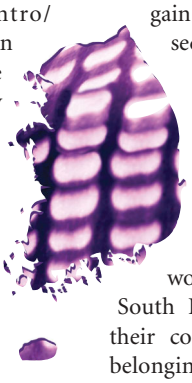
South Korean biotechnology—a rising industrial and scientific powerhouse

Joseph Wong, Uyen Quach, Halla Thorsteinsdóttir, Peter A Singer and Abdallah S Daar

Once among the world's poor nations, South Korea is an example of a country that was able to develop swiftly to become part of the industrial world. From cars to computers to cell phones, products designed and manufactured in South Korea are now found around the world. From a per capita gross national product (GNP) of about $100 in the early 1960s, South Korea has grown to be one of the world's major economies, with a per capita GNP of $10,000 in 2003. South Korean industry rapidly expanded from consumer electronics in the 1960s to heavy industry a decade later to information technology during the 1980s. The government is now touting biotechnology as South Korea's next star industrial sector. Despite being a late entrant into the life sciences field, South Korea is already making its mark in biotechnology innovation, making headlines when a Seoul National University professor announced that his team was the first to successfully extract stem cells from cloned human embryos. This breakthrough has put Korean life sciences research onto the global stage (see **Box 1**).

The success of South Korea's health biotechnology sector

In 1994, seven government ministries signed onto the 'Biotech 2000' plan, in which the government hoped to make South Korea one of the world's top seven biotechnology producing countries by 2010. A survey of respondents, company web sites and other sources, such as the Bioindustry Association of Korea (http://www.bak.or.kr/english/intro/purpose.html), suggests that between 450 and 600 Korean companies are using some aspect of biotechnology in their business. This covers brand and generic pharmaceutical firms with a business plan to diversify into biotechnology R&D as well as startup firms involved in cutting-edge biotechnologies (e.g., regenerative cell therapy). Therefore, the number of enterprises created solely for the purpose of healthcare biotechnology may be somewhat lower.



A glimpse at the Korean stock market (KOSDAQ; http://english.kosdaq.or.kr/) illustrates the recent explosive growth in Korean biotechnology: in 2000, only one South Korean biotechnology firm was publicly listed; by 2002, there were 23. These firms are focusing their efforts primarily on the development of new brand drugs, medical devices, bioinformatics and functional genomics research (see **Table 1**). According to government figures, over one-third of biotechnology products being developed in South Korea are in the biomedical field and the product pipeline is growing. Over 40 South Korean pharmaceutical firms have 130 new drugs in either phase 1 or 2 clinical trials. South Korean life science ventures, such as Macrogen (Seoul) and Bioneer (Daejeon, South Korea), are capitalizing on the post-genome era, and are beginning to gain an international reputation in DNA sequencing and synthesis (see **Box 2**).

Both demand-side pulls and supply-side pushes fuel South Korea's biotechnology ambitions. Unlike many developing countries, the urgency for health biotechnology development in South Korea is not in addressing so-called 'developing world diseases,' as the health profile of South Koreans is already on a par with their counterparts in industrial countries belonging to the Organization for Economic Cooperation and Development (Paris). The domestic demand for health biotechnology products is, in part, due to increasing household resources available for higher-cost medical treatments. The expansionary pressures of the domestic drug market are also driving biotechnology demand. This is a reflection of South Korea's public healthcare system, which features universal access and relatively low out-of-pocket payments[1]. The Ministry of Commerce, Industry and Energy (MOCIE, Gwacheon City, South Korea), South Korea's main industrial policy ministry, forecasts the market for biotechnology goods to reach $12 billion by 2010, and it expects biotechnology exports to increase ten times over the next decade, particularly as South Korean innovations gain patent recognition in overseas markets.

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Illustration by Erin Boyle

Box 1 Evolving from rapid follower to innovator

South Korea was one of the first non-Western countries to develop generic versions of brand protein products innovated in developed nations. In 1991, after 10 years of research, South Korea's LG Life Sciences (a spin-off of LG Chem Investment) developed Euvax-B, a *Saccharomyces cerevisiae*-derived recombinant hepatitis B surface antigen vaccine. In November 1992, the firm successfully commercialized the product and by 1996 it had obtained WHO accreditation. LG Life Sciences has since exported the vaccine to international organizations, such as UNICEF and the Pan-American Health Organization (Washington, DC, USA), as well as to developing countries, such as Egypt.

Today, progress by the country's researchers in the area of nuclear transplantation and human ES cells also suggests South Korea can lead Western nations in innovating biotechnologies. In February 2004, Hwang Woo-Suk of Seoul National University announced that his laboratory had successfully derived human ES cells from cloned embryos donated by Korean women. This important step in the development of therapeutic cloning was published in *Science*[7].

On the supply side of the equation, R&D spending in South Korea has skyrocketed in recent years. During the early 1970s, total R&D spending in the country was just 0.31% of GDP, but by 2001 South Korea's R&D expenditures had increased tenfold to nearly 3% of GDP—equaling Japan's (2.98%) and surpassing the United States' (2.70%) and the United Kingdom's (1.86%)[2]. Health-based R&D accounted for 12% of all university research spending in 2001 and almost 20% of all university researchers were engaged in biomedical science R&D[2].

These supply-side investments are beginning to pay off in terms of scientific productivity. The number of health biotechnology–related publications by South Korean researchers increased tenfold from 1992 to 2002 (ref. 3). In addition, on the basis of a July 2004 analysis of the United States Patent and Trademark Office's database from 1991 to 2002 (Washington, DC, USA, http://www.uspto.gov/), patents including South Korean inventors' addresses also increased, particularly rapidly in the mid-1990s (see **Fig. 1**). According to one respondent, the Korean Intellectual Property Office (KIPO, Daejeon, South Korea) granted over 800 genetics and biotechnology patents to domestic inventors in 2002 alone.

South Korea is thus emerging as a player in the global biotechnology scene. It is catching up with other Asian countries, such as Japan, and keeping pace with regional competitors like Taiwan, Singapore and China. Winning the bid in 2000 to be the permanent host of the International Vaccine Institute (IVI; http://www.ivi.org/) confirmed South Korea's strong global reputation in the field. The IVI—first initiated by the World Health Organization (WHO; Geneva), the World Bank (Washington, DC, USA), the Rockefeller Foundation (New York) and the United Nations (UN; specifically the UN Children's Fund (UNICEF) and the UN Development Program, both in New York)—seeks to develop and help distribute vaccines for children in impoverished parts of the developing world. The IVI is developing vaccines for diseases that developed countries and profit-seeking pharmaceutical firms are less likely to target, including influenza, pneumonia, meningitis, cholera and dengue fever. Funded in part by the South Korean government, and operated out of the Seoul National University campus, the IVI is a magnet for expertise. Already, it has attracted close to 50 researchers from places such as Bangladesh, China, Kenya, Japan, the United States and France.

It is clear South Korea is positioning itself to become a major contributor to both life science R&D and its commercialization in the near future. The country's success in developing high-technology brands, which started with the automobile sector and in information technology, increases the likelihood of its success in healthcare biotechnology.

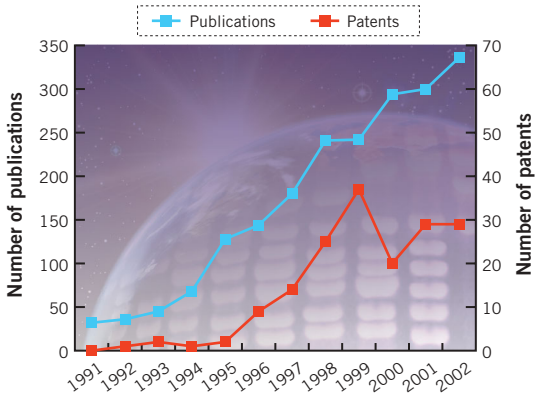

Figure 1 South Korean publications and patents in health biotechnology (1991–2002). Source: Publication data are from ref. 3. Patent data are from the USPTO.

Main features of the South Korean sector

The healthcare biotechnology sector in South Korea is competitive with that in many developed countries. The government has ploughed funding into both basic and applied research. Significantly, it has also recently started financing mechanisms for technology transfer from the country's excellent academic institutions to the private sector. Recent progress has also been made in providing a legal framework that gives greater intellectual property (IP) protection to companies, encouraging the growth of IP-dependent biotech enterprises. In tandem, decentralization and greater private investment in the sector is also fueling startup activity. With a highly educated population, and debates about embryonic stem (ES) cell research prominent in the national media, the Korean public is relatively knowledgeable about healthcare biotechnology and is optimistic about its promise for improving health and well being.

Government. The South Korean government continues to play a critical leadership role in helping the country realize its biotechnology ambitions. From 2000 to 2007, the government will have invested over 5.2 trillion South Korean Won (~$4.4 billion) in the field.

The Ministry of Science and Technology (MOST, Gwacheon City, South Korea), which is in charge of allocating nearly half of the government's total R&D budget, focuses on basic research (see **Box 3**). The ministry also administers the 21st Century Frontier R&D Program, of which seven of 19 designated projects are in the biotechnology field. Working with South Korea's elite research universities and publicly funded laboratories, such as the Korea Research Institute for Bioscience and Biotechnology (KRIBB; Daeduk Science Town, South Korea) and the Korea Institute of Science and Technology (KIST, Seoul), MOST has financed new R&D laboratories specifically designated for adult and embryonic stem cell research.

MOCIE focuses more on the applied biotechnology R&D (see **Box 3**). Using a similar approach to that of MOST, MOCIE provides direct subsidies and fiscal incentives for industrial R&D laboratories.

Illustration by R. Henretta

Table 1 Examples of South Korean health biotechnology products

Sector	Type	Product	Application	Producer[a]
Vaccines	Recombinant hepatitis B surface antigen	Euvax-B	Hepatitis B	LG Life Sciences
	Purified capsular polysaccharide Vi of *Salmonella typhi*	Typhoid-Kovax	Typhoid	Korean Vaccine (Seoul)
	Haemophilus influenzae type B small polysaccharide conjugated to CRM197 mutant *Corynebacterium diptheriae* toxin protein	Hib TITER	Bacterial meningitis	Dong Shin Pharmaceutical (Seoul)
Therapeutics	Recombinant human interferon α-2b	Alphaferon	Various cancers (e.g., renal cell carcinoma)	Cheil Jedang (Seoul)
	Recombinant human epidermal growth factor	Easyef	Antiulcerant for diabetics	Daewoong Pharmaceutical (Seoul)
	Autologous chondrocyte transplantation	Chondron	Cartilage damage	Cellontech (Seoul)
	Plant cell culture–derived paclitaxel	Genexol	Cancer	Samyang Genex (Seoul)
Diagnostics	Enzyme-linked immunosorbent assay for hepatitis C core/NS3 FP, E1/E2/NS4 FP NS4 antigens	LG HCD 3.0	Hepatitis C	LG Life Sciences
	Enzyme-linked immunosorbent assay for cross-linked *N*-telopeptides of bone type I collagen	OSTEOMARK NTx	Osteoporosis	Dong Shin Pharmaceutical
Other	DNA synthesis	N/A	Biomedical research	Bioneer
	384 human cDNAs from a Korean individual on a microarray	MAC Karyo 4000	Genotyping	Macrogen
	Cryopreservation of cord blood stem cells	N/A	Potential for developing cell therapies	Lifecord (Seoul)

[a]Some of these products have more than one producer in South Korea.

The Ministry of Health and Welfare (Gwacheon City, South Korea) enjoys far fewer resources for biotechnology R&D than either MOST or MOCIE, so it focuses on facilitating technology transfer for health biotechnology products. To this end, the ministry established the Health Technology Transfer Center (Seoul) in 2001. The center not only prospects for new health related technologies by maintaining close contact with researchers, but it also helps entrepreneurs in valuing and marketing such technologies.

The government is using public policy to create a more optimal legal environment for health biotechnology development. Long reputed as a country that did not respect IP rights, the South Korean government revised the 'Patent Law' as recently as 2001. Working with World Trade Organization (Geneva) officials, South Korean lawmakers have brought South Korea's patent regime in line with international standards and strengthened both enforcement and noncompliance measures. The number of patent applications received by KIPO from foreign researchers doubled between 1990 and 2000. According to one expert in South Korea, nearly half of all the biotechnology patent applications are now from foreign inventors.

In the regulatory area, South Korea has had for several years relatively high standards in healthcare delivery and in ensuring the efficacy and safety of biotechnology products. In 1998, the government administratively reorganized the South Korean Food and Drug Administration (KFDA; Seoul). The KFDA, which is modeled on the US Food and Drug Administration (FDA; Rockville, MD, USA), is now a centralized administrative agency legally overseen by the government, although in practice it functions as an autonomous regulatory institution.

Research institutes and universities. Research institutes and universities are the biggest contributors to knowledge production on the basis of health biotechnology publications in internationally peer-reviewed journals[3]. Universities play a key role in training experts, and lead in publishing. South Korean publications in health biotechnology have been steadily increasing since the 1990s[3]. Universities were responsible for 89.4% of all Korean publications between 1991 and 2002. Public research institutes were the second-highest contributor of publications in health biotechnology, accounting for 20.1% of the total[3]. Although the functions of research institutes and universities in South Korea are similar, there are some nuanced differences. Unlike university R&D, which focuses exclusively on basic research, public research institutes attempt to bridge basic and applied research.

For example, Seoul National University (SNU) is considered the country's premier research university, along with the Korea Advanced Institute of Science and Technology (KAIST; Daejeon, South Korea). Between 1991 and 2002, SNU has been the institutional leader in health biotechnology publications in internationally peer-reviewed journals, publishing 23% of the total health biotechnology papers for the country, whereas KAIST accounted for 13%[3]. The SNU also houses the Stem Cell Research Center (SCRC). With a total budget of $75 million spread over 10 years, the SCRC's R&D plans will be divided into three phases, with the goal of clinical applications of adult and embryonic stem cells, such as the development by 2012 of gene therapies through transplantation of gene-modified stem cells. However, according to its 'technology roadmap,' the primary focus of the project is on basic research[4].

Public research institutes involved in health biotechnology knowledge production include KIST and KRIBB. Of the country's health biotechnology publications in inter-

Box 2 Macrogen–a flagship for Korean biotechnology ventures

Established in 1997, Macrogen is considered one of South Korea's leading biotechnology startups. It is making its name in the design of DNA microarrays, DNA sequencing and in the Korean Genome Project, which hopes to map the 'Korean' genome structure. For example, in a recent milestone for the firm, it mapped a library of 100,000 Korean bacterial artificial chromosomes containing the whole genome of a Korean individual, which it has used to generate cDNA 'genome' arrays.

The company is the brainchild of Jeong-Sun Seo, a professor at Seoul National University. Drawing on his research in the early 1990s on transgenic and knockout technologies in mice (patented in both the United States and Japan), Seo was able to acquire financing from one of South Korea's largest pharmaceutical companies, Green Cross (Seoul), and from several VC funds and institutional investors.

He also took advantage of a temporary law designed specifically to promote the formation of technology venture businesses in South Korea. The 1997 'special' law effectively connects the academic world with industry by allowing university professors to become industrial entrepreneurs while still remaining employed at their home institution, a provision that is common in other industrialized countries, but had been prohibited in South Korea. Macrogen's laboratories were initially based at Seoul National University. Its facilities moved off-campus in 2000, the same year that the firm listed on South Korea's KOSDAQ (http://english.kosdaq.or.kr/), a stock market for knowledge-based and high-tech ventures. Macrogen first listed at slightly below $7, peaked at $182 soon thereafter, and has since hovered around $10. The company is now financially on solid ground and revenues are growing annually.

nationally peer-reviewed journals between 1991 and 2002, these two facilities accounted for almost 15% of the total (ref. 3). The Functional Proteomics Centre (FPC, Seoul) is administered by the KIST. The principal objective of the FPC is to use proteomic analysis to identify new diagnostic markers and new drug targets. More specifically, it is working on research for a range of cerebral, metabolic, cardiovascular and immune-related diseases. Unlike the SCRC at the SNU, it has a more aggressive plan for commercialization, reflecting the bridging role played by government research institutes. KRIBB hosts the Center for Functional Analysis of the Human Genome (Daejeon, South Korea). With high incidences of liver cancer in Asian populations, the Center is targeting genomic research at liver and stomach cancers. Like the FPC, it has explicit commercialization objectives[4].

Industry. In the past, the South Korean government collaborated with its industrial allies the chaebols (predominantly large conglomerate firms) to orchestrate technology commercialization in the country. Well-known companies, such as Samsung (Daegu Metropolitan City, South Korea), LG (Seoul) and Hyundai (Seoul), benefited disproportionately when it came to foreign technology licensing agreements and securing industrial investment. The emerging biotechnology sector faces a different environment. Centralized government control over the commercialization process has waned, the influence of the chaebols has diminished because of the 1997 Asian financial crisis, and small and medium-sized firms increasingly dominate the industrial terrain in South Korea.

The 1999 Technology Transfer Promotion Act sparked the creation of new technology transfer centers to facilitate the commercialization of cutting-edge technology ventures throughout South Korea. A wide range of public and private sector actors are actively involved, including government ministries, major university and public research laboratories, business associations and private sector R&D consortia, and even KIPO and KFDA.

MOCIE has actively encouraged biocluster in South Korea. The most important one is located in the Daeduk Science Town in Taejon, a few hours away from Seoul by train. Built around the KRIBB and its Bio Venture Center (BVC), the Daeduk biocluster promotes and incubates new biotechnology firms. For example, Bioneer, a company specializing in DNA synthesis, was started by Han-Oh Park (who conducted his doctoral research at the nearby KRIBB) and initially was incubated at the BVC. One respondent noted that since 2000, BVC researchers have spun off 16 startups, and the center itself has incubated 14 external firms. Sparked by the 'economies of proximity' (as opposed to those of 'scale' and 'scope'), the interactive synergies between entrepreneurs and research-based scientists in Daejeon are forging new opportunities for biotechnology firms.

Investment capital in South Korea is both abundant and smart. In the past, the overwhelming majority of R&D spending came from government coffers, but by 2001, private sector sources accounted for nearly three-quarters of R&D expenditures[2]. This is due, in part, to the availability of private sector capital resources. For instance, an important source of biotechnology financing is South Korea's burgeoning venture capital (VC) market. The liberalization of South Korea's financial markets began during the mid-1990s, and the process was accelerated after the 1997 financial crisis. VC funds exploded onto the industrial technology scene.

The general public. Bioethics is being debated not only in academic circles, but also in South Korean politics. The Ministry of Science and Technology formed the Korea Bioethics Advisory Committee in 1998, just as the Biotechnology Promotion Law was to be revisited in the national legislature. This political window of opportunity was seized upon by local politicians, academics and social movement groups, who quickly drew attention to contentious ethical issues in

Box 3 A private sector perspective on MOST and MOCIE

One respondent from a successful South Korean biotechnology firm highlighted the key difference between MOCIE and MOST. Because MOCIE's mandate is to promote industrial R&D among private sector firms, it works much more closely with industry, specifically with small- and medium-sized enterprises. Its projects generally run for 3–5 years, whereas MOST's R&D commitments last 10 years. The respondent noted, "Most people in [MOST] don't have much interest in business. Their role is to make world-class scientific researchers."

biotechnology research, primarily human ES cell research and nuclear transfer.

Most South Koreans agree that human cloning should be prohibited, and Hwang Woo-Suk, Korea's most famous stem cell researcher (**Box 1**), recently stated that he is also "against human cloning"[5]. The Science and Technology ministry feels it should be permitted, but the Ministry of Health and Welfare contends that allowing such research might inadvertently open the door to human cloning and should thus be banned outright. With South Korea's competitors, like Singapore, already clarifying their ethical and legal positions on such debates, the multiple branches of the South Korean administration reached consensus in December 2003, passing the 'Bioethics and Biosafety Act,' which comes into effect in early 2005. According to this act, human reproductive cloning and experiments such as fusion of human and animal embryos are strictly banned, but therapeutic cloning is permitted in limited cases for the cure of otherwise untreatable disease.

Main challenges for development

The healthcare biotechnology sector has been hyped as a future source of economic wealth for South Korea. There is insufficient understanding that life science enterprises take many years to develop products and that many often fail in the process. These inflated political and investor expectations may result in a backlash if the sector does not produce enough successful biotechnology companies. In addition, because healthcare biotechnology enterprises are dependent on the creation of novel technology and are valued on the basis of IP, South Korean R&D in academia and industry needs to place greater emphasis on innovation. Because South Koreans have been phenomenally successful at copying existing products and making them more efficiently, changing this mind-set will be a significant challenge.

Public and investor expectations. The most important challenge for South Korea's rapidly growing health biotechnology sector is in meeting expectations for a field that is characterized by its high-risk nature. Building a mature healthcare biotechnology sector takes many years, and for South Koreans, whose economy expanded at nearly 10% annually since the late 1960s and sustained above-average growth even after the 1997 financial crisis, patience for economic development is in short order.

Despite all of the positive indicators surrounding their biotechnology sector's prospects, South Koreans are waiting for that one major technological and commercial breakthrough that will place South Korean biotechnology in the same league as that of the United States or the United Kingdom. The reality is that the public does not realize that development of a mature biotechnology industry base is a slow process, fraught with many more failures than successes.

This impatience may have important consequences for future biotechnology investments. The government's decision to pour in hundreds of millions of dollars each year is increasingly challenged, and its commitment is beginning to wane, particularly in its financing of exploratory, long-term R&D endeavors. Investors are also increasingly skeptical, especially after the venture mini-bubble of the late 1990s burst.

Shifting mind-set to innovation. In the past, South Korean firms borrowed technology from abroad and used their domestic laboratories to reverse engineer it. This acquired know-how, in combination with a comparatively inexpensive workforce, has enabled South Korean companies to produce quality goods at a lower cost. However, as a 2001 report from South Korea's Science and Technology Policy Institute (Seoul) puts it: "The days of playing catch-up, a strategy which is no longer effective and realistic, are over for Korea"[6].

South Korea must evolve from the industrial learning paradigm to a new technology creation paradigm. For academics and policy makers, this sort of transition makes intuitive sense. For South Korean scientists, investors, entrepreneurs and the public, however, this paradigm shift is not simply an academic problem, nor easily manipulated through top-down policy instruments. Rather, at its most basic level, the move toward technological creativity requires an attitudinal shift. It cuts to the core of the postwar South Korean mind-set. Indeed, this may prove to be South Korea's biggest challenge in making it in biotechnology.

Conclusions

Healthcare biotechnology in South Korea is still in its nascent stages, although in recent years there has been an upward trajectory in the number of South Korean startups and significant advances in biotechnology research. Three major lessons are apparent for encouraging startup activity in countries with a relatively well-developed educational, research, financial and industrial infrastructure.

Create a mix of small and large firms. It is common knowledge that large, diversified firms spearheaded South Korea's industrial transformation in the postwar period. The chaebol enterprises still exist, and they are continuing to diversify their industrial ventures, including those in biotechnology. Their deep pockets, brand recognition and marketing networks are important resources. The current focus for industrial policy makers in South Korea, however, is in promoting small, venture firms. The argument is that small and highly adaptable firms are able to effectively leverage their 'economies of scope,' making them ideal sites for biotechnology innovation and niche marketing.

Both big and small firms are needed, however. Venture firms complement South Korea's chaebol industrial structure, not only in new investment opportunities both upwards and downwards, but also in knowledge transfer and the creation of backward-forward linkages.

Exploit existing competitive advantages. To reduce the inherent risks in the biotechnology field, South Korean industrial policy makers, along with private sector investors, are focusing on creating enterprises that most effectively use the country's existing industrial competitive advantages in fields like pharmaceuticals and information technology. South Korean biotechnology firms and laboratories tend to focus on new drug development, taking advantage of South Korea's already strong pharmaceutical manufacturing sector. An example of this is seen in LG Life Science's (Seoul; http://www.lgls.co.kr/) R&D alliances with various foreign firms for drug targets, including new anti-cancer and anti-bacterial drugs. Biotechnology ventures are also looking to develop diagnostic and bioinformatics capacities, building upon South Korea's skills in information and communication technology and in chip design.

Go global. From the early stages of R&D to downstream commercialization, biotechnology is a transnational enterprise. For basic R&D, South Korean–based scientists are increasingly working with researchers from other countries. Between 1991 and 2002, about one-third of all articles published by South Korean researchers in the fields of genomics and biotechnology were co-authored with international collaborators[3]. In a recent major policy shift, the South Korean government is proactively seeking out foreign direct investment, especially in high-tech fields, such as biotechnology. The amount of such investment coming into South Korea tripled between 1997 and 2001.

South Korean biotechnology firms are also leading the way in creating and participating in transnational collaborative linkages in R&D, investment, licensing partnerships and arrangements. These deals span Asia, North America, Europe and the Middle East.

ACKNOWLEDGMENTS

Publication of this supplement was supported by the Bill and Melinda Gates Foundation (Seattle, WA), Genome Canada (Ottawa, Canada), McLaughlin Centre for Molecular Medicine (Toronto, Canada) and the Rockefeller Foundation (New York, NY). Special thanks to Archana Bhatt, Zoe Costa-von Aesch and James Renihan for patent analysis, Éric Archambault, Frédéric Bertrand and Grégoire Côté at Science-Metrix (Montréal, Canada) for analysis of publication data and to Nina Mansoori for her research assistance and the 29 South Korean experts who were interviewed for this study and provided their valuable time and input. The Canadian Program on Genomics and Global Health is primarily supported by Genome Canada through the Ontario Genomics Institute and by the Ontario Research and Development Challenge Fund. Funding partners are listed at http://www.geneticsethics.net. P.A.S. is supported by a Canadian Institutes of Health Research Distinguished Investigator award. A.S.D. is supported by the McLaughlin Centre for Molecular Medicine, University of Toronto. The authors declare that they have no competing interests.

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