEARS WITH AN INCREASE IN THE NUMBER OF S&E PUBLICATIONS AND THE FOSTERING OF CROSS-SECTORAL MOVES BETWEEN THE INDUSTRY AND ACADEMIA



CROSS-COLLABORATION

- Historically, South Korea has implemented a 'top-down' innovation system which promotes close collaboration between government, industry, and the academic community in the process of nation-building, and this approach is reflected in the high cross-sectoral moves between industry and academia.[3]
- However, there are some factors hindering academic-industrial collaboration, including the small size of domestic Korean pharmaceutical companies and their pools of experts and the inefficiency of the system for distributing rewards for collaboration.[4]



Abbreviations: R&D: research and development; S&E: science and engineering; STEM: science technology engineering math

[1] Korean Citation Index. Available at: https://www.kci.go.kr/kciportal/main.kci [Accessed January 2023]

[2] 한국직업능력연구원, 교육부,「국내신규박사학위취득자조사」, 박사과정 중 총 학비 지출 현황. Available at: https://kosis.kr/statHtml/statHtml.do?orgId=389&tblId=DT_920009_A11&conn_path=I2 [Accessed January 2023]

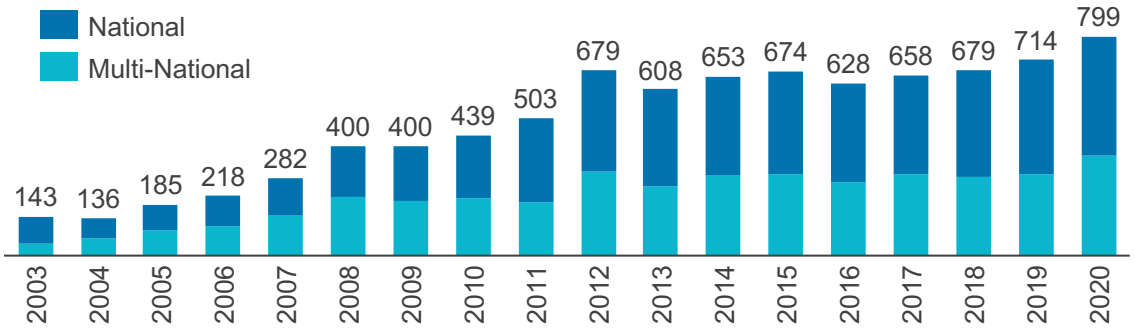
[3] Dayton (2020). "How South Korea made itself a global innovation leader". Available at: https://www.nature.com/articles/d41586-020-01466-7 [Accessed January 2023]

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

OUTPUTS OF INNOVATION: CLINICAL TRIALS

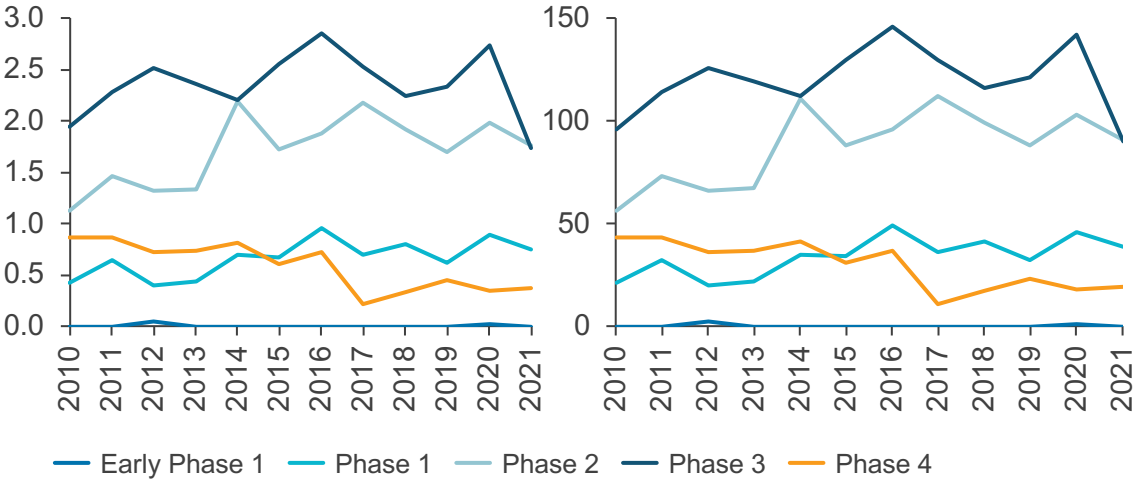
IN RECENT YEARS, KOREAN PHARMACEUTICAL COMPANIES AND BIO-VENTURES HAVE INVESTED MORE FUNDS IN NEW DRUG R&D, WHICH IS REFLECTED IN AN INCREASE IN THE NUMBER OF NEW DRUG CANDIDATES AND CLINICAL TRIAL ACTIVITY

Approved Clinical Trial Protocols[1]



Number of New Clinical Trials per 1M Population (2000 – 2021)[2]

Absolute Number of New Clinical Trials (2000 – 2021)[2]



Abbreviations: R&D: research and development

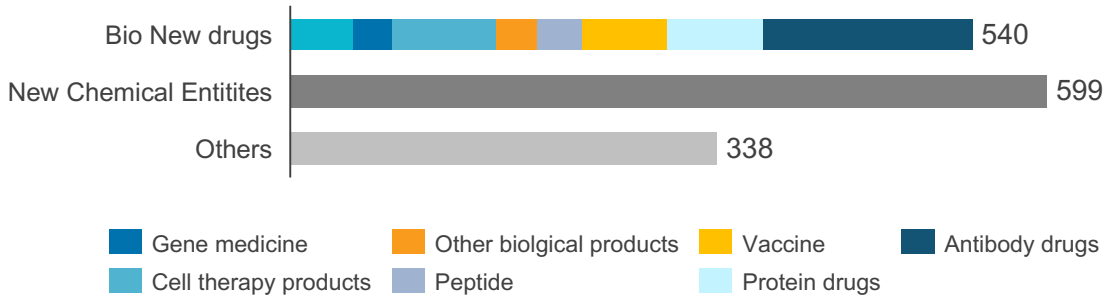
[1] 식품의약품안전처 임상정책과. Available at: https://nedrug.mfds.go.kr/searchClinic?page=1&searchYn=true&approvalStart=&approvalEnd=&searchType=ST3&searchKeyword=%EC%BD%94%EB%A1%9C%EB%82%98&approvalDtStart=2017-11-06&approvalDtEnd=2020-11-06&clinicStepCode=&examFinish=&domestic=&gender=&age=&localList=000&localList2= [Accessed January 2023]

[2] Clinicaltrials.gov. https://clinicaltrials.gov/ [Accessed February 2023]

CLINICAL TRIALS

- In 2007, there was a huge jump in clinical trials due to the opening in the domestic pharmaceutical market ahead of the KORUS FTA.[4]
- In 2019, the 35 multi-national pharmaceutical companies invested 483.7 billion won (360 million USD) toward clinical R&D activities, giving domestic patients new treatment opportunities free of charge.[5]
- Furthermore, in 2021, the KPBMA surveyed 299 domestic pharmaceutical companies on the progress of new drug development and found that there were 1,477 pipeline products, which include product iterations and new dosages (denoted as "Others" in the chart below).
    - This is a 157.8% increase from the results of the survey conducted by the association in 2018 (100 companies, 573 pipeline products). It demonstrates the active R&D investment of pharmaceutical companies.[6]

Pipeline products by type [3]



Abbreviations: R&D: research and development; KPBMA: Korea Pharmaceutical and Bio-Pharma Manufacturers Association

[3] Invest Korea (2022). The Korean Pharmaceutical Industry's New Leap forward into the Global Market. Available at: https://www.investkorea.org/ik-en/bbs/i-308/detail.do?ntt_sn=490775&clickArea=enmain00019 [Accessed February 2023]

[4] Han, H. (2007). 국내 의약품 시장 다국적 임상시험 증가 지적재산권 잰걸음. https://www.kgnews.co.kr/news/article.html?no=148859 [Accessed January 2023]

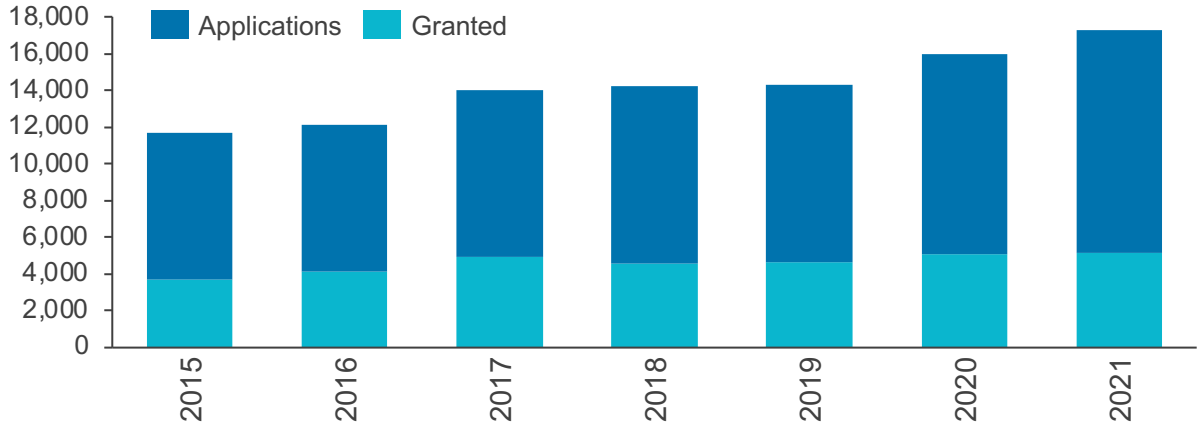
[5] KRPIA. "R&D Investment". Available at: https://www.krpia.or.kr/eng/contribute/investment [Accessed January 2023]

[6] Invest Korea (2022). The Korean Pharmaceutical Industry's New Leap forward into the Global Market. Available at: https://www.investkorea.org/ik-en/bbs/i-308/detail.do?ntt_sn=490775&clickArea=enmain00019 [Accessed January 2023]

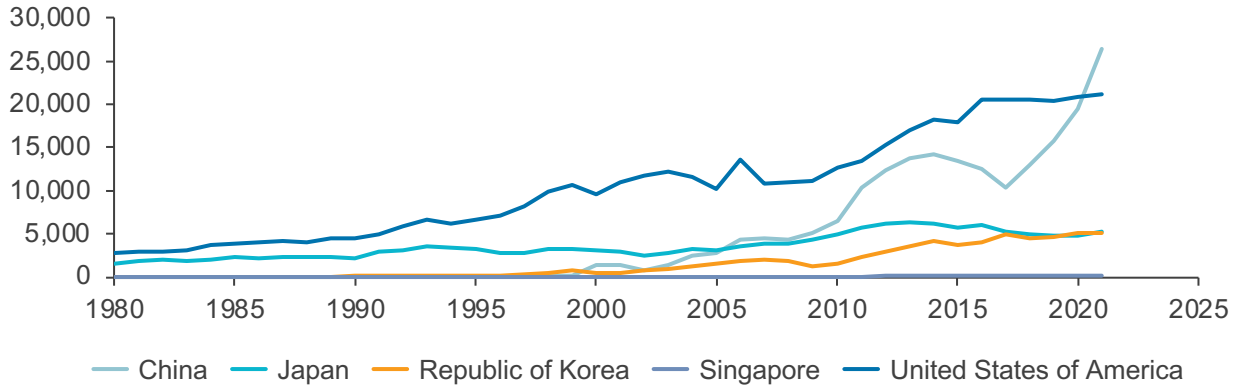
OUTPUTS OF INNOVATION:
PATENT FILINGS AND GRANTS

THROUGH THE STRENGTHENING OF THE PATENT SYSTEM, INTERNATIONAL PHARMACEUTICAL COMPANIES FILED MORE PATENTS IN KOREA, WHILST DOMESTIC COMPANIES STARTED INCREASING THEIR INNOVATIVE CAPABILITIES

Patent applications and grants Biotechnology and Pharmaceuticals[1]



Number of patent grants – Biotechnology and pharmaceuticals[3]



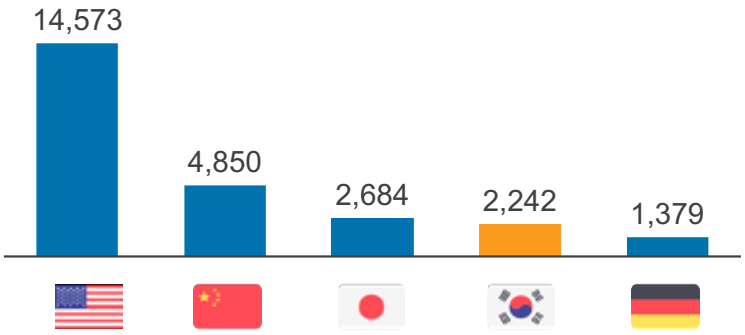
[1] 특허청,「지식재산권통계」, 기술분야별 특허 출원(WIPO 기술분류 기준). Available at: https://kosis.kr/statHtml/statHtml.do?orgId=138&tblId=TX_13801_A024_2&conn_path=I2 [Accessed January 2023] [2] Chemical Abstracts Service. 2022.
[3] WIPO (2022). WIPO statistics database. Available at: https://www3.wipo.int/ipstats/ [Accessed January 2023]

PATENT APPLICATION TRENDS

The introduction of the patent system in 1987 significantly increased the number of Korean patent applications. Domestic companies achieved growth by developing new products, evidenced by the expanding number of patent applications. This finding supports that there is increased innovative activity in domestic pharmaceutical companies in Korea compared to previous years.[4] However, Korea remains a generic market and most activities are bioequivalence studies and salt modification drugs.

In 2021, 39 companies registered 155 pharmaceutical biotechnology patents. Among those, 106 cases came from 21 multinational pharmaceutical companies and the remaining 49 cases came from 18 domestic companies.[5]

Applications for patents related to cell and gene therapies
Top 5 countries (1988-2017)[2]

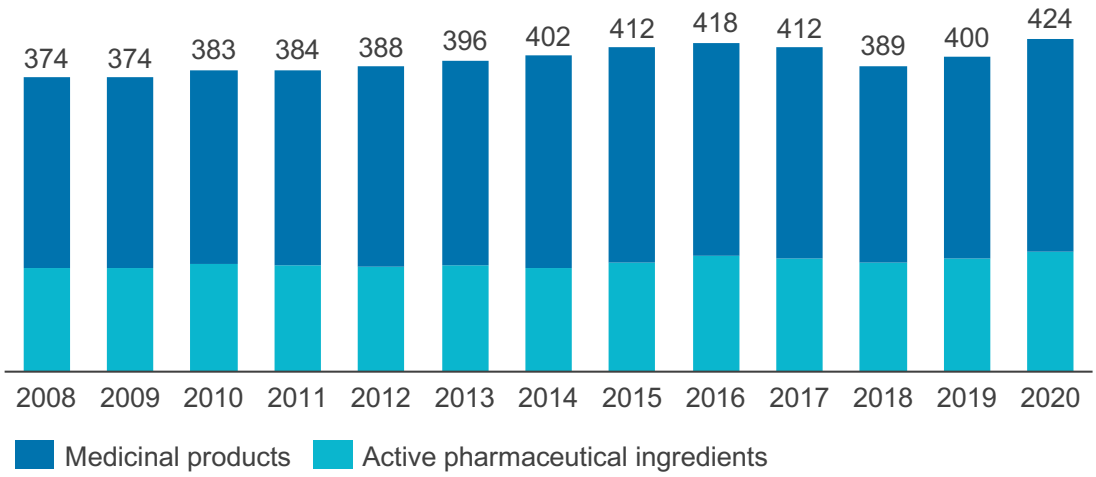


[2] Various
[4] Um, S. I., Sohn, U. D., Jung, S. Y., You, S. H., Kim, C., Lee, S., & Lee, H. (2022). Longitudinal study of the impact of three major regulations on the Korean pharmaceutical industry in the last 30 years. Health Research Policy and Systems, 20(1), 1-12.
[5] Kim (2022). 제약사 생명줄 '특허권'...다국적사 텃밭서 '힘 못쓴' 토종기업. Available at: https://www.medicopharma.co.kr/news/articleView.html?idxno=58501 [Accessed January 2023]

ECONOMIC ACTIVITIES:
NUMBER OF ENTERPRISES AND EMPLOYEES

THE NUMBER OF PERSONNEL EMPLOYED IN THE BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRY IN SOUTH KOREA IS INCREASING, AND SO IS THE NUMBER OF HIGH-QUALITY RESEARCH JOBS WITHIN THE INDUSTRY

Number of pharmaceutical manufacturers in compliance with GMP[1]



EMPLOYMENT

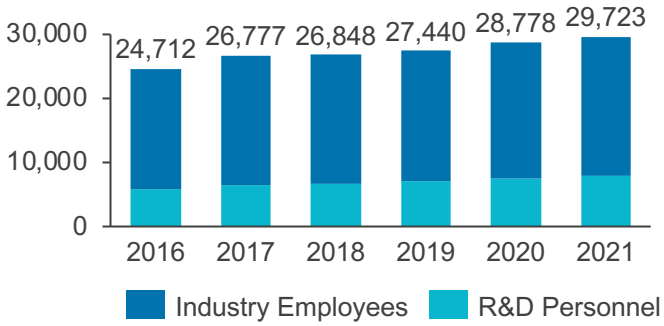
According to the employment index of the pharmaceutical industry, 5,400 to 6,100 jobs were generated per KRW 1 trillion of sales revenue, and to develop four blockbuster-level new drugs, about 150,000 to 170,000 jobs would be generated.[4]

The pharmaceutical industry has a ratio of Master's and Doctoral degrees among all researchers of 71.7%, which is over double that of the general manufacturing industry (33.7%).[4]

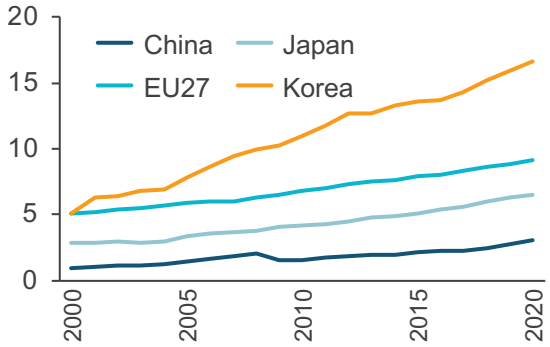
Abbreviations: GMP: good manufacturing practice; R&D: research and development;

[1] Pharma Korea (2020). "Potential of the Pharmaceutical Industry in Korea"
[4] KRPIA (2022). "Korean Research-based Pharmaceutical Industry Association Annual Report 2022"

Employment in the Biotechnology and Pharmaceutical Industry[2]



Total number of researchers per 1000 employed (across industries)[3]



R&D PERSONNEL

The total number of R&D workers at 35 global pharmaceutical companies that participated in a survey by KRPIA increased steadily to 1,702 in 2019. Global pharmaceutical companies are making contributions to creating jobs for high-quality researchers in Korea.[5]

A survey on the pharmaceutical industry at the Korean Statistical Information Service showed only 27.9% of all researchers in the industry were actually doing R&D for innovative drugs other than incrementally modified drugs or generics.[6]

Abbreviations: KRPIA: Korean Research-based Pharmaceutical Industry Association

[2] 산업통상자원부,「국내바이오산업실태조사」, 바이오산업 인력 현황. Available at: https://kosis.kr/statHtml/statHtml.do?orgId=115&tblId=DT_115015_002&conn_path=I2 [Accessed January 2023]

[3] OECD (2021). "Researchers, 2020". Available at: https://data.oecd.org/rd/researchers.htm [Accessed January 2023]

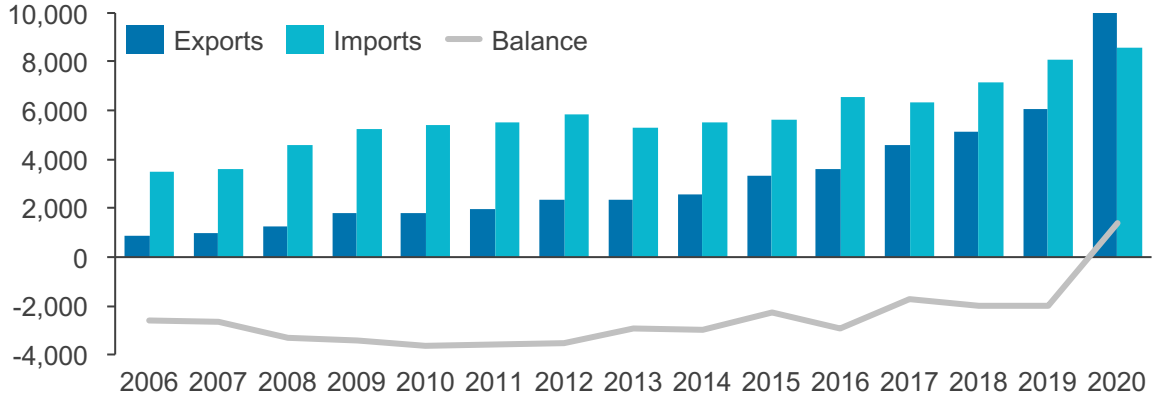
[5] KRPIA. "R&D Investment". Available at: https://www.krpia.or.kr/eng/contribute/investment [Accessed January 2023]

[6] Choi, Y. and Lee, H., 2022. How to boost and accelerate new drug development in Korea: business ecosystem perspectives. Translational and Clinical Pharmacology, 30(3), pp.129-135.

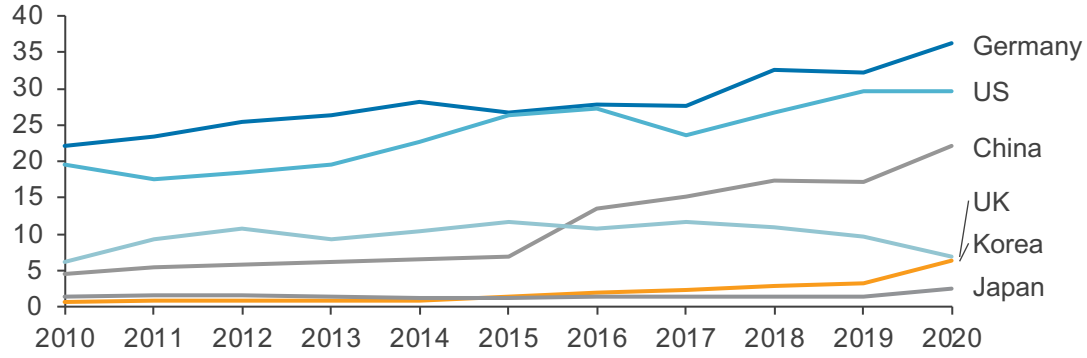
TRADE: IMPORTS AND EXPORTS OF PHARMACEUTICAL PRODUCTS ARE STEADILY GROWING

THE KOREAN PHARMACEUTICAL INDUSTRY HAD AN ESTIMATED ANNUAL GROWTH OF CAGR 6.9% FROM 2019 TO 2024,[3] WITH THE GOVERNMENT SELECTING THE PHARMACEUTICAL AND BIO-INDUSTRY AS ONE OF THREE KEY GROWTH INDUSTRIES

Imports and Exports of Pharmaceutical and Biopharmaceutical products (hundred million KRW)[1]



Exports of medicinal and pharmaceutical products (USD bn)[2]



[1] Pharma Korea (2020) "Potential of the Pharmaceutical Industry in Korea"
[2] Various sources
[3] Korea Institute of Intellectual Property (2020). A Study on Intellectual Property Issues and Responsive Strategies for Innovative Growth.

PHARMACEUTICAL EXPORTS

- Korea is the 11th largest pharmaceutical market in the world:[4]
    - The Korean pharmaceutical market is forecast to exceed US$18-22B value annually by 2025.
    - Growth is projected to continue at an annual rate of 4.5-7.5% at the domestic level, being close to the world average of 7-10%.
- By expanding exports of South Korean-made pharmaceutical products to the global market, the export volume in 2020 recorded close to KRW 10 trillion and marked a historic high of KRW 9.96 trillion with a year-on-year growth of 62.5%.[5]
    - According to the Ministry of Food and Drug Safety, domestic drug exports grew by roughly 30.5% from KRW 3.6 trillion in 2016 to 4.6025 trillion the following year and have steadily escalated since then, reaching KRW 9.9 trillion in 2020. The number of exporting countries amounts to 214, located in North America, Europe, and Asia.[6]
- Moreover, according to a survey by the KPBMA, 78 domestic pharmaceutical companies have 13 branch offices overseas and 192 overseas corporations.[6]

Abbreviations: KBPMA: Korea Pharmaceutical and Bio-Pharma Manufactures Association

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

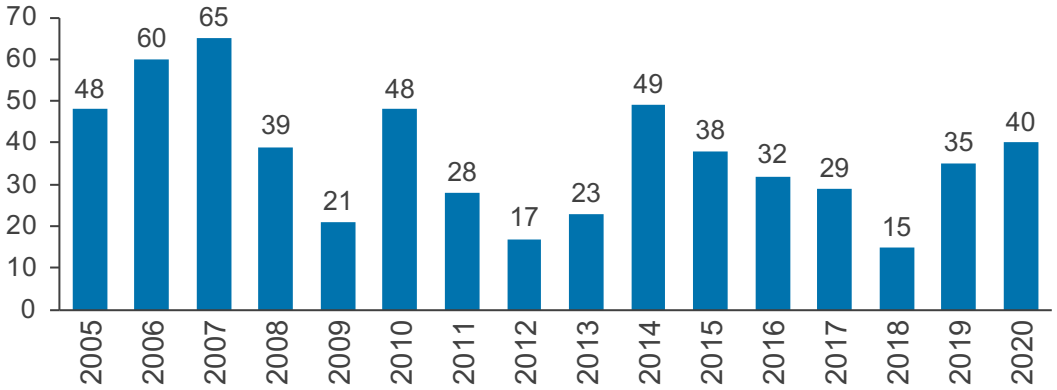
[5] KRPIA (2022). "Korean Research-based Pharmaceutical Industry Association Annual Report 2022".

[6] Invest Korea (2022). "The Korean Pharmaceutical Industry's New Leap forward into the Global Market". Available at: https://www.investkorea.org/ik-en/bbs/i-308/detail.do?ntt_sn=490775&clickArea=enmain00019 [Accessed January 2023]

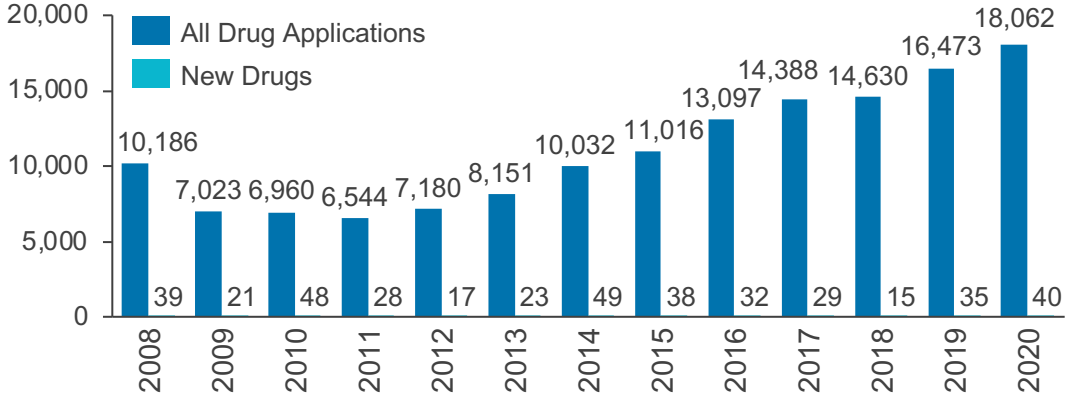
ACCESS TO MEDICINES: NEW DRUG APPROVALS

ACCESS TO SOME INNOVATIVE PRODUCTS IS LIMITED, HOWEVER, THE GOVERNMENT IS INTRODUCING MEASURES TO IMPROVE PATIENT ACCESS TO INNOVATIVE DRUGS, IN PARTICULAR, ONES WHICH ADDRESS HIGH UNMET NEEDS AND ARE FOR ORPHAN INDICATIONS

Acceptance of all new drug registration applications[1]



All approved drugs and new drug applications[1]



[1] 식품의약품안전처. Available at: https://www.mfds.go.kr/pgm/m_538/statInformation.do [Accessed January 2023]

NEW DRUG APPROVALS

- Almost every Korean (97%) is enrolled in the National Health Insurance program,[2] which is increasingly investing in innovative products. One study found that the total expenditure on orphan drugs increased annually to account for about 1.44% of total pharmaceutical expenditure in 2018. Orphan drug expenditure per patient increased on average by 8.7% per year.[3]
- However, the average level of access to medicines through the health insurance system is high but access to certain expensive essential medicines is difficult.[4]
- For example, Korea was ranked 19th out of 31 nations surveyed in terms of patient access to new drugs, as measured by the number of drugs launched in each country since 2005. This is partially attributed to the explicit and inflexible ICER threshold and the rigid economic evaluation and reimbursement mechanism in place.[5]
- However, the national health insurance utilises three methods for improving patient access to costly drugs: risk-sharing agreements, designation of essential drugs, and a waiver of cost-effectiveness analysis.[6]
- Furthermore, the South Korean government is expected to develop policies that will improve patient access to drugs with unmet needs for broadening health insurance coverage.[6]

[2] Ministry of Health and Welfare (2022). "Start with Korea". Available at: https://www.konect.or.kr/_img/en/Brochure_09_final.pdf
[3] Lee, S.H., Yoo, S.L., Bang, J.S. and Lee, J.H., 2020. Patient accessibility and budget impact of orphan drugs in South Korea: long-term and real-world data analysis (2007–2019). International journal of environmental research and public health, 17(9), p.2991.
[4] 정연 and 권순만. (2014). 지적재산권 강화에 따른 제약시장의 변화와 의약품 가격 및 이용에의 영향 ㅁ 5개 국가의 사례를 중심으로. 한국사회정책, 21(2), 183-228.
[5] Choi, Y. and Lee, H., (2022). How to boost and accelerate new drug development in Korea: business ecosystem perspectives. Translational and Clinical Pharmacology, 30(3), pp.129-135.
[6] Yoo, S.L., Kim, D.J., Lee, S.M., Kang, W.G., Kim, S.Y., Lee, J.H. and Suh, D.C., (2019). Improving patient access to new drugs in South Korea: evaluation of the national drug formulary system. International Journal of Environmental Research and Public Health, 16(2), p.288.

SOUTH KOREA: ASSESSMENT OF PERFORMANCE

- Compared to the South East Asia, East Asia and Oceania (SEAO) region, Korea comparatively has strong R&D capabilities and a robust healthcare system that covers the majority of the population. If more investment were to be allocated to innovation, Korea would experience higher innovative and economic activity.
  - Countries included in region include Australia, Brunei Darussalam, Cambodia, China, Hong Kong, Indonesia, Republic of Korea, Lao People's Democratic Republic, Malaysia, Mongolia, Myanmar, New Zealand, Philippines, Singapore, Vietnam,
- With renewed investments in R&D and increased IP incentives, Korea could attract more FDI and pharma confidence to create new medicines.

	INDICATORS	COMPARED TO SEAO REGION	COMPARED TO OECD
FUNDING FOR INNOVATION	R&D		
	Foreign direct Investment		
INNOVATIVE ACTIVITY	Early research (publications)		
	Clinical trials		
	Patents		
ECONOMIC ACTIVITY	Number of Enterprises		
	Employment		
	Trade		
PATIENT IMPACT	Access to medicines		

Improving performance

SUMMARY OF KOREA'S INNOVATION STRENGTHS AND WEAKNESSES

KEY STRENGTHS OF KOREA'S INNOVATION ENVIRONMENT

- Increased prioritization of R&D spending
- Recent growth and development of bio-clusters
- Robust academic output and academia-industry collaboration
- Increased number of clinical trials and new pipeline drug candidates
- Increased number of pharmaceutical patent filings and drug approvals
- Growing number of pharmaceutical SMEs and pharmaceutical export
- Adoption of pro-innovation policies and systems based on innovative markets

KEY WEAKNESSES OF KOREA'S INNOVATION ENVIRONMENT

- Lack of focus on creating an innovative ecosystem and attracting diverse talent
- Sporadic and disjointed approach towards innovation policy
- Pricing and reimbursement challenges
- Restrictive patentability criteria
- Patent term extensions
- Inadequate damages for patent infringement
- Patent enforcement concerns

KOREA'S WEAKNESSES IN THE INNOVATION POLICY SPACE AND INTELLECTUAL PROPERTY FRAMEWORK IMPACT THE OVERALL INNOVATION ECOSYSTEM

AREAS OF IMPROVEMENT IN THE INNOVATION POLICY SPACE	
Lack of focus on creating an innovative ecosystem and attracting diverse talent	Sweeping changes in innovation policy were implemented after the KORUS agreement but follow-up legislation to provide significant incentives for innovation and targeted workforce development has been lacking.[1,2] Korea's ability to attract and retain diverse and creative talent is lacking compared to more international markets.[5,6]
Sporadic and disjointed approach towards innovation policy	Literature points to a high number of government ministries and organisations involved in directing pharmaceutical innovation policy, with a disjointed approach that results in redundancies and lack of effectiveness.[1,4]
Pricing and reimbursement challenges	Due to strict and outdated cost-effectiveness criteria and low government-set prices, Korea is not an attractive market for pharmaceutical access. Automatic price reductions also harm both innovators and generics, diluting value.[7]

[1] Choi, Y. and Lee, H., (2022). How to boost and accelerate new drug development in Korea: business ecosystem perspectives. Translational and Clinical Pharmacology, 30(3), pp.129-135.
[2] Interview with domestic Korean company
[4] 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 [Accessed January 2023]
[5] Korea Immigration Service (2019). 출입국 외국인정책 통계월보. http://viewer.moj.go.kr/skin/doc.html?rs=/result/bbs/227&fn=temp_1581918117248100 [Accessed January 2023]
[6] Yoon (2022). This is how South Korea can become a global innovation hub. Available at: https://www.weforum.org/agenda/2022/01/startups-in-south-korea-are-thriving-this-is-why/ [Accessed January 2023]
[7] Pharmaceutical Research and Manufacturers of America (2022). "Special 301 Submission 2022"

AREAS OF IMPROVEMENT IN THE INNOVATION POLICY SPACE

Restrictive patentability criteria	Whilst there are defined patentability criteria for medicines in South Korea, these are strict compared to international standards and can result in valuable inventions recognised as such in other countries but not being granted appropriate protections in Korea.[7]
Patent Term Extensions	The KIPO is extremely conservative with granting extensions and policy requirements to grant approvals are much more restricted than their European/American counterparts. The recently proposed changes risk further restrictions. PTE needs to improve their scope, evaluation of international trials, and their all-or-nothing rule.[8,9]
Inadequate damages for patent infringement	In November 2020, the Korean Supreme Court held that generic companies were not liable for damages caused by a mandatory price reduction to a patented product even if the patent was upheld and the generic company entered the market illegally, forcing the price cut in question.[7]
Patent enforcement concerns	The Ministry of Food and Drug Safety (MFDS) has full discretion as to whether to list a patent in the Green List and it is extremely challenging for original patent owners to gain approval for generic sales suspension. Conversely, generic exclusivity is granted easily and patent owners are forced to dedicate resources to enforce their own patents.[7,10,11]

[7] Pharmaceutical Research and Manufacturers of America (2022). "Special 301 Submission 2022"
[8] KimChang (2017). Korean Patent Court Dismisses Generics' Challenges to PTE Terms. Available at: https://www.kimchang.com/newsletter/2018newsletter/ip/eng/html/newsletter_ip_en_Sping_Summer2018_article01.html [Accessed January 2023]
[9] KimChang (2018). Legal Developments Regarding Patent Term Extensions in Korea. Available at: https://www.kimchang.com/newsletter/2018newsletter/ip/eng/html/newsletter_ip_en_Sping_Summer2018_article01.html [Accessed January 2023]
[10] Son, K.B., 2022. Patenting and patent challenges in South Korea after introducing a patent linkage system. Globalization and Health, 18(1), pp.1-10
[11] Lim (2020). 의약품 허가-특허연계제도, 특허권자 보호 강화 목적 … 효과성 더 높일 중·장기적 검토는 필요. Available at: https://www.biotimes.co.kr/news/articleView.html?idxno=3477 [Accessed January 2023]

3.

Future opportunities for growth in innovation

OUTPUTS OF INNOVATION: ACADEMIC ACTIVITY AND ACADEMIA-INDUSTRY COLLABORATION

TWO MAIN QUESTIONS WERE CONSIDERED:

1. Building from the significant progress that has already been made, where are the **opportunities** for increasing the level of innovative and economic activity even further in the future?
2. What **lessons** can be drawn from other countries that have encountered similar challenges?

POLICY ENVIRONMENT SUMMARY: LEGISLATION TIMELINE

CHANGES IN THE IP REGIME

DATA PROTECTION THROUGH THE PHARMACEUTICAL AFFAIRS ACT (1995)

- The Korean Pharmaceutical Affairs Act was amended in 1995 to provide de-facto 4- or 6-year post marketing surveillance for new drugs.[1]

SIGNING OF THE KORUS FTA (2007)

- The FTA, which was signed in 2007, consisted of key IP changes in the pharmaceutical sector, such as the introduction of patent linkage, safety regulations for new drugs, and the protection of safety and efficacy information.[2]

PATENT LINKAGE (2015)

- The KORUS FTA introduced the approval-patent linkage system in South Korea. Patent linkage was implemented in 2015 based on the US Hatch-Waxman System, allowing patent owners to be informed of generic applications and implement measures to prevent generic entry during the patent term.[3]

THE SPECIAL ACT ON SUPPORTING AND FOSTERING THE PHARMACEUTICAL INDUSTRY (2011, AMENDED 2013, 2018, 2022)

- The Act aims to lay a foundation for the development of the pharmaceutical industry and by creating an environment to induce investment from foreign pharmaceutical enterprises.[6]
- The five-year plan envisioned making Korea one of the seven global centres of pharmaceutical innovation.[7]

INNOVATIVE PHARMACEUTICAL COMPANY (IPC) CERTIFICATION (2012)

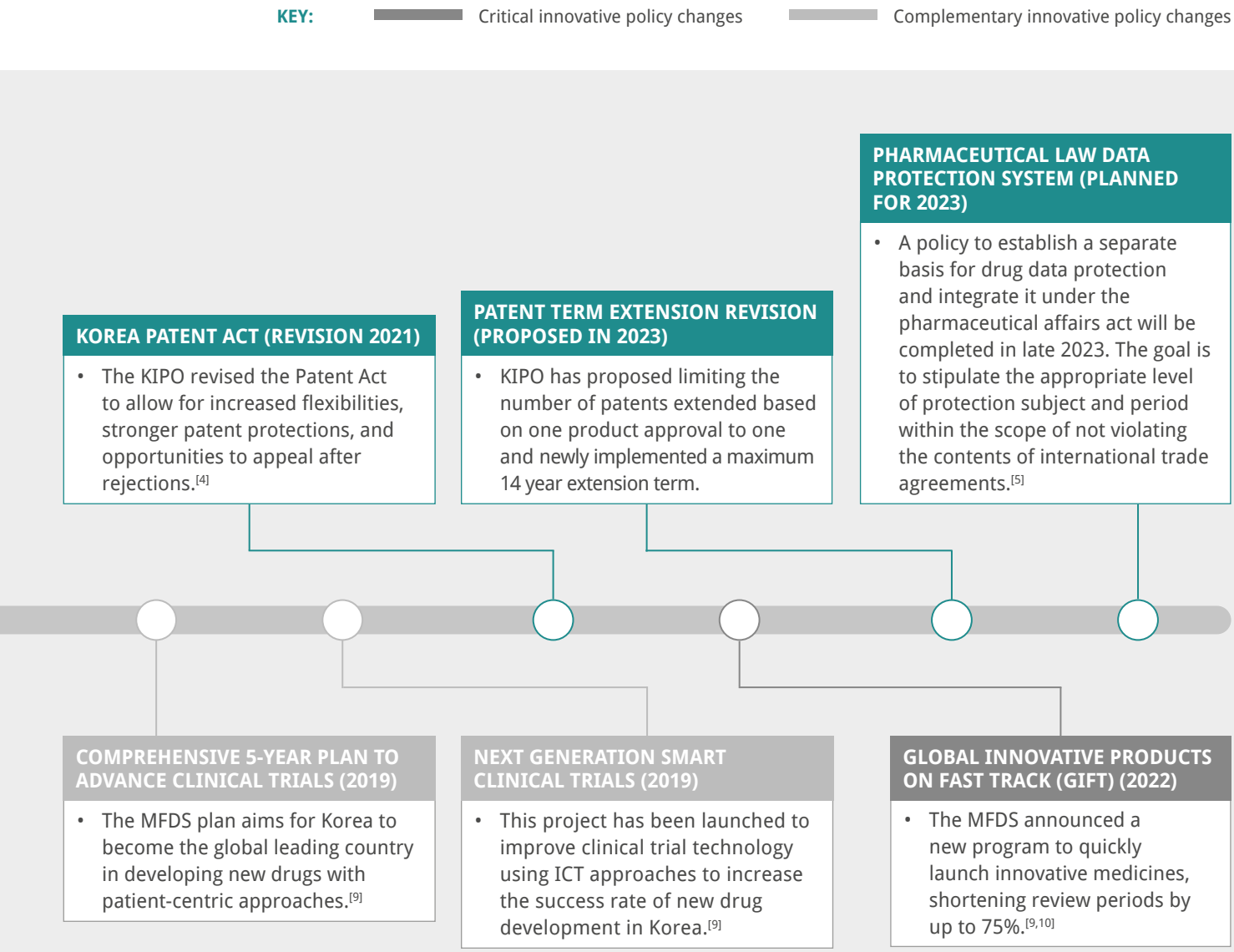
- As part of the KORUS FTA requirements, the Korean government began recognizing innovative pharmaceutical companies through a certification process to provide incentives to selected companies.[8]

INNOVATIVE STRATEGY ON THE BIO-HEALTH INDUSTRY (2019)

- The pan-government strategy aims to drive innovative growth via bio-health industry development.[9]

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
[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). 대웅제약, 신속심사 성공사례 '엔블로정' 발표. https://www.sentv.co.kr/news/view/644246

OPPORTUNITIES FOR GROWTH IN INNOVATION POLICY: LACK OF FOCUS ON CREATING AN INNOVATIVE ECOSYSTEM AND ATTRACTING DIVERSE TALENT

THE KOREAN PHARMACEUTICAL MARKET STILL HAS MUCH MORE FAVOURABLE CONDITIONS FOR THE GENERIC INDUSTRY, AND INNOVATION POLICIES HAVE NOT BEEN STRATEGICALLY IMPLEMENTED TO MAXIMISE INNOVATIVE OUTPUTS

CONTEXT

- Many Korean innovation policies were brought in with the KORUS FTA. The current innovation policies are not having their intended impact on innovation because they are not fully protecting and encouraging IP investment.[1]
    - For example, The primary goal of Korea's de-facto RDP, PMS, was to ensure drug safety; data protection was merely a side effect and it is not as robust as true RDP.[1]
- The Korean market is much more attractive to generics and the industry's priority has been to transition generic companies to innovative ones.[2]
    - Innovative R&D requires significant workforce that is currently being outsourced.[2]

Abbreviations: FTA: free trade agreement; IP: intellectual property; RDP: regulatory data protection; PMS: post-marketing surveillance; R&D: research and development; NIPA: National IT Industry Promotion Agency

[1] Interview with multinational pharmaceutical company

[2] Interview with domestic pharmaceutical company

CHALLENGES FOR INNOVATION

Uncertain IP protections

- Many of Korea's IP protections have been less favourable for multinational and domestic innovative companies compared to policies in the US and EU. Extended resources are required to gain access to incentives in Korea, increasing costs despite the limited market opportunities.[3]

Market conditions for generics

- Korea has been focusing on chemical, generic medicines, which means that it puts more importance on expanding the market size through generics than developing new compounds.[3]
- The disproportional focus on the generic industry has limited the domestic innovative workforce and created an overall market that prioritises fast approval and dissemination of generic products.[4]

OPPORTUNITIES FOR GROWTH AND BEST PRACTICES

Korea should strengthen IP protections in line with other markets

- The EU has relied upon strong IP protection for securing investment in underserved markets such as orphan medicines. Market exclusivity incentives were responsible for securing the economic viability of over half (74 of 142) the orphan drugs developed in Europe between 2000 and 2017.[5]

Korea needs to attract and retain increased professional capacity

- Most start-up support and innovation programs in Korea tend to be outbound to other markets. Inbound programs like NIPA's K-Startup Grand Challenge require further scaling to grow the domestic workforce.[6]

Abbreviations: FTA: free trade agreement; IP: intellectual property; RDP: regulatory data protection; PMS: post-marketing surveillance; R&D: research and development; NIPA: National IT Industry Promotion Agency

[3] Interview with Korean IP academic

[4] Interview with domestic biopharmaceutical trade association

[5] Dolon (2020) Estimated impact of EU Orphan Regulation on incentives for innovation. Available at: https://dolon.com/rare-knowledge/publications/estimated-impact-of-eu-orphan-regulation-on-incentives-for-innovation [Accessed January 2023]

[6] Yoon (2022). This is how South Korea can become a global innovation hub. Available at: https://www.weforum.org/agenda/2022/01/startups-in-south-korea-are-thriving-this-is-why/ [Accessed January 2023]

OPPORTUNITIES FOR GROWTH IN INNOVATION POLICY: SPORADIC AND DISJOINTED APPROACH TOWARDS INNOVATION POLICY

KOREAN POLICIES USED INCENTIVES AS A KEY 'PULL FACTOR' TO TRANSITION INTO INNOVATIVE MEDICINES, BUT THEY HAVE HAD MINIMAL IMPACT IN THE OVERALL INNOVATION ENVIRONMENT

CONTEXT

- In 2019, Korea was placed among the OECD countries that provide the largest level of tax relief to business R&D as a percentage of GDP, at a rate equivalent to 0.29% of GDP. Tax incentives account for 43% of this support.[1]
- The Special Act on Supporting and Fostering the Pharmaceutical Industry was also designed to introduce additional R&D incentives and jumpstart an innovative market in Korea.[2]

Abbreviations: OECD: Organization for Economic Co-operation and Development; R&D: research and development; GDP: Gross Domestic Product; FTA: free trade agreement; RDP: regulatory data protection; MoHW: Ministry of Health and Welfare

[1] OECD (2021). "R&D Tax Incentives". Available at: https://www.oecd.org/sti/rd-tax-stats-korea.pdf

[2] Interview with multinational pharmaceutical firm

CHALLENGES FOR INNOVATION

Lack of focus in incentive distribution and policymaking

- In the Korean medical industry, there are five different ministries and organisations: the Ministry of Industry, the Ministry of Science and Technology, the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, and the Korea Disease Control and Prevention Agency. These five organisations do not have a clear division of roles, presenting a key obstacle for effective policy. There has been a number of requests to simplify the existing processes.[4]
- Incentives have not resulted in sweeping changes and new policies outside of the KORUS FTA have faced many ministerial delays.[2]
    - For example, It was announced that a new policy to establish a separate basis for RDP will be completed by early 2023. There have been not been any new announcements as of June 2023.[3,4]

OPPORTUNITIES FOR GROWTH AND BEST PRACTICES

Establishing a "control tower"

- Acknowledging the issues of having a sporadic and disjointed approach within policymakers, the government announced a plan to establish a "control tower" to oversee biopharmaceutical innovation activities across the different actors. The control tower should make plans and implement them across the bioindustry, not only in the pharmaceutical sector but also in other novel areas such as digital health.[3]
- It is unclear if the control tower should be led by a new organisation or an existing one taking on these responsibilities.[5]
- The MoHW and the Yoon administration announced in 2022 that the biopharma innovation committee will take on this "control tower" role, but the discussions are still pending and there is no clear indication how this role will streamline activities and distribute incentives in a much more focused manner.[2]

Abbreviations: OECD: Organization for Economic Co-operation and Development; R&D: research and development; GDP: Gross Domestic Product; FTA: free trade agreement; RDP: regulatory data protection; MoHW: Ministry of Health and Welfare

[2] Interview with multinational pharmaceutical firm

[3] Interview with domestic biopharmaceutical trade association

[4] 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 [Accessed January 2023]

[5] Interview with IP academic

OPPORTUNITIES FOR GROWTH IN INNOVATION POLICY: PRICING AND REIMBURSEMENT CHALLENGES

KOREA'S PRICING AND REIMBURSEMENT CREATE UNCERTAINTY FOR INVESTORS, DISINCENTIVIZING MARKET ENTRY

CONTEXT

- The number of people insured under the National Health Insurance System (NHIS) in Korea almost matches the population. Thus, reimbursement prices of medicinal products are strictly regulated if they are reimbursed under the NHIS.[1]
- Manufactures or importers apply for pricing and reimbursement and the Health Insurance Review and Assessment service (HIRA) set the reimbursement ceilings.[1]
- A positive reimbursement system was introduced in 2007 determining value of medicines on cost reduction as a price-containment policy. The incremental cost per QALY threshold was set based on Korean GDP per capita in 2007 and it has not since been updated.[2]

Abbreviations: NHIS: National Health Insurance System; HIRA: Health Insurance Review and Assessment; QALY: quality-adjusted life years; GDP: gross domestic product; OECD: Organisation for Economic Co-operation and Development; MNC: multinational company; SME: Small and medium-sized enterprises; KHIDI: Korea Health Industry Development Institute; MoHW: Ministry of Health and Welfare

[1] Lee, H., Shin, E., & Song, H. (2021). Medicinal product regulation and product liability in South Korea: overview. Available at: https://content.next.westlaw.com/practical-law/document/Id4af1a8f1cb511e38578f7ccc38dcbee/Medicinal-product-regulation-and-product-liability-in-South-Korea-overview?contextData=(sc.Default)&transitionType=Default&firstPage=true&bhcp=1%5b&viewType=FullText

[2] Bae, E. Y., & Lee, E. K. (2009). Pharmacoeconomic guidelines and their implementation in the positive list system in South Korea. *Value in Health*, 12, S36-S41.

CHALLENGES FOR INNOVATION

Restrictive cost-effective thresholds for innovative drugs

- Despite evidence of clinical benefit, HIRA only values innovative medicines against their cost-effectiveness thresholds. The NHIS can also require additional discounts for insurance reimbursement, resulting in Korea prices being among the lowest in the OECD.[3]

Patients' delayed access to medicines

- 86% percent of new medicines launched since 2011 are available in the US compared to 35% in Korea, with Korean patients waiting an average of 30 months from global first launch for the fewer medicines that do become available.[3] This has indirectly encouraged illegal import of medicines.[4]

Price preferences negatively impact global drugs

- The 2016 global innovative drug price preferential system is biased against MNCs and prevent global innovation.[5]

OPPORTUNITIES FOR GROWTH AND BEST PRACTICES

Update cost-effectiveness thresholds and improve the pricing policy to align with innovation

- Korea must adopt more appropriate pricing protocols for novel therapies. This will increase Korea's status as a priority market for MNCs and manage concerns of low reference pricing.[6]
- More attractive pricing will also encourage domestic innovative SMEs.[6]
- The appeal of high generic prices encourages multiple generics to gain first-line generic status upon patent expiry. However, the sheer number of generic competitors, compounded by drug price reductions, causes price erosions for patent owners, and generics and limits the attractiveness of the domestic market.[7]

Establishing a new preferential drug system

- KHIDI and MoHW are researching drug price support policies. New policies should secure predictable marketability for innovation.[8]

[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 January 2023]
[4] Woo. (2023). Customs agency on campaign against drugs, illegal imports. Available at: https://www.koreatimes.co.kr/www/biz/2023/04/488_349265.html [Accessed January 2023]
[5] Lee (2019). 한미FTA로 사문화된 혁신신약 약가제도…또다시 반발하는 다국적제약사들. Available at: https://www.hankyung.com/it/article/201901042833f#:~:text=%EB%AC%B8%EC%A0%9C%EA%B0%80%20%EB%90%9C%20%EA%B8%80%EB%A1%9C%EB%B2%8C%20%ED%98%81%EC%8B%A0,%EA%B0%92%EC%9D%84%20%EB%B0%9B%EC%9D%84%20%EC%88%98%20%EC%9E%88%EB%8B%A4. [Accessed January 2023]
[6] Interview with multinational pharmaceutical firm
[7] Interview with domestic generic pharmaceutical firm
[8] Noh (2022). "신약 글로벌 경쟁력은 '약가 우대정책'에 달렸다". Available at: http://www.dailypharm.com/Users/News/NewsView.html?ID=288168 [Accessed January 2023]

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: RESTRICTIVE PATENTABILITY CRITERIA

PATENTABILITY SCOPE IS VERY NARROW IN KOREA AND THERE ARE SIGNIFICANT DELAYS IN GRANTING PRELIMINARY INJUNCTIONS

CONTEXT

- Strict patentability prevents valuable innovative products from being recognized and granted the appropriate protections in Korea.[1]
- KIPO requires very specific pharmacological data that must be supplied at the time of application, which is not the case in many other countries.[2]
- Patentability criteria is even stricter for secondary patents and selection inventions.[2]
- Furthermore, preliminary injunctions take several months to be granted, thereby frustrating the ability of innovators to prevent irreparable damages in the event potentially infringing products enter the market.[1]

Abbreviations: KIPO: Korea Intellectual Property Office; MFDS: Ministry of Food and Drug Safety; FDA: Food and drug administration

[1] Pharmaceutical Research and Manufacturers of America (2022). "Special 301 Submission 2022"

[2] Interview with multinational pharmaceutical firm

CHALLENGES FOR INNOVATION

Restricted value recognition

- Medical use of a pharmaceutical composition must be claimed as a type of a second medical use claim such as "A pharmaceutical composition comprising X for treatment of Y", even when X is a new compound. Thus, claiming combination therapy is challenging.[3]
- While other industries have similar criteria for patentability across countries, the pharmaceutical is a clear exception. Representatives from the generic industry often claim these differentiated standards are needed to accommodate Korea's market structure.[4]
- Unlike the US, Korea's MFDS has an official evaluation system of all patents to screen and evaluate the patent quality. This system results in limited opportunities to review patent decisions and challenge them with evaluators, presenting a much more restricted system than the US FDA.[5]

OPPORTUNITIES FOR GROWTH AND BEST PRACTICES

Standards for patentability should be in line with global standards

- There are strong voices in Korea compared to Japan's more conservative pharmaceutical market to improve patentability criteria. [4]
- The EU and the US often benchmark to one another and there are limited differences in patentability. For example, they have been at the forefront of allowing the patentability of second/subsequent uses of existing pharmaceutical products. [4] These large markets clearly set a global standard and could represent the standardised criteria. [5]

Abbreviations: KIPO: Korea Intellectual Property Office; MFDS: Ministry of Food and Drug Safety; FDA: Food and drug administration

[2] Interview with multinational pharmaceutical firm

[3] Managing IP (2016). "South Korea: Patentable subject matter – what's new?". Available from: https://www.managingip.com/article/2a5bxcod5m03pbixu2z28/south-korea-patentable-subject-matter-whats-new [Accessed January 2023]

[4] Adachi, K., 2022. The Patentability of Second and Subsequent Medical Uses in Asia's Patent Legislation. Asian Journal of Law and Economics. https://www.degruyter.com/document/doi/10.1515/ajle-2022-0091/html

[5] Interview with IP academic

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: PATENT TERM EXTENSIONS (1/2)

KOREA IS INTRODUCING MORE RESTRICTIONS AND UNCERTAINTIES, DETERRING INNOVATIVE COMPANIES

CONTEXT

- The design of PTE makes the Korean system less effective:
- **All-or-nothing rule:** KIPO will either accept or reject the PTE calculation in entirety.[1]
- **PTE scope:** the scope of the PTE is not clear, and this leads to skinny labels for specific indications.[2]
- **PTE Length:** in practice, the extension term is much shorter than the US or EU because various periods are exempted from calculation.[3]
- **Lack of considering international trials:** the Patent Court does not normally include foreign trials in PTE calculations unless the Supreme Court explicitly allows for this.[4]

Abbreviations: PTE: Patent Term Extension; KIPO: Korea Intellectual Property Office; MNC: multi-national company; SPC: Supplementary Protection Certificate

[1] Choi, Y. and Lee, H., (2022). How to boost and accelerate new drug development in Korea: business ecosystem perspectives. Translational and Clinical Pharmacology, 30(3), pp.129-135.

[2] Interview with multinational pharmaceutical firm

[3] KRPIA (2022). 허가등에 따른 특허권 존속기간연장제도 개선 검토(안)에 대한 한국글로벌의약산업협회(KRPIA) 의견서.

[4] Interview with IP lawyer

CHALLENGES FOR INNOVATION

Perception of favouring multinational companies

- The Korean government had to mitigate public opposition by limiting incentives of PTE due to the negative perception of MNCs.[2]
- Thus, the current rules make it difficult to challenge PTE calculations and the all-or-nothing rule discourages both domestic and international innovative companies.[2]

Introduction of further uncertainties

- The new proposed changes to the Korean PTE system involve limiting multiple patent extensions and implementing a maximum of 14 years that a patent can be extended in addition to the already existing five year limit extension term.
- These additional restrictions moves further away from international PTE standards and introduces more risk and uncertainty to the industry, decreasing opportunities to maximise market access in Korea.[5]

OPPORTUNITIES FOR GROWTH AND BEST PRACTICES

Improved PTE systems can benefit both domestics and MNCs

- PTE provisions should be communicated in a way that conveys the benefits to both domestic and multinational companies.[2]
- Public pressure led to PTE "cherry-picking" from different systems around the world without cohesively considering effectiveness.[2]

Korea could set a new standard in the APAC region by widening PTE provisions

- To some degree, investors are rethinking investments in China and Taiwan due to PTE restriction policies and Korea can set a precedent in the market with their multiple patent extension eligibility.[2]
- By conserving existing provisions and adopting wider regulations (e.g., SPCs applying extensions to any use of a compound), PTE could provide much better provisions to protect the innovative market.[2]

Abbreviations: PTE: Patent Term Extension; KIPO: Korea Intellectual Property Office; MNC: multi-national company; SPC: Supplementary Protection Certificate

[2] Interview with multinational pharmaceutical firm

[5] Interpat (2023). Opinion on Proposed Amendments to Patent Act.

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: PATENT TERM EXTENSIONS (2/2)

PATENT TERM EXTENSION POLICIES DO NOT BALANCE ELIGIBILITY, PATENT TERMS, AND THE EFFECTIVE PATENT SCOPE

ELIGIBILITY

	KOREA	US	EU	JAPAN
Approval which can be basis for PTE and allowable number of filing PTEs	Once based on the first approval	Once based on the first approval	Once based on the first approval	Multiple times based on multiple approvals
Number of patents which can be extended	Multiple	Single	Single	Multiple
Years	A maximum period of 5 years[2]	A maximum period of 5 years[3]	A maximum period of 5 years + an additional 6-month paediatric extension[4]	A minimum period of 2 years and a maximum period of 5 years[5,6]

[1] KRPIA (2022). 허가등에 따른 특허권 존속기간연장제도 개선 검토(안)에 대한 한국글로벌의약산업협회(KRPIA) 의견서.
[2] Lexology (2020). "Patent Term Extension in Korea". Available at: https://www.lexology.com/library/detail.aspx?g=0857b0e9-3fa8-4dc7-8858-c89c4dbb5518
[3] FDA (2020). "Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program". Available at: https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program#:~:text=What%20is%20the%20maximum%20amount,years%20of%20potential%20marketing%20time [Accessed January 2023]
[4] European Commission. "Supplementary protection certificates for pharmaceutical and plant protection products". Available at: https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products_en#:~:text=An%20SPC%20can%20extend%20a,Paediatric%20Investigation%20Plan%20(PIP) [Accessed January 2023]

EFFECTIVE PATENT SCOPE DURING PTE

	KOREA	US	EU	JAPAN
Substance	Unclear whether it refers to the active ingredient (including easily selectable salts)	Active ingredient (including salt and ester)	Active ingredient (including salt and ester)	Substantially identical substance
Use	First approved use (though interpretation of use is disputed)	Any approved use including later approved uses	Any approved use including later approved uses	Substantially identical to the approved use

[5] Kawaguti & Partners. "Overview of the Patent Term Extension in Japan". Available at: https://www.kawaguti.gr.jp/aboutlaw/jp_practices/01_1.html#:~:text=What%20is%20the%20maximum%20amount,has%2014%20or%20more%20years [Accessed January 2023]
[6] Mondaq (2019). "Worldwide: Patent Term Extension In Different Countries". Available at: https://www.mondaq.com/india/patent/823376/patent-term-extension-in-different-countries [Accessed January 2023]
[7] Sterne Kessler (2020). "Patent Term Adjustment". Available at: https://www.sternekessler.com/sites/default/files/2020-07/tab_12_-_patent_term_adjustment.pdf [Accessed January 2023]
[8] Beall, R.F., Darrow, J.J. and Kesselheim, A.S., 2019. Patent term restoration for top-selling drugs in the United States. Drug Discovery Today, 24(1), pp.20-25.

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: STRONGER APPLICATION OF PATENT INFRINGEMENT

HIGH INVALIDATION RATES AND NOTABLE COURT DECISIONS, HAVE CREATED A MARKET THAT ENCOURAGES UNREGULATED GENERIC ENTRY AND UNDERMINES THE VALUE OF DRUG PATENTS

CONTEXT

- Korea has a high invalidation rate, particularly for medicinal use patents. Furthermore, the invalidation rate of pharmaceutical patents in Korea is higher than that of other industries and other countries.[1]
- In the notable 2020 Zyprexa case, the Supreme court found a generic company not liable to compensate for damages caused by drug price reductions from premature entry.[2]
    - The generic company was not liable for the damages because market entry was erroneously granted. Thus, it is argued the patent owner was not adequately compensated by the court, nor the generic.[2,3]

[1] Interview with multinational pharmaceutical company
[2] KRPIA (2021). 유효특허 약품의 약가인하로 인한 손해배상에 관한 한국글로벌의약산업협회(KRPIA)의 의견서
[3] Interview with IP academic
[4] Kim & Chang IP Legal Updates March 2023
[5] Interview with Korean IP lawyer
[6] Kim & Chang IP Legal Updates April 2023
[7] Harness IP (2018). "Doug Robinson Parses Out Drug Patent Invalidation Rates with Law360". Available at: https://www.harnessip.com/news-and-awards/doug-robinson-parses-out-drug-patent-invalidation-rates-with-law360/ [Accessed January 2023]
[8] Jones Day (2017). "Report Details Success of Japan's New Patent Opposition System". Available at: https://www.jonesday.com/en/insights/2017/10/report-details-success-of-japans-new-patent-opposition-system [Accessed January 2023]

CHALLENGES FOR INNOVATION

The value of drug patents for patent owners are becoming increasingly eroded

- The court can wait up to 6-10 months for the outcome of the invalidation action, and appeals can take another 8-12 months. Thus, filing for infringement forces innovators to defend the validity of their patent for 1-2 years before the court will acknowledge the infringement claim.[5]
    - One estimate found that Korea's invalidation rate is around 48%.[4]
- There are concerns that the Zyprexa decision will encourage generic competitors to commit more drug patent infringing activities in the future. The court attempted to acknowledge both the loss for the patent owner and the systemic errors that led to generic entry.[2,3]
- In April 2023, a new act was passed providing recoupment of losses incurred due to court ordered stays of drug price cuts but this will likely reduce granted stays of drug price cuts.[6]

OPPORTUNITIES FOR GROWTH AND BEST PRACTICES

Be in line with international invalidation rates

- The US has relatively low invalidation rates in both the Patent Trial and Appeal Board (PTAB) and district level, with district courts having a higher patent invalidation rate than PTAB. A recent study found that 23% of PTAB decisions involving Orange Book patents invalidated all challenged claims, whereas 24% of district court proceedings invalidated all challenged claims.[7]
- In Japan's invalidation trials, 21.3% of trials in 2015, and 30.9% of trials in 2016 resulted in the invalidation of one or more claims.[8] Between 2011-2021, an average of 27% of trials resulted in the invalidation of one or more claims.[9]
- In Europe, the patent is declared invalid in approximately one-third of the cases and in about another third of cases the patent is maintained.[10]
- In China, 34.29% of compound patents have been declared invalid in the past 10 years.[11]

[9] JPO (2022). "Patent Invalidation and Opposition Systems in Japan". Available at: https://www.jpo.go.jp/e/system/trial_appeal/document/chizaishihou-2022/e_15.pdf [Accessed January 2023]
[10] PV (2017). "Oppositions before the European Patent Office (EPO) – as a proactive risk management tool". Available at: https://www.pv.eu/news/oppositions-before-the-european-patent-office-epo-as-a-proactive-risk-management-tool/#:~:text=Opposition%20proceedings%20before%20the%20EPO%20can%20have%20three%20different%20outcomes&text=Experience%20shows%20that%20the%20patent,patent%20is%20maintained%20as%20granted [Accessed January 2023]
[11] Lexology (2021). "Stability Analysis of Patents with Compound Subject Matter during Invalidation Stage". Available at: https://www.lexology.com/library/detail.aspx?g=00a8f877-3f1f-4d88-830d-b2a37994df4e [Accessed January 2023]

OPPORTUNITIES FOR GROWTH IN THE IP FRAMEWORK: PATENT ENFORCEMENT CONCERNS

PATENT ENFORCEMENT THROUGH THE PATENT LINKAGE SYSTEM CREATES UNCERTAINTY FOR PATENT OWNERS

CONTEXT

- The South Korea-US free trade agreement introduced the approval-patent linkage system on 15 March 2012, based on the US Hatch Waxman act.[1]
- Under this system, original patent owners can list their patents and challenge generic companies seeking approval and suspend generic sales for up to nine months until resolution of the infringement litigation.
- There are distinctive features in Korea's linkage system that result in significant administrative burden and disputes.
- However, some academics acknowledge that Korea was the first country without a domestic pharmaceutical MNC to establish patent linkage successfully and see it as a best practice model for other countries.[2]

Abbreviations: MNC: multinational company

[1] Shin, E. J., Kim, S., & Han, Y. (2022). The Pharmaceutical Intellectual Property and Competition Law Review: South Korea. In D. Kracov (Ed.), The Pharmaceutical Intellectual Property and Competition Law Review. Law Business Research Limited.

[2] Interview with IP academic

CHALLENGES FOR INNOVATION

Uncertain sales suspension criteria:

- A sales suspension period is difficult to acquire for most original patent owners
- It is even rarer to be granted the full nine-month period for suspension. One study found that the average was only two months.[3]

Proliferation of generic challenges:

- First-line generic exclusivity rights are granted to any company that files within the first 14 days, resulting in multiple first-line generics. There have been cases where 50+ companies are granted first-line status, forcing generic companies to rely on filing as a sales tactic.[4]

Green book management:

- The Korean green book is managed directly by the MFDS. There have been reported cases of the authority amending the list to encourage generic challenges although some may deem this a needed intervention.[5]

OPPORTUNITIES FOR GROWTH AND BEST PRACTICES

Patent linkage should balance incentives for innovative companies and generic companies

- The Hatch-Waxman act is widely accepted a best practice model that balances incentives for both innovative companies and generics through sales suspensions and administrative efficiencies.[5]

Patent linkage should limit generic challenges

- Under the US Hatch-Waxman act, first line generic status is granted to one product and they are granted 180 days of market exclusivity. This is subject to detailed criteria and regulations.[5]

Patent authorities should have limited control

- The US patent authority cannot amend or delete patents in the Orange book on its own. Although a regulatory body is needed, they should not have the sole authority to remove patents.[6]

[3] Lim (2020). 의약품 허가-특허연계제도, 특허권자 보호 강화 목적 … 효과성 더 높일 중·장기적 검토는 필요. Available at: https://www.biotimes.co.kr/news/articleView.html?idxno=3477 [Accessed January 2023]
[4] Interview with Multinational Pharmaceutical Firm
[5] Son, K. B. (2022). Patenting and patent challenges in South Korea after introducing a patent linkage system. Globalization and Health, 18(1), 1-10.
[6] Interview with IP lawyer

4. Innovation policy implications for South Korea

WE USE CASES STUDIES TO DRAW LESSONS FROM COMPARABLE MARKETS

IN THIS STEP OF THE PROJECT, WE INVESTIGATE THE PERFORMANCE OF COMPARABLE MARKETS TO SOUTH KOREA (DRAWING FROM DIFFERENT GEOGRAPHICAL REGIONS)

Using case studies, our aim is to investigate

1. The changes in the policy regime supporting innovation
2. The innovative environment and economic activities related to innovation across a range of areas
3. Whether growth in innovation activity experienced in the case study markets could be extrapolated to South Korea if South Korea were to implement similar changes in its policy regime

It is important to note that this is a challenging approach, due to:

- Many factors affect innovative activity
- Factors work together and need to be considered as a package rather than in isolation

METHOD FOR ESTIMATING GROWTH SCENARIOS FOR SOUTH KOREA

STEP 1

South Korea baseline growth

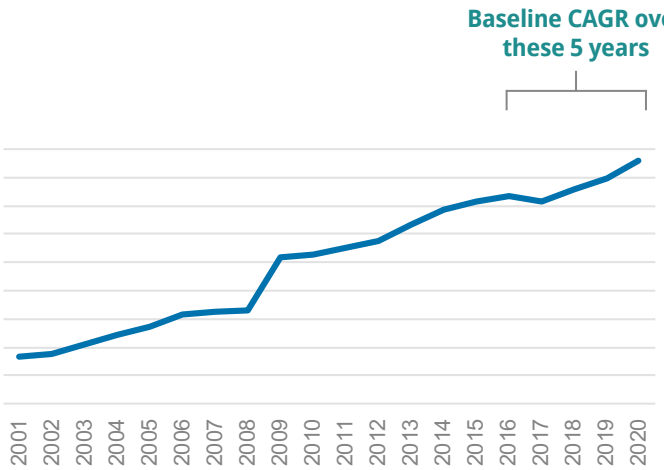
- Construct baseline scenario in which South Korea continues on its current growth rate for key metrics
- Specifically, we calculate the compound annual growth rate (CAGR) over the previous 5 years for which data is available

STEP 2

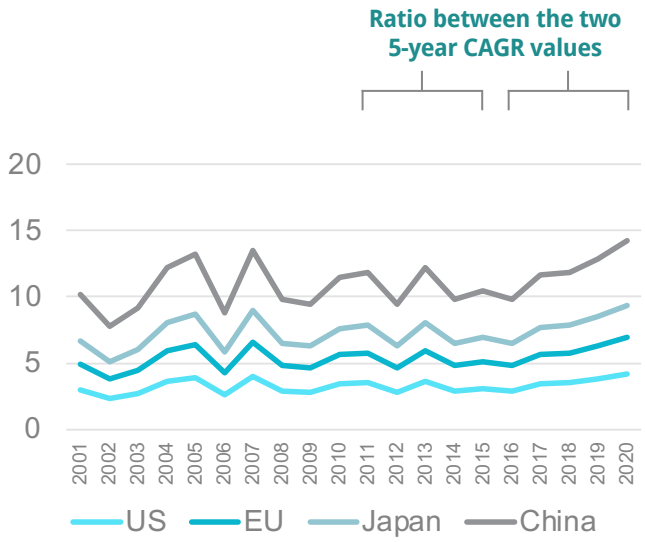
Case study growth rate changes*

- Calculate the 5-year CAGR for the most recent years for which data is available, and compare versus the 5-year CAGR of the previous 5-year period
- This ratio was calculated for four case study comparator countries or regions

Number of publications: South Korea



Number of publications in case study countries



Abbreviations: CAGR = Compound annual growth rate

*As opposed to the LatAm studies, in which the growth rates were estimated based on the growth experienced after specific policies have been implemented, in this study the growth rates were based on the CAGR of the most recent 5-year (of data) versus the CAGR of the previous 5-year period. This is because the key comparator countries (US and EU) have implemented the relevant policies in the past, for which period there is no robust data available.

STEP 3

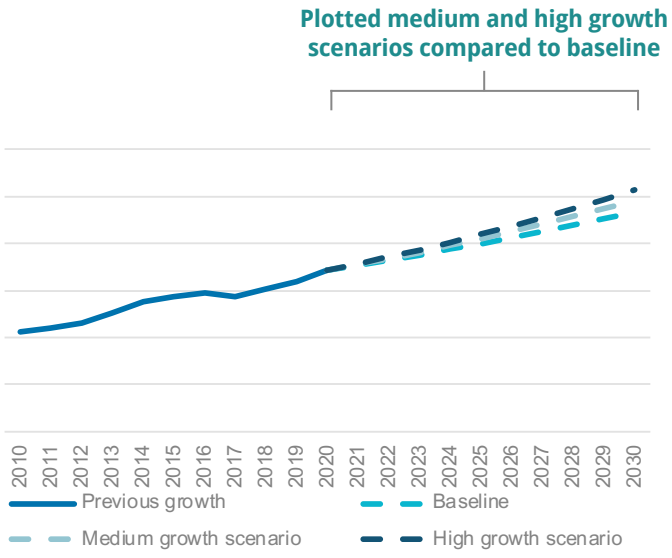
South Korea growth scenarios

Estimate two scenarios for South Korea:

a) Medium growth scenario in which South Korea's growth rate increases in line with the average of case study CAGR differences

b) High growth scenario in which it increases in line with the highest increase for a case study country

Number of publications: Scenarios



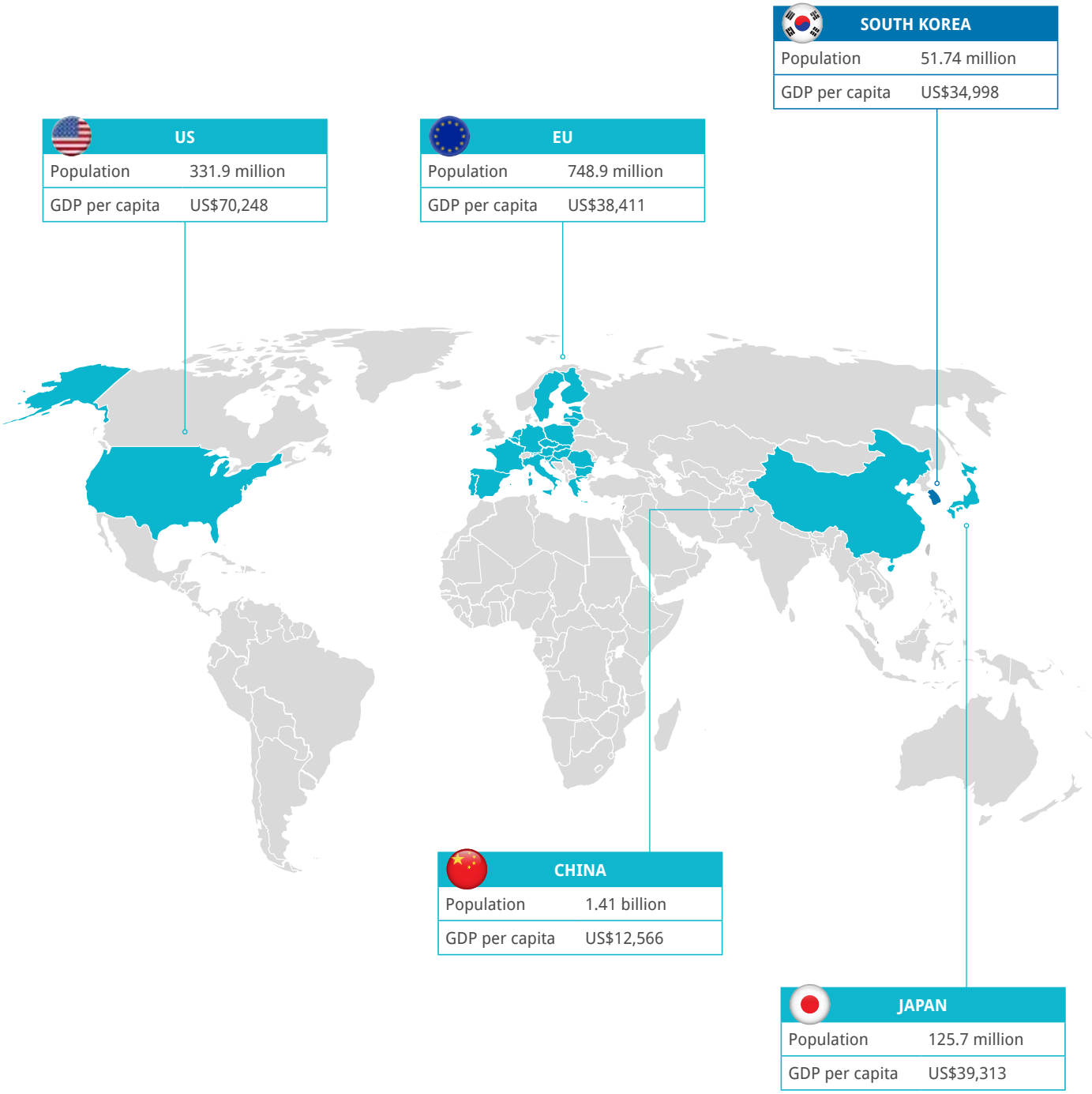
CRITERIA FOR THE SELECTED CASE STUDY MARKETS INCLUDED HAVING OBSERVABLE OUTCOMES FROM INNOVATION AND IP POLICY CHANGES

THE SELECTION CRITERIA FOR OUR CASE STUDY MARKETS INCLUDE:

1. Have shown a focus on strengthening innovative environment, particularly the IP protection
2. Placed broadly in the same income and development category as South Korea when key innovation policies were introduced
3. Show an observable impact on innovative activity and have good data availability

KEY POLICY CHANGES

EU	EU	JAPAN
• Protection of biotechnological inventions (1998) • Patent package (2012) • A pharmaceutical strategy for Europe (2020) • European industrial strategy (2020) • Clinical Trials Regulation (CTR) (2022)	• Bayh-Dole Act (1980) • The Orphan Drug Act (1983) • The Fast Track pathway (1988) • The Accelerated Approval pathway (1992) • The Breakthrough Therapy pathway (2012) • Patents 4 Partnerships (2020)	• 1st – 5th Science & Technology Basic Plan (1996 to 2021) • Intellectual Property Basic Act (2002) • Policies Aimed at the Patent Backlog (2004 – 2007) • Cross-ministerial Strategic Innovation Promotion Program (SIP) (2014, 2018)


SOUTH KOREA
Population 51.74 million
GDP per capita US$34,998
US
Population 331.9 million
GDP per capita US$70,248
EU
Population 748.9 million
GDP per capita US$38,411
CHINA
Population 1.41 billion
GDP per capita US$12,566
JAPAN
Population 125.7 million
GDP per capita US$39,313

SCENARIOS ANALYSIS:
ESTIMATED MEDIUM AND HIGH GROWTH RATES FOR EACH METRIC

SCENARIO DETAILS	BASIC RESEARCH	R&D EXPENDITURE
	CAGR of biological and biomedical sciences publications per 1000 researchers	CAGR of pharmaceutical R&D expenditure per 1000 persons
BASELINE GROWTH IN SOUTH KOREA • South Korea's current 5-year compound annual growth rate (CAGR); latest 5 years of available data[(i)]	**3.0%**	**14.9%**
IP REGIME AND INNOVATION POLICY – MEDIUM GROWTH • Paced growth scenario based on an improvement of the IP regime and other innovation incentives but with limitations in implementation • Based on average of changes in growth rates for case study countries	**5.3%[(ii)]** ▲	**18.4%[(iii)]** ▲
IP REGIME AND INNOVATION POLICY – HIGH GROWTH • Escalated growth scenario based on an improvement of the IP regime and other innovation incentives with good implementation • Based on the highest change in growth rate for the four case study countries	**8.0%[(iii)]** ▲▲	**25.9%[(iii)]** ▲▲

Abbreviations: CAGR = Compound annual growth rate

[(i)] The latest available data for basic research, R&D expenditure and patent grants was for the 5-year period 2016-2020 whereas for employment some countries (China, EU, and Korea) had data available for the period 2018-2020 whereas for the US data for 2014-2018 was used

[(ii)] Using Germany and UK's growth as a proxy for the EU's growth estimates

[(iii)] As growth has been very high in recent years, we divided the scenario growth rates by two/four to provide a more realistic projection

SCENARIO DETAILS	EMPLOYMENT	R&D EXPENDITURE
	CAGR of medicines R&D personnel	CAGR of biopharmaceutical patent grants
BASELINE GROWTH IN SOUTH KOREA		
• South Korea's current 5-year compound annual growth rate (CAGR); latest 5 years of available data[(i)]	**2.1%**	**1.6%**
IP REGIME AND INNOVATION POLICY – MEDIUM GROWTH		
• Paced growth scenario based on an improvement of the IP regime and other innovation incentives but with limitations in implementation • Based on average of changes in growth rates for case study countries	**3.0%[(iv)]** ▲	**2.2%[(v)]** ▲
IP REGIME AND INNOVATION POLICY – HIGH GROWTH		
• Escalated growth scenario based on an improvement of the IP regime and other innovation incentives with good implementation • Based on the highest change in growth rate for the four case study countries	**4.2%** ▲▲	**2.7%** ▲▲

Abbreviations: CAGR = Compound annual growth rate

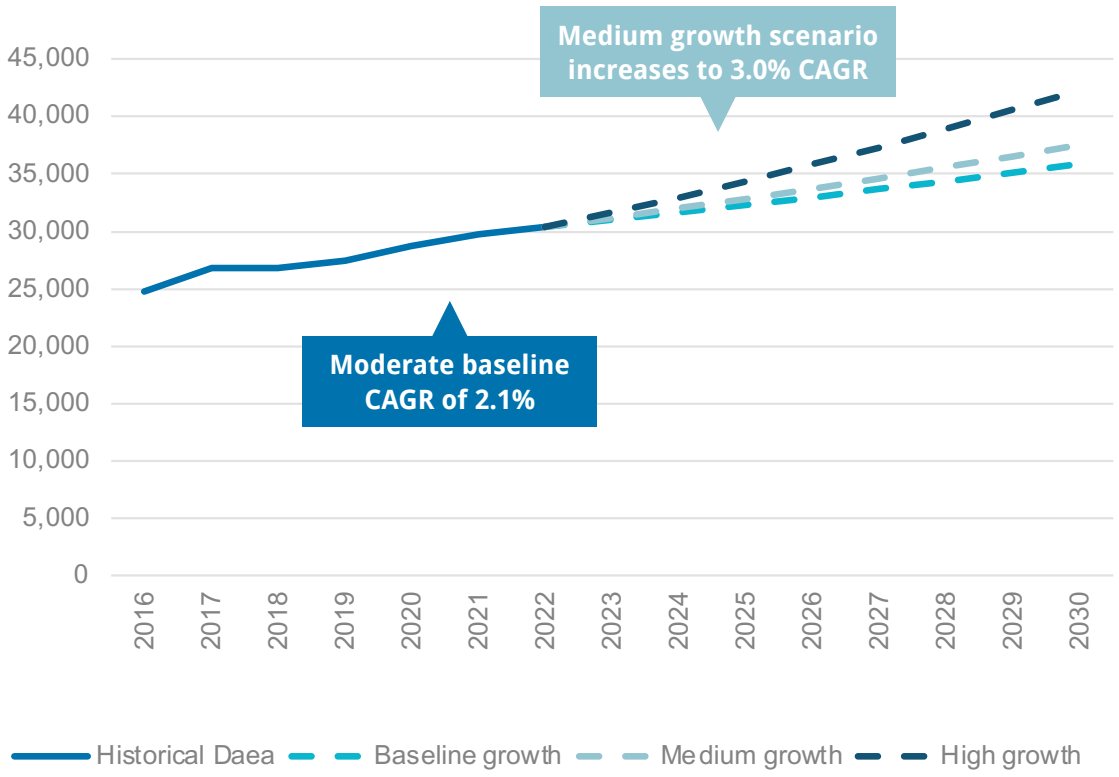
[(i)] The latest available data for basic research, R&D expenditure and patent grants was for the 5-year period 2016-2020 whereas for employment some countries (China, EU, and Korea) had data available for the period 2018-2020 whereas for the US data for 2014-2018 was used

[(iv)] Excluded Japan due to limited data

[(v)] In this case, the medium growth was calculated as the average of the baseline and high growth scenarios

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

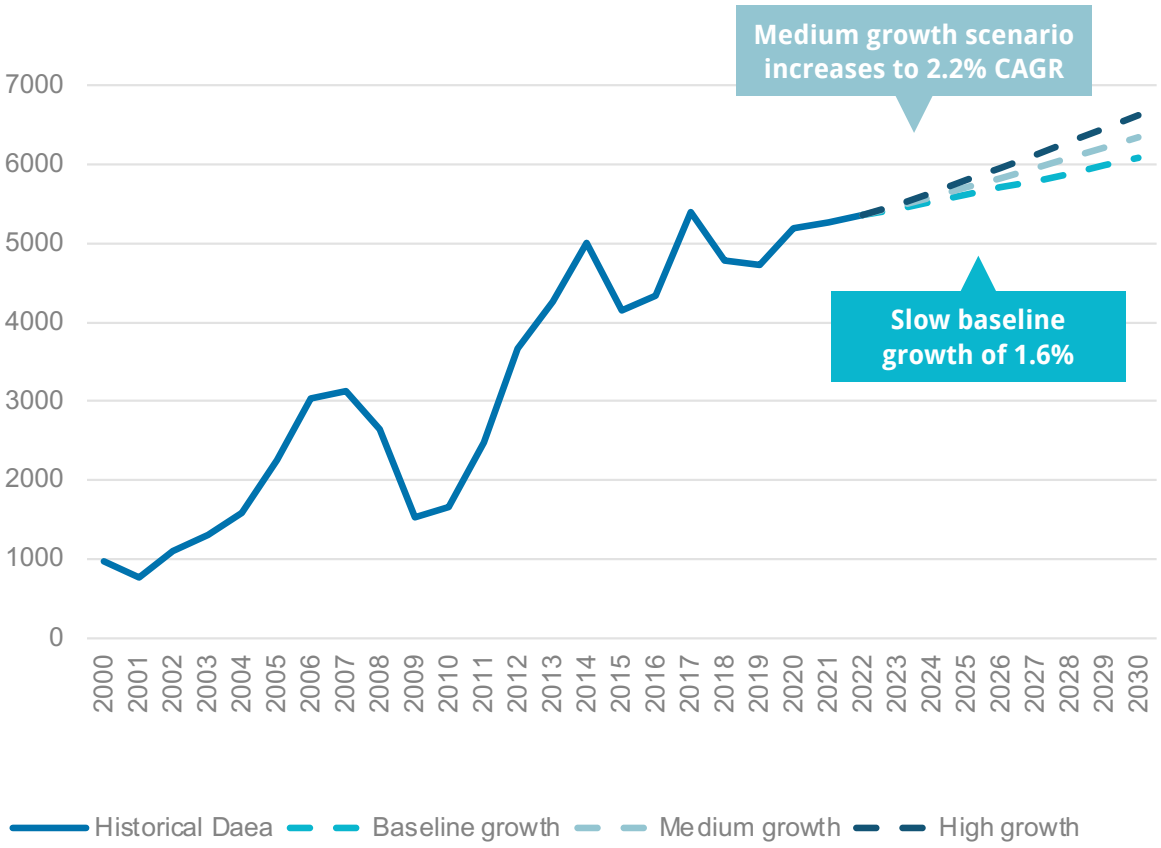
PHARMACEUTICAL R&D EMPLOYMENT GAINS



- 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

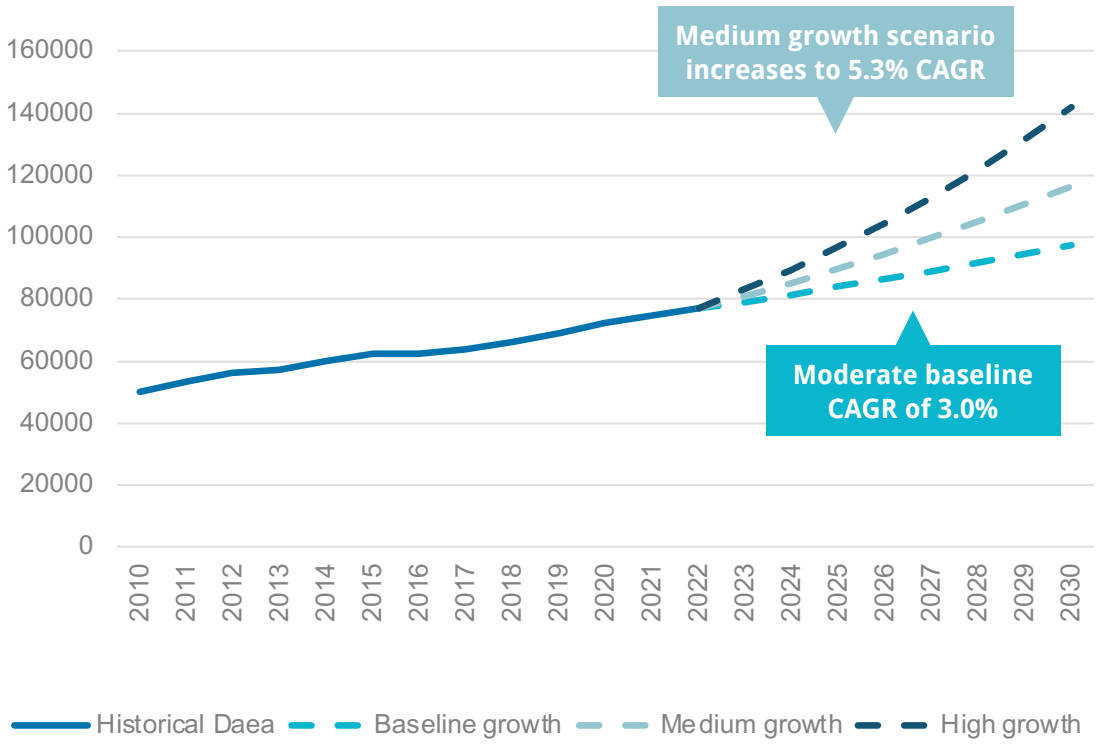
PATENT GRANT GAINS



- 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

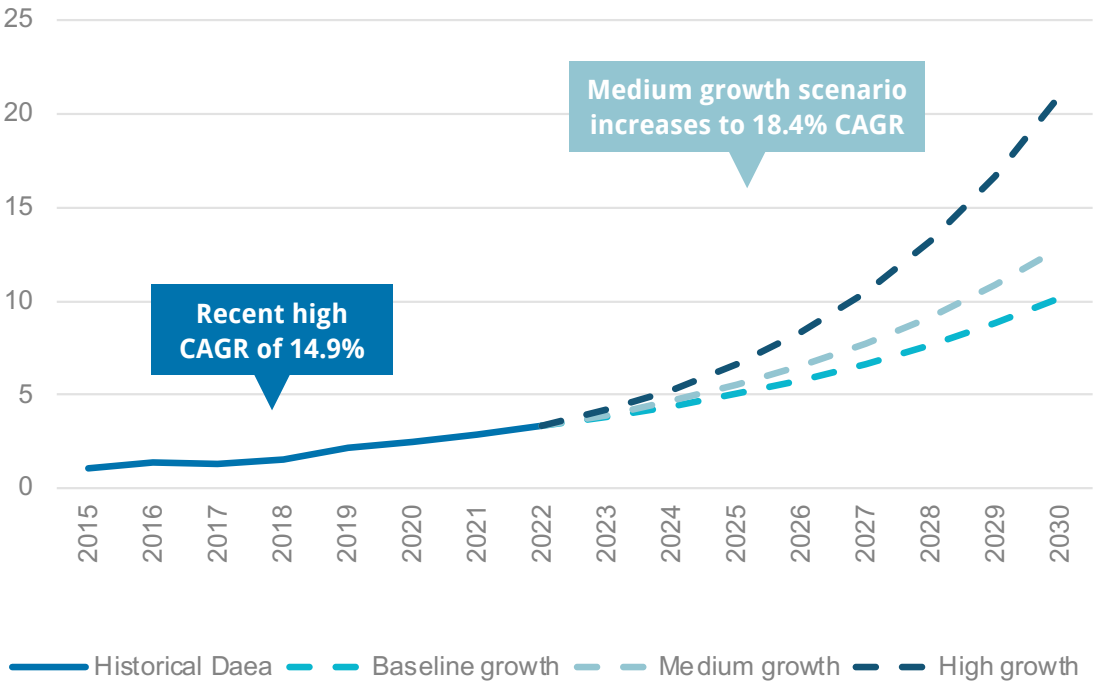
BASED ON THE GROWTH SCENARIOS, POTENTIAL GAINS FROM IMPROVEMENT IN THE INNOVATION ENVIRONMENT COULD BE SIGNIFICANT FOR R&D EXPENDITURE GAINS

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

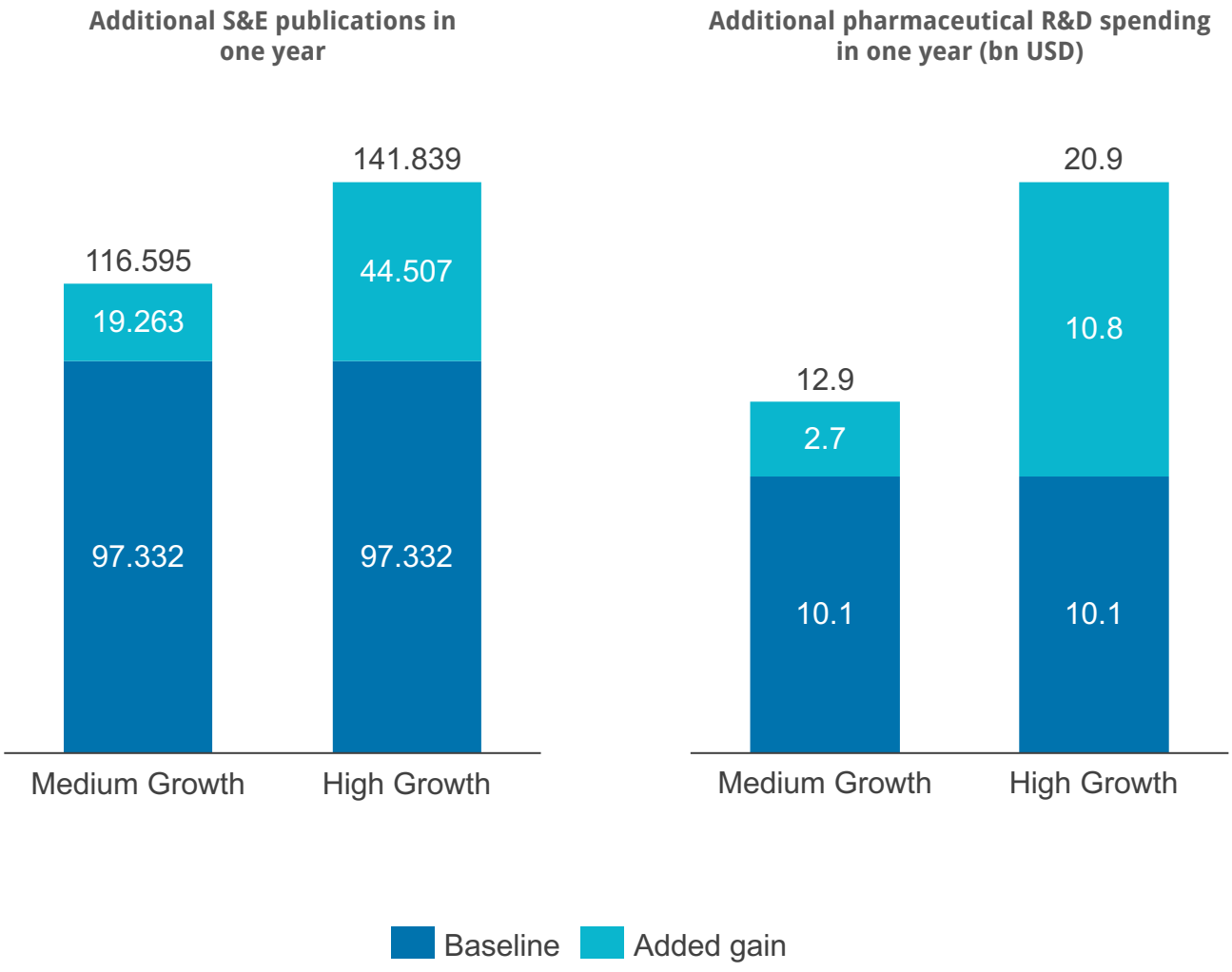
PHARMACEUTICAL R&D EXPENDITURE GAINS (BN USD)



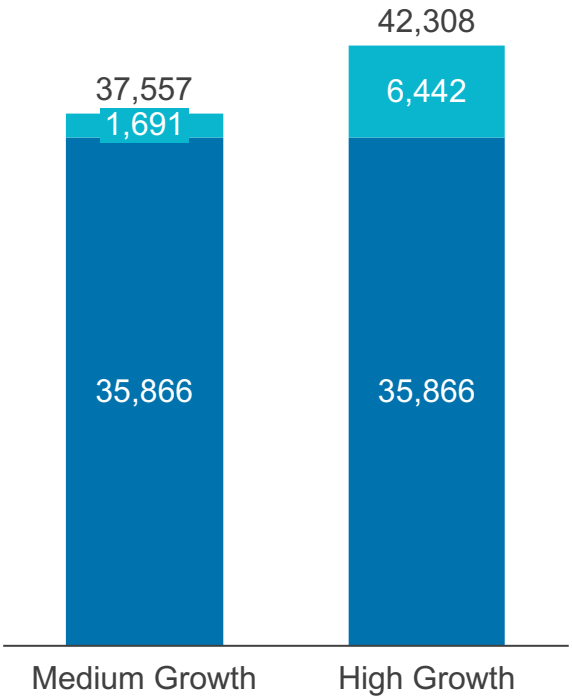
- Pharmaceutical R&D expenditure in South Korea is already rapidly growing, so further changes based on alternative markets make it appear that growth in South Korea would increase much faster

ILLUSTRATION OF GAINS FOR SOUTH KOREA (ABSOLUTE GAINS)

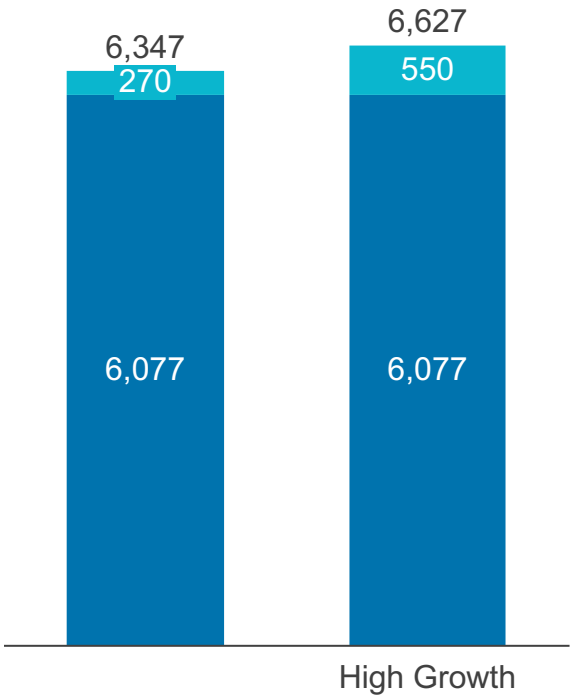
BASED ON THE SCENARIOS ANALYSIS, WE ARE ABLE TO PROJECT THE POTENTIAL ABSOLUTE GAINS AFTER 10 YEARS COMPARED TO SOUTH KOREA'S BASELINE GROWTH RATE FOR THE MEDIUM GROWTH AND HIGH GROWTH SCENARIOS.



Additional new pharma R&D employees in one year



Additional new patents in one year



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 Korean's economy and society.

- This could be underpinned by adopting a more long-term strategy to foster growth of innovative activity in Korea.

BIBLIOGRAPHY

Adachi, K., 2022. The Patentability of Second and Subsequent Medical Uses in Asia's Patent Legislation. Asian Journal of Law and Economics. https://www.degruyter.com/document/doi/10.1515/ajle-2022-0091/html

Bae, E. Y., & Lee, E. K. (2009). Pharmacoeconomic guidelines and their implementation in the positive list system in South Korea. *Value in Health*, 12, S36-S41.

Beall, R.F., Darrow, J.J. and Kesselheim, A.S., 2019. Patent term restoration for top-selling drugs in the United States. Drug Discovery Today, 24(1), pp.20-25.

Choi, Y. and Lee, H., (2022). How to boost and accelerate new drug development in Korea: business ecosystem perspectives. Translational and Clinical Pharmacology, 30(3), pp.129-135.

Clinicaltrials.gov. https://clinicaltrials.gov/ [Accessed February 2023]

Contract Research Map. Available at: https://www.contractresearchmap.com/places/korea [Accessed January 2023]

Dayton (2020). "How South Korea made itself a global innovation leader". Available at: https://www.nature.com/articles/d41586-020-01466-7 [Accessed January 2023]

Dolon (2020) Estimated impact of EU Orphan Regulation on incentives for innovation. Available at: https://dolon.com/rare-knowledge/publications/estimated-impact-of-eu-orphan-regulation-on-incentives-for-innovation [Accessed January 2023]

European Commission. "Supplementary protection certificates for pharmaceutical and plant protection products". Available at: https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products_en#:~:text=An%20SPC%20can%20extend%20a,Paediatric%20Investigation%20Plan%20(PIP). [Accessed January 2023]

FDA (2020). "Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program". Available at: https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program#:~:text=What%20is%20the%20maximum%20amount,years%20of%20potential%20marketing%20time [Accessed January 2023]

Han, H. (2007). 국내 의약품 시장 다국적 임상시험 증가 지적재산권 잰걸음. https://www.kgnews.co.kr/news/article.html?no=148859 [Accessed January 2023]

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 [Accessed January 2023]

Harness IP (2018). "Doug Robinson Parses Out Drug Patent Invalidation Rates with Law360". Available at: https://www.harnessip.com/news-and-awards/doug-robinson-parses-out-drug-patent-invalidation-rates-with-law360/ [Accessed January 2023]

Interpat (2023). Opinion on Proposed Amendments to Patent Act.

Invest Korea (2022). The Korean Pharmaceutical Industry's New Leap forward into the Global Market. Available at: https://www.investkorea.org/ik-en/bbs/i-308/detail.do?ntt_sn=490775&clickArea=enmain00019 [Accessed February 2023]

Jeong, C.W. (2004). 제약산업의 지적재산권 조명. Available at: http://www.bosa.co.kr/news/articleView.html?idxno=47457 [Accessed January 2023]

Jones Day (2017). "Report Details Success of Japan's New Patent Opposition System". Available at: https://www.jonesday.com/en/insights/2017/10/report-details-success-of-japans-new-patent-opposition-system [Accessed January 2023]

JPO (2022). "Patent Invalidation and Opposition Systems in Japan". Available at: https://www.jpo.go.jp/e/system/trial_appeal/document/chizaishihou-2022/e_15.pdf [Accessed January 2023]

Kasan Insight. Patent Term Extension (PTE) in Korea. Available at: http://koreaniplaw.blogspot.com/2017/09/patent-term-extension-pte-in-korea.html [Accessed February 2023]

Kawaguti & Partners. "Overview of the Patent Term Extension in Japan". Available at: https://www.kawaguti.gr.jp/aboutlaw/jp_practices/01_1.html#:~:text=What%20is%20the%20maximum%20amount,has%2014%20or%20more%20years [Accessed January 2023]

Kim & Chang IP Legal Updates April 2023

Kim & Chang IP Legal Updates March 2023

Kim (2022). 제약사 생명줄 '특허권'…다국적사 텃밭서 '힘 못쓴' 토종기업. Available at: https://www.medicopharma.co.kr/news/articleView.html?idxno=58501 [Accessed January 2023]

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

KimChang (2017). Korean Patent Court Dismisses Generics' Challenges to PTE Terms. Available at: https://www.kimchang.com/newsletter/2018newsletter/ip/eng/html/newsletter_ip_en_Sping_Summer2018_article01.html [Accessed January 2023]

KimChang (2018). Legal Developments Regarding Patent Term Extensions in Korea. Available at: https://www.kimchang.com/newsletter/2018newsletter/ip/eng/html/newsletter_ip_en_Sping_Summer2018_article01.html [Accessed January 2023]

KLRI (2016). PHARMACEUTICAL AFFAIRS ACT. Available at: https://elaw.klri.re.kr/eng_service/lawView.do?hseq=40196&lang=ENG [Accessed January 2023]

Korea Immigration Service (2019). 출입국 외국인정책 통계월보. http://viewer.moj.go.kr/skin/doc.html?rs=/result/bbs/227&fn=temp_1581918117248100 [Accessed January 2023]

Korea Institute of Intellectual Property (2020). A Study on Intellectual Property Issues and Responsive Strategies for Innovative Growth.

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 [Accessed January 2023]

Korean Citation Index. Available at: https://www.kci.go.kr/kciportal/main.kci [Accessed January 2023]

KRPIA (2019). KRPIA-KOTRA, 글로벌 오픈이노베이션 코리아에서 설명회 및 파트너링 상담회 진행. Available at: https://www.krpia.or.kr/board/select/press/10041 [Accessed January 2023]

KRPIA (2021). 유효특허 약품의 약가인하로 인한 손해배상에 관한 한국글로벌의약산업협회(KRPIA)의 의견서

KRPIA (2022). "Korean Research-based Pharmaceutical Industry Association Annual Report 2022".

KRPIA (2022). 허가등에 따른 특허권 존속기간연장제도 개선 검토(안)에 대한 한국글로벌의약산업협회(KRPIA) 의견서.

KRPIA. "R&D Investment". Available at: https://www.krpia.or.kr/eng/contribute/investment [Accessed January 2023]

Lee (2019). 한미FTA로 사문화된 혁신신약 약가제도...또다시 반발하는 다국적제약사들. Available at: https://www.hankyung.com/it/article/201901042833f#:~:text=%EB%AC%B8%EC%A0%9C%EA%B0%80%20%EB%90%9C%20%EA%B8%80%EB%A1%9C%EB%B2%8C%20%ED%98%81%EC%8B%A0,%EA%B0%92%EC%9D%84%20%EB%B0%9B%EC%9D%84%20%EC%88%98%20%EC%9E%88%EB%8B%A4 [Accessed January 2023]

Lee (2023). 복지부, 글로벌 신약 2개 개발·제약바이오혁신위원회 추진. Available at: http://www.hitnews.co.kr/news/articleView.html?idxno=43221 [Accessed January 2023]

Lee J. (2023) 실효성 논란에도 혁신형 제약기업 4개사 신규 인. Available at: https://www.yakup.com/news/index.html?mode=view&cat=11&nid=277944 [Accessed January 2023]

Lee, H., Shin, E., & Song, H. (2021). Medicinal product regulation and product liability in South Korea: overview. Available at: https://content.next.westlaw.com/practical-law/document/Id4af1a8f1cb511e38578f7ccc38dcbee/Medicinal-product-regulation-and-product-liability-in-South-Korea-overview?contextData=(sc.Default)&transitionType=Default&firstPage=true&bhcp=1%5b&viewType=FullText

Lee, S.H., Yoo, S.L., Bang, J.S. and Lee, J.H., 2020. Patient accessibility and budget impact of orphan drugs in South Korea: long-term and real-world data analysis (2007–2019). International journal of environmental research and public health, 17(9), p.2991.

Lexology (2020). "Patent Term Extension in Korea". Available at: https://www.lexology.com/library/detail.aspx?g=0857b0e9-3fa8-4dc7-8858-c89c4dbb5518

Lexology (2021). "Stability Analysis of Patents with Compound Subject Matter during Invalidation Stage". Available at: https://www.lexology.com/library/detail.aspx?g=00a8f877-3f1f-4d88-830d-b2a37994df4e [Accessed January 2023]

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 [Accessed January 2023]

Lim (2020). 의약품 허가-특허연계제도, 특허권자 보호 강화 목적 … 효과성 더 높일 중·장기적 검토는 필요. Available at: https://www.biotimes.co.kr/news/articleView.html?idxno=3477 [Accessed January 2023]

Managing IP (2016). "South Korea: Patentable subject matter – what's new?". Available from: https://www.managingip.com/article/2a5bxcod5m03pbixu2z28/south-korea-patentable-subject-matter-whats-new [Accessed January 2023]

BIBLIOGRAPHY

Ministry of Food and Drug Safety (2022). About Gift. Available at: https://www.mfds.go.kr/wpge/m_1113/de080101l0001.do [Accessed January 2023]

Ministry of Health and Welfare (2022). "Start with Korea". Available at: https://www.konect.or.kr/_img/en/Brochure_09_final.pdf [Accessed January 2023]

Mondaq (2019). "Worldwide: Patent Term Extension In Different Countries". Available at: https://www.mondaq.com/india/patent/823376/patent-term-extension-in-different-countries [Accessed January 2023]

Noh (2022). "신약 글로벌 경쟁력은 '약가 우대정책'에 달렸다". Available at: http://www.dailypharm.com/Users/News/NewsView.html?ID=288168 [Accessed January 2023]

OECD (2020). "R&D tax expenditure and direct government funding of BERD". Available at: https://stats.oecd.org/Index.aspx?DataSetCode=RDTAX

Korea Health Industry Development Institute. "Potential of the Pharmaceutical Industry in Korea". Available at: https://www.khidi.or.kr/board?menuId=MENU02288&siteId=SITE00032 [Accessed January 2023]

OECD (2021). "R&D Tax Incentives: Korea, 2021". Available at: https://www.oecd.org/sti/rd-tax-stats-korea.pdf [Accessed January 2023]

OECD (2021). "Researchers, 2020". Available at: https://data.oecd.org/rd/researchers.htm [Accessed January 2023]

OECD (2021). "R&D Tax Incentives". Available at: https://www.oecd.org/sti/rd-tax-stats-korea.pdf

Pharma Korea (2020) "Potential of the Pharmaceutical Industry in Korea"

Pharmaceutical Research and Manufacturers of America (2022). "Special 301 Submission 2022"

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 January 2023]

PV (2017). "Oppositions before the European Patent Office (EPO) – as a proactive risk management tool". Available at: https://www.pv.eu/news/oppositions-before-the-european-patent-office-epo-as-a-proactive-risk-management-tool/#:~:text=Opposition%20proceedings%20before%20the%20EPO%20can%20have%20three%20different%20outcomes&text=Experience%20shows%20that%20the%20patent,patent%20is%20maintained%20as%20granted [Accessed January 2023]

Santander (2023). "SOUTH KOREA: FOREIGN INVESTMENT". Available at: https://santandertrade.com/en/portal/establish-overseas/south-korea/foreign-investment [Accessed January 2023]

Seo (2023). 대웅제약, 신속심사 성공사례 '엔블로정' 발표. Available at: https://www.sentv.co.kr/news/view/644246 [Accessed January 2023]

Shin, E. J., Kim, S., & Han, Y. (2022). The Pharmaceutical Intellectual Property and Competition Law Review: South Korea. In D. Kracov (Ed.), The Pharmaceutical Intellectual Property and Competition Law Review. Law Business Research Limited.

Son, K.B., 2022. Patenting and patent challenges in South Korea after introducing a patent linkage system. Globalization and Health, 18(1), pp.1-10

Sterne Kessler (2020). "Patent Term Adjustment". Available at: https://www.sternekessler.com/sites/default/files/2020-07/tab_12_-_patent_term_adjustment.pdf [Accessed January 2023]

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 [Accessed January 2023]

U.S. Department of State (2022). "2022 Investment Climate Statements: South Korea". Available at: https://www.state.gov/reports/2022-investment-climate-statements/south-korea/ [Accessed January 2023]

Um, S. I., Sohn, U. D., Jung, S. Y., You, S. H., Kim, C., Lee, S., & Lee, H. (2022). Longitudinal study of the impact of three major regulations on the Korean pharmaceutical industry in the last 30 years. Health Research Policy and Systems, 20(1), 1-12.

WIPO (2022). "Global Innovation Index 2022 What is the future of innovation driven growth?". Available at: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-2000-2022-en-main-report-global-innovation-index-2022-15th-edition.pdf [Accessed January 2023]

WIPO (2022). WIPO statistics database. Available at: https://www3.wipo.int/ipstats/ [Accessed January 2023]

Woo. (2023). Customs agency on campaign against drugs, illegal imports. Available at: https://www.koreatimes.co.kr/www/biz/2023/04/488_349265.html [Accessed January 2023]

World Bank (2020). Foreign direct investment, net inflows (% of GDP) - Korea, Rep. Available at: https://data.worldbank.org/indicator/BX.KLT.DINV.WD.GD.ZS?locations=KR

Yoo, S.L., Kim, D.J., Lee, S.M., Kang, W.G., Kim, S.Y., Lee, J.H. and Suh, D.C., (2019). Improving patient access to new drugs in South Korea: evaluation of the national drug formulary system. International Journal of Environmental Research and Public Health, 16(2), p.288.

Yoon (2022). This is how South Korea can become a global innovation hub. Available at: https://www.weforum.org/agenda/2022/01/startups-in-south-korea-are-thriving-this-is-why/ [Accessed January 2023]

과학기술정보통신부·한국과학기술기획평가원, 연구개발활동조사, 각 년도. Available from: http://210.179.230.152:8083/statHtml/statHtml.do?orgId=358&tblId=DT_WER34&conn_path=I2 [Accessed January 2023]

산업통상자원부,「국내바이오산업실태조사」, 바이오산업 인력 현황. Available at: https://kosis.kr/statHtml/statHtml.do?orgId=115&tblId=DT_115015_002&conn_path=I2 [Accessed January 2023]

산업통상자원부,「외국인직접투자통계」, 산업별 외국인 투자 유치 실적. Available from: https://kosis.kr/statHtml/statHtml.do?orgId=115&tblId=DT_115_2009_H3001_18_1&vw_cd=MT_ZTITLE&list_id=S2_14&scrId=&seqNo=&lang_mode=ko&obj_var_id=&itm_id=&conn_path=MT_ZTITLE&path=%252FstatisticsList%252FstatisticsListIndex.do [Accessed January 2023]

식품의약품안전처 임상정책과. Available at: https://nedrug.mfds.go.kr/

온라인 중앙일보 (2015). "혁신형 제약 인증 실패기업 살펴보니". Available at: https://www.joongang.co.kr/article/18127405#home [Accessed January 2023]

정연 and 권순만. (2014). 지적재산권 강화에 따른 제약시장의 변화와 의약품 가격 및 이용에의 영향 ㅁ 5개 국가의 사례를 중심으로. 한국사회정책, 21(2), 183-228.

특허청,「지식재산권통계」, 기술분야별 특허 출원(WIPO 기술분류 기준). Available at: https://kosis.kr/statHtml/statHtml.do?orgId=138&tblId=TX_13801_A024_2&conn_path=I2 [Accessed January 2023] [2] Chemical Abstracts Service. 2022.

한국직업능력연구원, 교육부,「국내신규박사학위취득자조사」, 박사과정 중 총 학비 지출 현황. Available at: https://kosis.kr/statHtml/statHtml.do?orgId=389&tblId=DT_920009_A11&conn_path=I2 [Accessed January 2023]

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