

BUILDING THE BIOECONOMY 2015 ANNEX

Enabling Factors and Economy Case Studies

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LIST OF ABBREVIATIONS

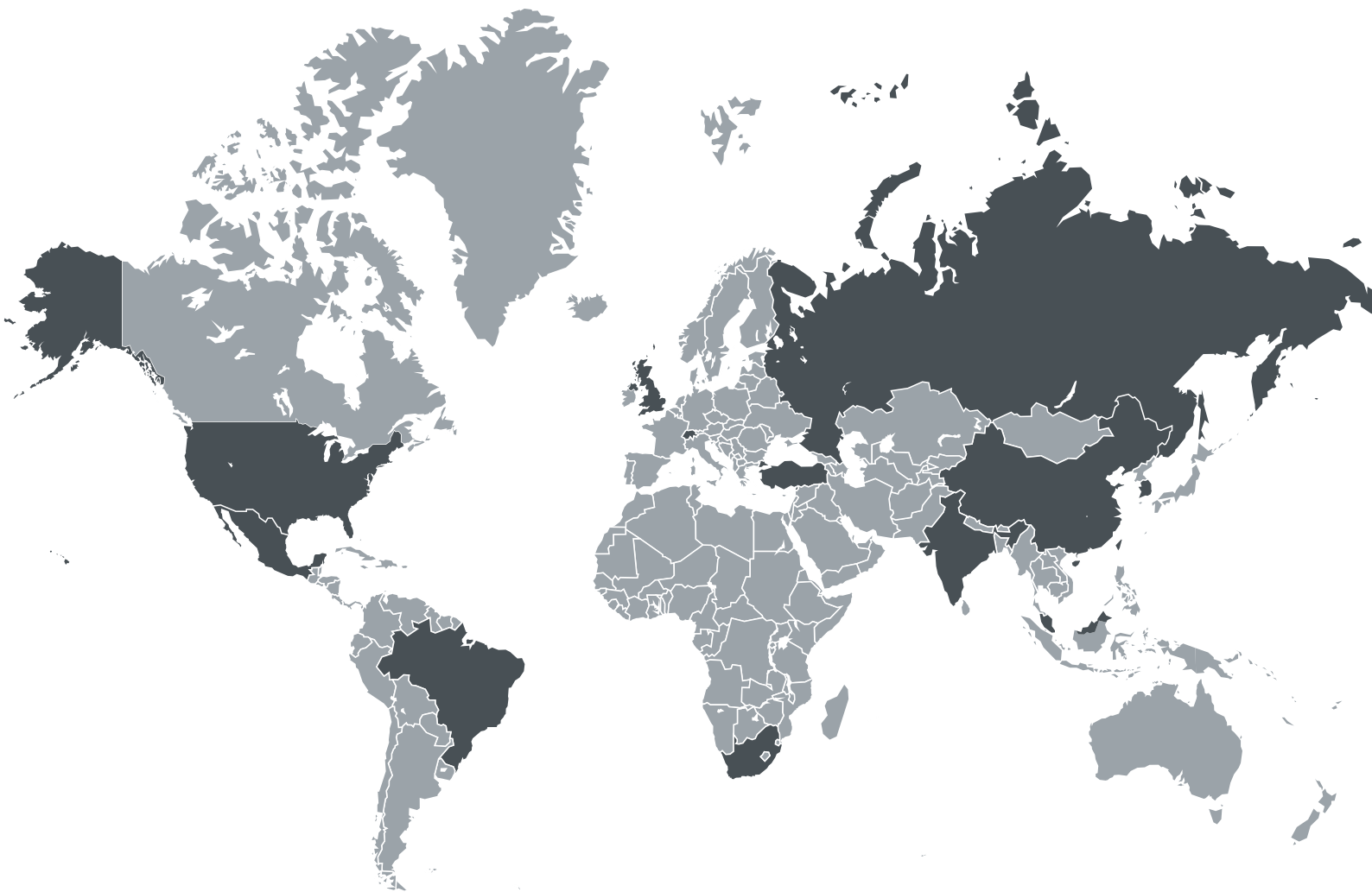
ANVISA	Brazilian National Health Surveillance Agency
API	Active Pharmaceutical Ingredient
A*STAR	Agency for Science, Technology and Research (Singapore)
BNDES	Brazilian Development Bank
CDSC	Central Drugs Standard Control (India)
CLs	Compulsory Licenses
CTNBio	Brazilian Biosafety Technical Commission
EMBRAPA	Brazilian Agricultural Research Corporation
EPA	US Environmental Protection Agency
FINEP	Funding Authority for Studies and Projects (Brazil)
FDA	US Food and Drug Administration
FDI	Foreign direct investment
GCP	Good Clinical Practices
GMP	Good Manufacturing Practices
GM	Genetically Modified
GMO	Genetically Modified Organism
ICT	Information and Communications Technologies
INPI	Brazilian Patent Office
IP	Intellectual Property
IPRs	Intellectual Property Rights
IRP	International Reference Pricing
NGO	Non-Governmental Organization
NIH	US National Institutes of Health
OECD	Organisation for Economic Co-operation and Development

LIST OF ABBREVIATIONS (continued)

PE	Private Equity
PCT	Patent Cooperation Treaty
PRO	Public Research Organization
RDP	Regulatory Data Protection
R&D	Research and Development
SFDA	State Food and Drug Administration (China)
SME	Small and Medium Enterprises
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USDA	US Department of Agriculture
USTR	US Trade Representative
VC	Venture Capital
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

ENABLING FACTORS AND ECONOMY CASE STUDIES

Accompanying the *Building the Bioeconomy 2015* main report this Annex contains a full and detailed discussion of each of the seven enabling factors used to map each economy's biotechnology environment. The Annex provides the complete set of data and information for each enabling factor used for the main report including the Biotech Policy Performance Measure. It is a reference tool to be used together with the main report.



Brazil

Human capital

Brazilian universities are not widely recognized in international rankings. No Brazilian university is included in the top 100 of the 2014-15 *Times Higher Education* rankings.¹ However, looking at the life sciences the University of São Paulo is included in the top 100 at 92nd place.² In terms of academic and research publications, Brazil has a relatively high number of scientific and technical journal articles published. Data from the World Bank shows that for the latest available year (2011) 13,148 such articles were published.³ This is an increase of over 100% since 2000 when 6,407 articles were published.

Examining the number of graduates in higher education and number of researchers Brazil has seen a steady increase in the last decade. In the latest year for which comparable data is available (2011) Brazil had a total of 13 million people in the age group 25-64 attaining some level of tertiary education.⁴ As a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, this was a rate of 13%.⁵

Looking at number of researchers in the population the latest (2010) data from the World Bank shows that Brazil had 710 researchers per million people.⁶ This is almost a doubling of researchers since 2000 when the equivalent figure per million population was 423.

Brazil in 2011 introduced an international student exchange program *Ciência sem Fronteiras* (Science Without Borders). This program seeks to:

- place Brazilian science and technology students at international universities and research institutions;
- attract foreign science and technology students to study in Brazil;
- internationalize Brazilian higher education institutions by promoting partnerships and collaboration with institutions in other countries; and

- promote the return of Brazilian scientists and graduates to Brazil.⁷

Infrastructure for R&D

Brazil is a major investor in research and development in Latin America. In 2011, Brazilian gross domestic R&D spending totalled USD25.3 billion at PPP.⁸ Brazil also has a relatively competitive level of R&D spending as a percentage of GDP in comparison to other BRICS and middle income countries. Updated 2011 figures show R&D spending as a percentage of GDP at 1.21%.⁹ This is lower than the OECD average of 2.40%.¹⁰

Looking at rates of patenting Brazil is on an absolute and per capita terms not a prolific patenting country. In 2012 the number of triadic patent families with an inventor resident in Brazil was 76.9.¹¹ The estimated global total for 2012 was 51,975. Similarly, looking at biotechnology patenting rates filed under PCT Brazilian residents were part of 45.2 filings in 2011 the latest year for which international data is available.¹²

With regards to clinical trials although the total number of trials in Brazil is relatively high with currently 4,259 trials being conducted in Brazil out of a regional total of 6,263 in Latin America, Brazil is still behind other markets on an absolute and per capita basis.¹³ Moreover, a relatively small proportion of Brazil's newer trials are in the realm of riskier, more complex trials (particularly Phase I). Here, Brazil currently has only 27 Phase I trials in operation; significantly less than the OECD average of 90.¹⁴

Overall the clinical trials environment is challenging and clinical research in Brazil is below levels expected. Brazil has less than 2% of the clinical centers in the world performing research and, according to local scientists and clinicians, is losing potential trials to other countries due to its regulatory requirements.¹⁵ Approval for clinical research needs to go through two separate bodies (CONEP, the National Commission for Ethics in Research, and ANVISA) and can stretch to over one year compared to three months in the US and EU.¹⁶

Intellectual property protection

The protection and enforcement of intellectual property rights in Brazil is challenging, particularly in the biopharmaceutical space. The last year has seen suggestions by the INPI to repeal the 10-year minimum patent period guarantee (which is in place to safeguard innovators for the long delays and backlog at INPI) and reduce an innovator's exclusivity period to a fraction of the internationally accepted 20-year period enshrined in the TRIPS agreement.

Furthermore, ANVISA has the right to provide prior consent to pharmaceutical patents that are being examined by the INPI. Consequently, decisions on whether to grant a pharmaceutical patent are not solely based on the examination by patent specialists and officials at INPI, but also by ANVISA. Brazil also does not allow patents for secondary claims for novel uses.

With regards to biotechnology patentability rules for biotech are narrow by international comparisons. For example, fundamental research areas in industrial and environmental biotech such as isolated microorganisms (including bacteria and yeast) are not patentable.¹⁷ Existing patent law only allows patents for transgenic microorganisms even though the use of all microorganisms in biotech R&D is increasing and leading to new innovations.¹⁸

Unlike many OECD economies and a growing number of middle income countries Brazil only provides regulatory data protection of submitted clinical test data for fertilizers, agrochemical products, and pharmaceuticals for veterinary use. Biopharmaceuticals for human use are not covered by existing regulations.

The regulatory environment

Biotechnology in Brazil is regulated primarily by ANVISA and CTNBio. ANVISA is responsible for the regulation of biologics as well as biosimilars (a biosimilars pathway was introduced in 2010/11).¹⁹ CTNBio is responsible for the regulation of all activities (including research and commercialization) of biotech and GM products or technologies.²⁰

With regards to the processing of patent applications the INPI continues to have a large

backlog of patents (estimated at about 10 years) and processing times are quite long for all art groups. Problems are particularly pronounced for high tech sectors including biopharmaceuticals and telecommunications where delays can reach 13 years.²¹ Recent public discussions by the head of INPI, Júlio César Moreira, suggest that the long backlog is the top priority for the agency and fresh initiatives are to be launched including the hiring of more examiners and new administrative procedures.²²

Technology transfer

Brazil has a number of policies and regulations in place to promote the transfer of technology. For instance, a key tenet of the 2004 Innovation Law was to encourage the transfer and commercialization of technologies through incubation services for public researchers and greater encouragement of start-up activities.²³ The law provides incentives including royalty guarantees to inventors. Although by international comparison still quite limited, since 2004 and passage of the law Brazilian universities have increased both their patenting and licensing activities. And there has been growth in the use of IPRs by Brazilian universities and public research bodies. For example, between 2000 and 2007 patenting by universities more than quintupled, from 60 patents to 325.²⁴ During the same time period, patenting by public research organizations increased from 20 to 39. Similarly, a 2011 survey of 7 universities in Brazil found that patenting, licensing and collaboration was taking place between universities and industry but that this was still at an early incipient stage.²⁵ One of the more successful PROs in pursuing technology transfer and protecting its R&D and IP is EMBRAPA. EMBRAPA runs its own program of technology transfer maintained by the Technology Transfer Department. Items available for technology transfer are searchable on the agency's website through keyword searches.²⁶ For example, the "grow" category under products yields 380 items available for technology transfer, a majority of which are GE seeds.²⁷ Over the years EMBRAPA has accumulated over 200 international patents and developed 350 cultivars.²⁸

Still, there are regulatory and formal requirements in place that limit the attractiveness of licensing and wide-spread technology transfer. For

example, to become effective and binding on third parties licensing agreements must be published in the INPI's *Official Gazette*.²⁹ Agreements must also be approved by INPI. There are also limitations on fees and payments between the contracting parties.³⁰ Exclusive licensing agreements are also subject to more onerous publication requirements than non-exclusive licenses making this process more time-consuming.³¹

Market and commercial incentives

Brazil has R&D tax credits in place under Law No. 11.196. These include a potential 60% deduction on corporation tax liability and social contributions.³² This deduction can also escalate if there is a year-on-year cumulative increase in R&D spending. There is also an additional 20% deduction available once an invention has been patented. However, this is available only once a patent has been issued.

Brazil also has in place policies and laws encouraging local manufacturing in a number of industries including biopharmaceuticals. The 2010 law 12,349 established preferences for businesses producing goods in Brazil with a local preference margin of up to 25% over an equivalent bid from an importing company.³³ As part of the *Brasil Maior* initiative these preference margins were extended to the pharmaceutical industry in 2012 with decrees 7709 and 7713 with margins ranging from 8 or 20 percent.³⁴

With regards to the biopharmaceutical market relatively strict price controls are in place. Reference pricing is used extensively and is calculated on the lowest average ex-manufacturing price of the biopharmaceutical product in a basket of countries. Countries included in the basket are Australia, Canada, Spain, US, France, Greece, Italy, New Zealand, Portugal as well as the country of origin of the drug. In addition, there is a separate price calculation for "exceptional medicines" to which a "Coefficient Adequacy Price" (*Coeficiente de Adequação de Preço*) or CAP is applied.³⁵ The CAP is calculated comparing Brazil's GDP with the GDP of the selected reference country. CAP calculation can be applied when the product being priced is not on the market in at least 3 countries in the IRP basket.

Legal certainty (including the rule of law)

The Brazilian judiciary is independent although the courts are overburdened and the resolution of contract disputes can be a lengthy process.³⁶ These challenges are reflected in Brazil's ranking on international indices measuring the rule of law. For example, in the 2014 *Rule of Law Index* Brazil ranked 42nd out of 99 countries mapped.³⁷

China

Human capital

Chinese universities are becoming more competitive internationally. In the 2014-15 *Times Higher Education* rankings Peking University is ranked 48th overall and Tsinghua University is ranked 59th.³⁸ Looking at academic and research publications, China has a high number of scientific and technical journal articles published. Data from the World Bank shows that for the latest available year (2011) over 89,000 articles were published.³⁹ This is over a four-fold increase since 2000 when 18,478 articles were published.

The past decade China has seen tremendous growth in the number of university graduates particularly in science and engineering. The total number of natural science and engineering graduates has jumped from just under 240,000 in 1998 to over 1.1 million in 2010 and China produces by far the greatest absolute number of these graduates in the world.⁴⁰ China also produces a very high number of doctoral degrees in science and engineering. In 2010 this was close to 31,000 degrees with only the US, at just over 33,000, having a higher rate.⁴¹ China is estimated to have one of the highest number of life sciences graduates in the world and a large number of Western educated life sciences PhDs (80,000) have returned back to China to work in industry and academic research.⁴² In the latest year for which comparable data is available (2010) as a percentage of the total population in the age group 25-64 that has attained some level of tertiary education China had a rate of 4%.⁴³

A growing share of China's workforce consists of researchers. Looking at the number of researchers in the population the latest (2012) data from

the World Bank shows that China had 1,020 researchers per million people.^{43a} This is an increase of close to 100% since 2000 when the equivalent figure per million population was 547.

Infrastructure for R&D

As a percentage of GDP R&D spending in China is quite high compared to other countries. 2012 figures show R&D spending as a percentage of GDP at 1.98%, which is greater than many higher income countries such as Spain, (1.30%), the UK (1.73%) as well as the estimated EU28 average (1.98%).⁴⁴ Chinese R&D spending is largely made up of industry spending. The latest data from 2012 show industry expenditure on R&D at 74% of the national total.⁴⁵

Chinese patenting activity has grown tremendously in the past decades. Looking at high-quality patents filed under triadic patenting, the Chinese share of the global total is 2.33% at 2012 figures.⁴⁶ This is a significant increase from levels in 2000 when China had a global share of 0.16%. Looking at biotechnology patents China is now one of the top patenting countries in the world. In 2011 the number of patents filed by Chinese residents under the PCT was 494.⁴⁷

Intellectual property protection

Although improving, the protection of IP and enforcement of IPRs in China has long been a challenge to innovators. In particular, while China has in some of the legal and regulatory framework to protect IP, the enforcement of IPRs has long been difficult with the counterfeiting of goods (including biopharmaceuticals) rife.⁴⁸

As a WTO member China offers standard 20 year patent protection. However, while this protection has been available for biopharmaceuticals the patent examination practice and basis for awarding patents has been out of line with international best practices. First, with regards to biologics the scope for patent protection is narrower in China than in other countries.⁴⁹ Second, patent examiners have often required a significant amount of biological data and often ended in the denial of patents for pharmaceutical products and technologies that have been granted in other jurisdictions. Recent

steps, including a change in the interpretation of patent examination guidelines to allow for supplementation of data during patent prosecution, may help resolve this.

Under its WTO commitments and article 35 of the regulations implementing the Drug Administration Law China offers regulatory data protection for submitted test and clinical data for pharmaceutical or agricultural chemical products which utilizes new chemical entities. However, it is not clear whether this period of exclusivity also applies to biologics.⁵⁰

Looking at ag-bio products, protection of IP has long been problematic. Illegal production of seeds and brand infringement are pervasive despite government enforcement efforts.⁵¹

The regulatory environment

2015 saw the release of new, finalised guidelines for the approval of biosimilars. Released in March the "Technical Guideline for the Research, Development and Evaluation of Biosimilars" build on a draft version published for public consultation in late 2014. Key differences between the draft and finalised version include:

- a clear definition that the Guideline constitutes a new approval pathway;
- definitions of biosimilars and reference products now include the provision that they are products that have been approved for market in China or elsewhere; and
- clarification that all samples used in comparisons and testing "should come from the same manufacture".⁵²

More generally, the Chinese drug regulatory authority, the SFDA, has by comparison to many middle income countries a relatively elaborate and detailed regulatory structure in place.⁵³

Still, a number of challenges remain for all biotech sectors.

In the biopharmaceutical space current regulatory requirements and procedures for clinical trials are by international comparisons onerous and delay product registration. There are also challenges

in existing pharmacovigilance programs with reporting requirements for manufacturers of ADRs being an area in need of reform and enforcement.⁵⁴

With regards to agricultural biotechnology the MOA and the National Biosafety Committee are responsible for the regulation and approval of imported agricultural GM products and/or the domestic production of GM products in China.⁵⁵ However, for this sector there are a number of regulatory related barriers to market entry. They include: the requirement that a product must be registered and approved in the country of export prior to an application for approval can be made in China; and a requirement that import applications include viable seeds.⁵⁶ The latter requirement has raised concerns among manufacturers about the protection of their IP.⁵⁷

Finally and more broadly, since the mid-2000s, China has introduced and implemented a range of policies making access to the Chinese market conditional on the sharing of technology and IP with domestic entities. These policies include the transfer of proprietary technologies in procurement, joint ventures, and standardization processes; local manufacturing requirements; and limitations on investment by foreign entities, without guarantee they will be protected from unauthorized disclosure, duplication, distribution, and use. Although some policies have been revoked at the central level at the provincial and local level these policies are still in place and continue to be introduced.

Technology transfer

With regards to technology transfer and IP commercialization, Chinese universities have been encouraged since the mid-1980s to manage and use inventions produced by their researchers, although formal ownership was retained by the state. This was changed through a number of reform initiatives culminating in the 2002 “Opinion on Exerting the Role of Universities in Science and Technological Innovation”.⁵⁸ Combined with the overall growth and development of the Chinese economy, the results of this relative freedom for universities and researchers to pursue commercial ventures has been a sharp increase in university patenting, patent and technology transfers

and number of spin-offs. Looking at university and PRO patenting rates these have increased dramatically and been a major contributor to China’s rise as one of the world’s top patenting nations. The latest figures from WIPO show how China’s share of global university patenting applications under the PCT increased from 2.5% in 2008 to 7.5% in 2013.⁵⁹ For PROs the increase was even more pronounced growing from 3.1% in 2008 to 16.3% in 2013.⁶⁰

Nevertheless there remain important challenges. First, many Chinese universities and research institutes have explicitly had a policy of promotion and evaluation based in part on number of patent applications. According to some studies patenting has become a substitute for peer-reviewed publications.⁶¹ Second, there is still a lack of experience and tradition with regards to commercialization activities especially in the life sciences. According to industry sources Chinese universities and research institutions (with a few exceptions) do not have the institutional and professional experience to fully commercialise their research.⁶²

Market and commercial incentives

China has a number of tax incentives in place to encourage R&D and high technology manufacturing from R&D deductions, exemption from VAT, technology transfer special rates, as well as a host of sector specific incentives. There is a super deduction available equal to 150% of qualifying R&D spending.⁶³ Moreover, high-tech and innovative companies (this includes the biopharmaceutical and industrial biotechnology sectors) can receive a special reduced corporation tax rate of 15%. Technology transfer activities up to RMB 5million (circa USD800,000) are exempt from corporation tax with activities over this amount exempt at a 50% rate.⁶⁴

Targeted subsidies and support mechanisms for the biotechnology sectors are also in place. For example, there are direct subsidies for biofuels and industrial biotechnology. A direct subsidy between USD365-405 per hectare is offered to farmers using forest for biofuels production and/or biofuels crops.⁶⁵ The authorities also impose price controls on the cost of fuels with ethanol being priced at roughly 90% of the price of gasoline.⁶⁶

With regards to the biopharmaceutical market this is hampered by a difficult pricing and reimbursement environment. Relatively strict reimbursement policies have limited the number of biological drugs available on the market. For example, the National Reimbursement Drug List does not include any monoclonal antibodies (used for example in cancer treatment) and there is also limited availability on provincial drugs lists.⁶⁷

Legal certainty (including the rule of law)

The Chinese legal environment can be challenging generally and for specific industries and sectors. Legal redress, enforcement of contracts and administrative justice can be difficult and inconsistently available or applied. In the 2014 *Rule of Law Index* China was ranked 76th out of 99 countries.⁶⁸

India

Human capital

In the 2014-15 *Times Higher Education* rankings no Indian university is ranked in the top 250 universities generally or in the top 100 universities for life sciences.⁶⁹ Looking at academic publications India does better and is ranked 11th on the total number of academic papers published in Thomson Reuters-indexed journals from January 2001 through August 31, 2011.⁷⁰ However, looking at citations per paper – which implies impact of academic work – India is ranked outside of the top 20 with 5.9 citations per paper.⁷¹

In terms of number of researchers per million India is not a top performer.⁷² There is a paucity of data but the most recent figures from the World Bank (2010) show that India had 160 researchers per million population.⁷³ This is the lowest rate among the BRICS and significantly behind other developed OECD economies.

Infrastructure for R&D

India is not a prolific spender on R&D. 2011 figures show total R&D expenditure at 0.81% of GDP.⁷⁴ This is significantly behind the other BRIC economies and mature OECD economies. Traditionally, the majority of this R&D is

government funded at 66% which is the inverse to spending patterns in other countries.⁷⁵

Looking at rates of general as well as biotechnology specific patenting as an indicator of R&D activity, India is more competitive in some areas than others. In 2012 the number of triadic patent families with an inventor resident in India was 502 out of a global total of 51,975.⁷⁶ In the biotechnology field Indian inventors filed 106 patents under the PCT route in 2011.⁷⁷

In terms of biotech infrastructure and R&D capacity, the Department of Biotechnology has through its policy initiatives expanded and increased India's biotech capacity and infrastructure. For example, through the Biotechnology Industry Partnership Programme partnerships have been developed and agreements signed with close to 100 companies with a budget of INR8 billion (797 crore).⁷⁸ Similarly, the Small Business Innovation Research Initiative provides grants to SMEs with 134 such projects being funded since 2007.⁷⁹ In both these programs the private sector financial contribution has been significant.

However, while these initiatives are promising they are still quite small. Relatively speaking India does not have an advanced R&D infrastructure and does not attract the type of investment required to build this capacity. Looking for example at biopharmaceutical investment and R&D funding by multinationals, the percentage of R&D budgets spent in India is small. Figures published by PhRMA on R&D spending by its member companies show that USD59.7 million or 0.1% of total R&D spending took place in India.⁸⁰

As of 2015 the aggregated number of clinical trials taking place (or having taken place) was 2,612.⁸¹ This is behind all other BRICS as well as more mature economies such as Korea on an absolute and a per capita basis. Moreover, looking at more recent trends in clinical research, most of the trials taking place in India are late-stage. In 2013 out of 117 total new trials taking place over half (60) were the less complex phase III trials.⁸²

Intellectual property protection

The protection of IP and enforcement of IPRs in India has long been a challenge to innovators.

However, as discussed in the main report *Building the Bioeconomy 2015*, a number of positive steps were taken by the new Indian Government in particular by Prime Minister Modi himself.

Key challenges include Indian patent law which has in place an additional requirement to the international norms of patentability that goes beyond the required novelty, inventive step and industrial applicability requirements. Under Section 3(d) of the Indian Patent Act, there is an additional “fourth hurdle” with regards to inventive step and enhanced efficacy that limits patentability for certain types of pharmaceutical inventions and chemical compounds. This has led to a number of patent revocations in recent years. India has also made use of the threat and actual use of issuing compulsory licenses for biopharmaceutical products. Since 2006 India has been involved in almost half of all major international CL disputes.⁸³ In 2012 Bayer was instructed by the Indian patent office to agree to have Bayer’s cancer drug, Nexavar, duplicated by a local generic company through a CL. With regards to patent revocations Roche in 2012 had its patent for the hepatitis C drug, Pegasys retracted by the Intellectual Property Appellate Board of India due to a simple design that could be copied rather easily by competitors. Similarly, the Delhi Patent Office also revoked the patent for the drug Sutent in 2012. This revocation was in response to a post-grant opposition and based on an alleged lack of inventive step. The drug is currently under patent in the US.⁸⁴

Although it has been discussed extensively in the past by the Indian authorities and recommended, India does not offer regulatory data protection for clinical test data submitted during market authorization applications.⁸⁵

With regards to ag-biotech India’s current legal framework on the protection of plant varieties differs from international best practices as found with the International Union for the Protection of New Varieties of Plants. Specifically, requirements relating to the submission process, compulsory deposit of parental lines to a public gene bank, and potential claims of benefit sharing and compensation if crop performance is less than expected, make this framework less attractive than in other countries.⁸⁶

The regulatory environment

India’s regulatory environment faces a number of critical challenges. For ag-bio the past few years has seen a great deal of regulatory uncertainty. The key body for approving new products for market and imports (the Genetic Engineering Appraisal Committee) was not in session between 2012-2014.⁸⁷ Field trials of new seeds and plant varieties suspended by the previous government were allowed in 2014 only to be suspended again.⁸⁸ A committee appointed by the Supreme Court of India recommend a moratorium on the commercialization of ag-bio products due to safety and regulatory concerns.⁸⁹ Overall the regulatory environment for ag-bio and commercialization of ag-bio products remains highly uncertain.

Looking at biopharmaceuticals the availability of counterfeit and substandard medicines remains high with lapses in manufacturing biopharmaceutical practices uncovered in the last few years. Serious quality-related concerns have recently been raised about some of India’s largest biopharmaceutical firms, most notably with regards to manufacturing and quality control procedures at Ranbaxy.⁹⁰ The *New York Times* reported in 2014 that following the increased inspections by the FDA and uncovering of the quality irregularities by Ranbaxy (and the resulting FDA imposed fine and ban) India’s top drug regulator was quoted as saying: “If I have to follow US standards in inspecting facilities supplying to the Indian market we will have to shut almost all of those.”⁹¹ There exists no equivalent to the Chinese SFDA, the US FDA or the EU’s EMA. Instead, authority over medicines and pharmaceutical drugs is spread out over various layers of the Indian central government and state governments. On many critical issues of quality and safety regulations, there is divided authority between Central Government and the governments of individual Indian States.⁹²

India introduced biosimilar guidelines in 2012. These guidelines incorporate elements of the pathways in place in the US and EU. However, a key difference is the lack of market exclusivity provided through regulatory data protection.⁹³ Moreover, prior to the publication of these guidelines India had approved a number of non-innovative biologics under its old regulatory structure.⁹⁴

Technology transfer

Technology transfer and commercialization of public funded research remains limited. 2014 statistics from WIPO suggest that patenting by Indian PROs and universities is still quite limited. In 2013 a total of 55 PCT patent applications were made by Indian universities and 104 by PROs. This compares with 3,920 applications by US universities (which were the largest source of patenting applications by all universities globally) and 829 PCT applications from PROs in France which filed the most applications globally in 2013.⁹⁵

As these figures suggest, technology transfer and university patenting rates are still relatively low. Indeed, very few Indian universities have functioning TTOs. The institutions with the most advanced and developed technology transfer capabilities are the Indian Institutes for Technology. The institutes in Madras and Mumbai have technology and start-up incubators in place and have incubated a growing number of start-ups in the past few years.⁹⁶

In acknowledgement of this and in an effort to encourage greater rates of technology transfer and commercialization India has since the mid-2000s explored developing its own private-public technology transfer framework, the Protection and Utilisation of Public Funded Intellectual Property Bill, introduced in 2008.⁹⁷ No laws have since been passed and introduction and passage of the bill and corresponding legislation was included as an action item in the 2014 National Biotechnology Plan.⁹⁸

Market and commercial incentives

India offers a number of general and biotech specific tax incentives. The primary tax incentive is a 200% biotech specific R&D deduction.⁹⁹ The facility and expenses for which the deduction is for must be pre-qualified by the Indian Government. In addition, there are general R&D deductions (up to 100%) as well as super deductions for contracted out research to Indian entities.¹⁰⁰

Looking at the biopharmaceutical market relatively strict price controls are in place for drugs and pharmaceuticals available through the National List

of Essential Medicines. In 2014 the price controls were extended to an additional 88 medicines.¹⁰¹

Legal certainty (including the rule of law)

The Indian legal environment presents a number of challenges. Legal redress, enforcement of contracts and administrative justice is not always available or consistently applied. In the 2014 *Global Rule of Law Index* India was ranked 66th out of 99 countries.¹⁰²

Korea

Human capital

Korean universities are relatively well regarded, particularly in the biomedical and life science fields. For example, in the 2014-15 *Times Higher Education* rankings the Pohang University of Science and Technology (Postech) and Seoul National University are respectively ranked 84th and 85th in the life sciences ranking.¹⁰³ As a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, Korea had a 2011 rate of 40% which is above the OECD average of 32%.¹⁰⁴ In terms of the life sciences, Korea had 12,466 life sciences graduates in 2011 which is an increase of 136% since 2000.¹⁰⁵

In terms of number of researchers in full-time equivalent Korea had 288,901 in 2011 the latest year for which OECD figures are available.¹⁰⁶ Looking at the number of researchers in relation to the total work force, Korea was ahead of the OECD average of 7.7. In 2011 Korea had 11.9 total researchers in full-time equivalent per thousand of total employment.¹⁰⁷

Infrastructure for R&D

Korea is a leading investor in research and development. When measured as a percentage of GDP 2012 figures show R&D spending at 4.36%.¹⁰⁸ This is the highest figure in the OECD.¹⁰⁹ Korean R&D spending is largely made up of private sector and industry spending. The latest data from 2012 show industry expenditure on R&D at 74.7% of the national total.¹¹⁰ Biotech R&D accounted for 2.72% of overall industry R&D spending.¹¹¹

Korea has quite advanced medical and biomedical research facilities. Indicative of the competitive clinical environment is the high level of clinical trials. Korea currently has 5,974 clinical trials in operation.¹¹² Moreover, showing the strength and sophistication of its clinical research environment almost half of current (registered in or after 2013) trials were Phase I or Phase II trials.¹¹³

Korean patenting activity is substantially higher than other larger countries. Looking at high-quality patents filed under triadic patenting, the Korean share of the global total is 4.47% at 2012 figures.¹¹⁴ With regards to biotechnology patenting activity in 2012 the number of patents filed by Korean residents under the PCT was 533.¹¹⁵

Korea could be more attractive as a VC market. According to the IESE 2014 VC and PE Attractiveness Index, Korea is outside the top-10 in the world ranked 17th.¹¹⁶

Intellectual property protection

Overall, Korea has a strong system of protecting IP and enforcing IPRs. Korea provides a standard 20 year term of protection for patents as well as a 5 year term of patent restoration for pharmaceuticals. In conjunction with the US-Korea Free Trade Agreement, Korea also introduced a 5 year regulatory data protection period similar to that in the US. Korea introduced legislation relating to the development of orphan drugs in 2003. Incentives include marketing rights for 6 years and nationally funded research programs along with support from the Ministry of Family Affairs, Health and Welfare and the Korean Centers for Disease Control and Prevention to encourage the development of orphan drugs.¹¹⁷

Still, there remain some important challenges. For example, with regards to biopharmaceutical patents Korean patent law and examiners require significant amounts of pharmacological data to be submitted in the original patent application, not, as is the more common international practice, of submitting such data during either patent prosecution or post-grant validity proceedings.¹¹⁸ There also remains uncertainty over the implementation of the patent linkage system agreed between the US and Korea.¹¹⁹ The patent listing requirements appear to call for innovators to

share patent information beyond what is typically provided in similar patent lists (e.g., in the United States' Orange Book), and listing applications can be rejected by the Korean Ministry of Food and Drug Safety if they do not meet specific criteria (although approximately 85% of patent listing applications are reportedly accepted). In addition, it is possible for patent information submitted by rights holders to be modified somewhat in the final list published by the Ministry. Concerns have been raised that the new system as such does not strengthen patent enforcement.¹²⁰

Finally, there are some challenges with regards to the enforcement of IPRs, particularly patent rights. For example, rights-holders cannot apply directly to Korean customs authorities for the suspension of suspected patent infringing goods entering Korea as they can with copyright and trademark infringing goods. Instead, an application must be lodged with the Korean Trade Commission which can order a suspension. Evidence suggests that the Commission has investigated relatively few such applications and that, consequently, the patent enforcement environment in Korea could be improved.¹²¹

The regulatory environment

Korea has a relatively strong clinical and regulatory environment. For biopharmaceuticals the Ministry of Food and Drug Safety (formerly the Korean Food and Drug Administration) is responsible for the authorisation and safety supervision of pharmaceuticals. The agency is highly regarded internationally and has been recently praised by the FDA.¹²² Korea introduced a biosimilar pathway in 2009.

Korea has ratified the Cartagena Protocol on Biosafety in 2007 and implemented this through the Living Modified Organism Act in 2008. Imports of biotech grains as well as genetically engineered animals are regulated under this Act. Korea does not commercially produce any biotech crops and most research is still at the laboratory stage.¹²³

Technology transfer

Korea early on recognized the importance of closer working relations between universities and businesses and encouraging the

commercialization of publicly funded research. A number of technology transfer laws have been introduced.¹²⁴ These include the 2000 Technology Transfer Promotion Act as well as more recent laws such as the Technology Transfer and Commercialization Promotion Act. These acts provide direct support, opportunities and incentives for universities and research institutions to engage in technology transfer and commercialization activities. This includes support for tech transfer infrastructure, financial support through investment and loans to help small and medium enterprises as well as concessions with regards to state property and IP. There are also legal provisions for assisting international cooperation in mutual transfer and commercialization between national and foreign governments, enterprises, colleges and universities, research institutes, and organizations.¹²⁵

Since the early 2000s and the initial interest in developing technology transfer Korea has seen a steady growth in university licensing income and patent rates.¹²⁶ The latest 2014 statistics from WIPO show Korean universities as some of the most prolific patenting entities in the world. Between 2008 and 2013 Korean universities more than doubled their global share of PCT patent applications from 5.1% to 10.5%.¹²⁷ While still constituting a major share of global PCT applications, Korean PROs saw their share fall from 17.4% of all PCT PRO applications in 2008 to 14% in 2013.¹²⁸

Furthermore, the building of the Korean biotechnology industry has benefited from government-backed initiatives through the Law for the Creation and Promotion of the Government Research Institutes enacted in 1999. This program sought to promote technology transfer and the commercialisation of biotechnology through start-ups, venture capital partnerships and spin-offs. As of August 2007, 1,386 ventures had been spun off from these institutes and 482 from universities.¹²⁹ The success of this initiative and of the Korean biotechnology sector in general is reflected by the 612 publications and 277 patents issued in 2012 alone.¹³⁰

There are also a range of schemes in place in order to improve knowledge flow and commercialization from public sector research.

Examples include the Technology Holding Company system (which seeks to promote the foundation of venture capital businesses from universities and research institutes); the Leaders in Industry-University Programme and the Brain Korea Programme, which are aimed at promoting collaboration between industry and academia.¹³¹ Examples of government tech transfer institutions include the Korea Institute for Advancement of Technology whose activities include developing a national technology strategy, supporting technology transfer and commercialization, and fostering international technological cooperation.¹³²

Market and commercial incentives

Korea offers R&D tax incentives for both large and SMEs. The incentives are based around deductions ranging from 40-50% for qualifying expenditure.¹³³

In terms of its biopharmaceutical environment Korea has strict biopharmaceutical pricing and reimbursement policies in place. A positive list system was introduced in December 2006. Price negotiations are in place for drugs and pharmaceuticals available through basic insurance. There have been cuts for a number of years and quite aggressive cost containment policies are in place.¹³⁴

Legal certainty (including the rule of law)

The Korean legal environment is generally considered stable and certain. Legal redress, enforcement of contracts and administrative justice is generally available and viewed as effective. Korea ranked 14th overall in the 2014 *Rule of Law Index*.¹³⁵

Malaysia

Human capital

Globally, Malaysian Universities are not considered among the top; the 2014-15 *Times Higher Education* world rankings does not feature any Malaysian universities in its top 500.¹³⁶ However, Universiti Teknologi Malaysia is included on the *Times Higher Education* rankings

of top universities in BRICS and emerging market economics.¹³⁷

Malaysia has a growing share of the population attending tertiary education. In 2011 this totalled 1,036,354 enrolled in a full time or part time tertiary education.¹³⁸ Of students who successfully completed their tertiary education program in 2011, 21,171 held a degree in the sciences and 16,304 held a degree in health and welfare.¹³⁹ Given the graduation rate of 16.5% this is a relatively high proportion with health and welfare degrees.

Malaysia's research capacity is growing rapidly. In terms of number of researchers, Malaysia had 1,643 researchers per million population in 2011; the latest date for which figures are available.¹⁴⁰ This is a significant increase over the levels in 2000 when the equivalent figure was 274 researchers.

Infrastructure for R&D

2011 figures show R&D spending as a percentage of GDP at 1.07%.¹⁴¹ Internationally, this is below the OECD average of 2.40%.¹⁴² The majority of R&D spending comes from the private sector. The latest data shows industry expenditure on R&D at 70% of the national total.¹⁴³

As of 2015 the aggregated number of clinical trials taking place (or having taken place) was 718.¹⁴⁴ Looking at more recent trends in clinical research, most of the trials taking place in Malaysia are late-stage. In 2013 out of 57 total new trials taking place only 3 were the more complex Phase I trials.¹⁴⁵

Malaysian patenting activity has increased significantly over the last decade, albeit from a low base. In 2012 the number of triadic patent families with an inventor resident in Malaysia was 35 out of a global total of 51,975; in 1999 the number was 4.5.¹⁴⁶ In the biotechnology field Malaysian inventors filed 36.45 patents under the PCT route in 2011.¹⁴⁷

Intellectual property protection

With regards to the protection of IP, while Malaysia has made significant progress over the last decade, a number of issues remain, particularly for the biopharmaceutical sector.

Overall basic IP protection and mechanisms are in place but, like many emerging markets, enforcement and application are more difficult. Although a specialist IP court does exist. Malaysian law on trade secrets and the protection of confidential information is not codified. Instead, it is guided by case law, and only civil remedies are available. Recent Malaysian High Court rulings (such as in the 2011 case *Soon Seng Palm Oil Mill et al v. Jang Kim Luang@Yeo Kim Luang et al*) suggests confidential information and trade secrets are reasonably protected.¹⁴⁸ Looking at biopharmaceuticals, Malaysia introduced a five-year term of RDP protection in 2011. While this is a positive achievement, challenges remain. Specifically, the full term of protection is not offered to new products introduced in Malaysia. Instead, the term of protection begins whenever a product was introduced globally. This significantly weakens the actual exclusivity and incentive being offered to pharmaceutical innovators through RDP. Moreover, there is an 18-month deadline for registration of a product.¹⁴⁹ Additionally, Malaysia does not allow any amount of patent term restoration.

The regulatory environment

For biopharmaceuticals, the Drug Control Authority (DCA) is responsible for authorisation and safety supervision of pharmaceuticals and operates under the guidance of the National Pharmaceutical Control Bureau.¹⁵⁰ While the agency and Ministry of Health have a target of 210 days for market approval industry reports suggest that lengthy delays are not uncommon.¹⁵¹ In a positive step Malaysia introduced biosimilar guidelines in 2008.

With regards to the use of biotechnology in agricultural, Malaysia has strict laws relating to the growing and sale of ag-bio products.¹⁵² The 2007 Biosafety Law stipulates that the National Biosafety Board must review and approve any modified organisms before they are released into the market. As of June 2014 the board had deemed six types of corn and five types of soybean marketable. Life science companies have complained that the NBB 180 day review period is unreasonably slow. A GM food labelling law was passed and set to be rolled out in July 2014 however at the time of research the law had not been implemented.¹⁵³

Technology transfer

Malaysia does not have in place a specific technology transfer law akin to the American Bayh-Dole framework. Instead, technology transfer at universities and public research institutions are guided by internal guidelines (often developed together with the main funder of the program, the Malaysian Government) and two Government regulations: the 1999 Government Circular and the 2009 Intellectual Property Policy.¹⁵⁴ While the former by and large retains IP ownership with the Malaysian Government the latter Policy vests ownership with the recipient of the relevant funding. As a result, under this policy publicly funded innovators and creators are able to retain ownership of their creations. While the data sample is limited patenting rates by Malaysian universities and PROs has increased between 2005 and 2010. For universities this grew from a total of 80 applications in 2005 to 507 in 2010. For PROs the increase over the same time span was from 36 to 195. Significantly, there was a jump in patenting at academic institutions following the introduction of the 2009 Intellectual Property Policy.¹⁵⁵ Of the PROs the Malaysian Palm Oil Board had the second highest level of patenting activity of all PROs with 98 patents filed between 2005-2010.¹⁵⁶

The Malaysian Government promotes technology transfer primarily through the Malaysian Technology Development Corporation. The agency accomplishes this by linking individual entrepreneurs and small businesses with large companies, research institutions and government agencies. Major universities in Malaysia have also set up technology transfer offices in recent years to attempt to capitalize on their research. The technology transfer office at the National University of Malaysia works with multiple government entities, major industry players and investment funds to commercialize university R&D.¹⁵⁷

Market and commercial incentives

There are a number of general as well as sector specific tax and commercial incentives in place. For the biopharmaceutical and biomedical sector there is the BioNexus incentive program. BioNexus status is available to biotechnology companies and companies that derive a

substantial amount of their final product from biotechnology. Qualifying entities receive a tax exemption on 100% of relevant income for a period of five-ten years (depending on the age of the entity) and a 20% tax exemption after the initial period has expired. Further, the company will be exempt from income duties and sales tax of raw materials and machinery along with a generous tax deductions on R&D expenditures. BioNexus status also incentivizes private sector investment by making the entire amount of investment in seed capital and early-stage BioNexus status tax deductible.¹⁵⁸

There are other general R&D incentives available including the Investment Tax Allowance and R&D super deductions. The Investment Tax Allowance can take several forms including a 50% tax allowance on capital expenditures for ten years for companies performing in-house R&D and 100% tax allowance on capital expenditures for ten years for R&D service providers.¹⁵⁹ On top of these tax allowances, the government offers a 200% super deduction on non-capital expenditures for companies conducting in-house R&D, donations to research institutes and on the registration of patents, trademarks and licenses overseas if it promotes an exported product.¹⁶⁰ In addition, the Minister of Finance has the ability to grant Pioneer Status to domestic companies capable of producing high-class products that will benefit the Malaysian economy. Companies receiving this designation pay no income tax on statutory income for five years and this benefit can be extended for an additional five years.¹⁶¹

With regards to incentives for the biopharmaceutical sector, the pricing and reimbursement environment is challenging.¹⁶² Reimbursement decisions are often delayed with industry reports suggesting delays of up to five years after regulatory approval. Moreover, there is, for example, no automatic inclusion of products onto the national formulary even if they were developed in Malaysia including through local clinical trials involving local patients.¹⁶³

Legal certainty (including the rule of law)

Malaysia ranked 35th of the WJP 2014 *Rule of Law Index*, scoring high marks for public safety, levels of corruption and efficiency of the court system.¹⁶⁴

Mexico

Human capital

No Mexican university is included in the 2014-15 *Times Higher Education* general rankings or life science specific.¹⁶⁵ As a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, Mexico had a 2012 rate of 18% which is below the OECD average of 32%.¹⁶⁶ In terms of the life sciences, Mexico had 10,665 life sciences graduates in 2012 which is an increase of over 500% since 2000.¹⁶⁷

In terms of number of researchers in full-time equivalent Mexico had over 46,000 in 2011, the latest year for which OECD figures are available.¹⁶⁸ Looking at the number of researchers in relation to the total work force, Mexico was behind the OECD average of 7.7. In 2011 Mexico had 1.0 total researchers in full-time equivalent per thousand of total employment.¹⁶⁹

Infrastructure for R&D

Mexico has a low level of R&D spending when measured as a percentage of GDP. 2011 figures show R&D spending as a percentage of GDP at 0.43%. For comparison, this is below China's rate of 1.98% (2012), Russia's rate of 1.12% (2012), and South Africa's rate of 0.76% (2010).¹⁷⁰ Approximately one-third of Mexican R&D spending is made up of private sector and industry spending. The latest data from 2011 show industry expenditure on R&D at 36.8% of the national total.¹⁷¹

Looking at the level of clinical research, as of 2015 the aggregated number of clinical trials taking place (or having taken place) was 2,340.¹⁷² Looking at more recent trends in clinical research, most of the trials taking place in Mexico are late-stage. In 2013 out of 140 total new trials taking place only 7 were the more complex Phase I trials.¹⁷³

Mexican patenting activity is substantially lower than other large countries. Looking at high-quality patents filed under triadic patenting, the Mexican share of the global total was 0.02% at 2012 figures.¹⁷⁴ This figure has essentially stood still since 2000. In the biotechnology field Mexican inventors filed 12 patents under the PCT route in 2012.¹⁷⁵

Intellectual property protection

Mexico faces a number of challenges with regards to the protection and enforcement of IPRs, particularly with regards to the life sciences. In 2012, COFEPRIS introduced a five-year regulatory data protection term. While this is a positive step there remains concern over enforcement and, most importantly, biologics were left out from this announcement. Similarly although a 2003 Presidential Decree introduced a basic system for early adjudication of generic-innovator disputes, it does not represent a transparent pathway as the patent holder receives no notification of infringing issues and is not formally involved in the adjudication process. In addition, the regulatory pathway is currently limited to substance and formulation patents only; use patents are still not included. Looking at enforcement resolution of patent disputes is delayed and often ineffective, whether through administrative or judicial routes and more broadly protecting trade secrets is difficult. The rate of prosecution of trade secret violations is extremely low. Security experts report that although 1 out of 10 companies in Mexico has suffered from industrial espionage, 97% of cases go unpunished.¹⁷⁶ Of the cases that are brought to authorities, only 56% result in damages or fines.¹⁷⁷

The regulatory environment

Mexico has reformed its regulatory environment quite considerably over the last few years. For example, COFEPRIS (the Mexican drug regulator) has introduced a number of reforms and committed to cutting market authorization times. The agency has been commended for quickly approving medicines that meet urgent local needs,¹⁷⁸ reducing the approval time for drugs already approved in the US, Canada, and EU from 360 days to 60 days. COFERIS approved medications are also approved with less scrutiny in many other South American countries.¹⁷⁹ In 2014 the agency also cut the pre-approval time for clinical trials from 3 months to 1 month reflecting a desire to attract more biopharmaceutical investment and trial activity.

With regards to the use of biotechnology in agricultural Mexico has had a framework in place for over a decade. In 2005, the government passed the Biosafety Law that clarified regulatory

issues relating to the research, production and marketing of biotech foods.¹⁸⁰ The Inter-Ministerial Commission on Biosecurity and Genetically Modified Organisms and its subsidiary bodies oversees food related biotech activities. The biotechnology regulations enforced by the Commission are not considered burdensome.¹⁸¹ The Commission has authorized 103 GMO products and the importation of 52 additional GMO products for food and feed uses.¹⁸² In addition to regulating the biotech food industry, the Commission has also provided funding to advance the sector. The organization has funded research to investigate the drought tolerance of GM maize, and the fungal resistance of GM cotton and beans.¹⁸³ Over the past several years the Commission has funded research into the genetic diversity of corn in the country and plans to use the outcome of this research to support the approval or disapproval of future GE corn strains.¹⁸⁴

Technology transfer

Mexico does not currently have a comprehensive technology transfer law in place or policies equivalent to an American Bayh-Dole style framework. In late 2013 as part of a broader reform package (including raising public investment in science and technology research) the new Mexican Government put forth proposal to clarify how publicly funded research could be commercialized.¹⁸⁵ At the time of research no law had been passed or put into effect. The existing Mexican technology framework is ad hoc and is based largely on the policies in place at the institution receiving the public funding.¹⁸⁶ There are however some initiatives in place to promote technology transfer. In August 2011, the National Council of Science and Technology launched a program to provide academic institutions with funding to promote technology transfer.¹⁸⁷ Academic institutions can propose projects to the council that would foster technology transfer. If accepted, the Council will cover a majority of costs related to IP management capabilities, developing a business plan for a technology transfer office, and enhancing the capabilities of any existing technology transfer office.¹⁸⁸ As of 2012, 60 projects had been accepted.¹⁸⁹ However, the method by which the Council funds researchers hinders efforts to promote technology transfer.¹⁹⁰ The Council pays for

two-thirds of academic researcher's salary and the amount of published information is a major component of determining workload. As a result, researchers are continually encouraged to publish but provided with very little time or incentive to file for patents or collaborate with outside industry.¹⁹¹

Market and commercial incentives

Mexico eliminated R&D tax credits and incentives in its 2010 tax reform.¹⁹² Instead, R&D and scientific research is supported through direct grants from the National Council for Science and Technology. These grants are available for both public and private institutions including commercial entities. However, the grants are primarily focused on research projects that include a partnering public research organization of higher education entity.

Mexico maintains maximum price regulations for patented medications (which mainly affects prices in the private sector). The maximum price for these medications is determined by a price referencing system generated from a weighted average of the ex-factory price of the medication in the product's six largest markets.¹⁹³ In the public sector, the procurement process is overseen by the Coordinating Commission for Medicines Price Negotiation.¹⁹⁴ The Commission determines recommended pricing for all medications available to public institutions; however, after determining prices Mexico's public institutions are able to further review pricing levels and request that they be lowered.¹⁹⁵ Industry sources suggest that for the past three years an average of only 5% of medicines submitted for institutional approval have been accepted.¹⁹⁶ On average, for medicines that are accepted the process takes two years from submission for approval to public sector usage.¹⁹⁷ In the public sector, products are not made available until reimbursement prices are determined and many private sector institutions follow the decisions made in the public sector.¹⁹⁸

Legal certainty (including the rule of law)

In the 2014 *Global Rule of Law Index* Mexico was ranked 79th out of 99 countries.¹⁹⁹ The Index praised Mexico for having effective checks on government power and having an open government with an independent judiciary.

However, the rankings also acknowledged that Mexico has issues with political corruption and civilian security.²⁰⁰

Russia

Human capital

The Lomonosov Moscow State University is the only Russian university featured on the 2014-15 *Times Higher Education* rankings (ranked 196th) and no Russian universities are ranked for life sciences.²⁰¹ Looking at academic and research publications, the number of scientific and technical journal articles published in Russia has dropped since 2000. Data from the World Bank shows that for the latest available year (2011) only 14,151 articles were published, while in 2000 the number was 17,180.²⁰² This is in contrast to other major emerging economies which all experienced at least a two-fold increase during the same period. Russia has also seen little growth in the number of science and engineering graduates, particularly in the life sciences. During 2001-2010, the number of doctoral degrees in natural sciences and engineering remained about 10,000, which is on par with Germany and the UK, but lower than China and the US.²⁰³

However, Russians have traditionally had a high level of enrolment in tertiary education. As a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, Russia had a 2011 rate of 53%, which is higher than any OECD country and well above the OECD average of 32%.²⁰⁴ Similarly, although the number has dropped somewhat in the last decade, Russia has a high number of researchers in the population. The latest data (2012) from the World Bank shows that Russia had 3,096 researchers per million people.²⁰⁵

As part of the package of socio-economic reforms in the 2020 Strategy Russia has set a goal of building world class science and technology universities. Programs and funding have focused on creating a network of 27 research universities and attracting leading international scientists.²⁰⁶

Russia ranks 13th out of 147 countries on the Thomson Reuters "Essential Science Indicators",

with over 265,000 publications in accredited journals over the period 2001-2011.²⁰⁷

Infrastructure for R&D

2012 figures show R&D spending as a percentage of GDP at 1.12%.²⁰⁸ This is behind Brazil (1.21%) and China (1.98%) as well as the OECD average of 2.40%.²⁰⁹ Russian R&D spending is largely made up of government spending – the latest data from 2012 show government expenditure on R&D at 67.8% of the national total.²¹⁰ Under ten percent (9.3%) of government-funded R&D is performed by universities, reflecting the emphasis on basic research conducted in public research institutions as opposed to academic institutions.²¹¹ According to 2011 OECD data, biotechnological R&D accounted for only a small percentage of business enterprise R&D (under 1%).²¹² Though somewhat higher, biotech R&D still only represented a little over 7% of total government and higher education sectors R&D spending.²¹³

Russian patenting activity has remained at a relatively low level for the last decade. Looking at high-quality patents filed under triadic patenting, the Russian share of the global total is 0.11% at 2012 figures.²¹⁴ With regards to biotechnology patenting activity in 2011 the number of patents filed by Russian residents under the PCT was 45.²¹⁵

In terms of general R&D support mechanisms, the Russian Foundation for Basic Research provides direct grants to researchers and scientists in basic research.²¹⁶ The Foundation for Assistance to Small Innovative Enterprises provides grants and loans to innovative SMEs seeking to commercialize basic research, including in the seed and start-up phases.²¹⁷ The Russian Foundation for Technological Development also offers loans to public-private ventures aimed at bringing to market new technologies.²¹⁸ Another effort to attract and stimulate investment in R&D is the Skolkovo Innovation Center outside of Moscow which includes a planned 'biomedical cluster' and R&D center involving international and local scientists, companies and venture capital funds. The cluster has reportedly established strategic partnerships with over 100 companies including Johnson & Johnson and EMC and several world-class research universities.²¹⁹ In terms of the entire Innovation Center, partners have committed to

R&D centers worth USD 420million and involving over 1,100 researchers.²²⁰ Yet reports suggest that development of the Skolkovo cluster has slowed down in 2014 with employment targets and investments not materializing.²²¹

Looking at biotech specific R&D policies biotechnology is one of the Russian government's strategic innovation priorities under the 2020 Strategy. The State Coordination Program for the Development of Biotechnology (BIO 2020) and the Strategy of Development of the Pharmaceutical and Medical Industries (Pharma 2020) are among several policy instruments aimed at building a bio-industry, starting with creating the necessary human and physical capital.²²² The bulk of the funding is aimed at the bioenergy, biopharmaceuticals, agriculture and food biotechnology and industrial biotechnology fields, relying on a mix of government funding and FDI.²²³ The field of biotechnology is also a key focus in research programs of the Russian Academy for Sciences, the Russian Academy of Medical Sciences and the Russian Agriculture Academy. In addition, state-owned enterprise, Rusnano (focused on developing the nanotechnology industry in Russia) co-finance R&D projects and infrastructure building including in biotechnology.²²⁴

Nevertheless, despite the market potential in Russia and the government's desire to attract investment in R&D in recent years, these policies have not yet generated significant investment in biotech R&D in Russia. For example, although the biopharmaceutical space has seen a few large investments by international research-based companies (including the St. Petersburg pharmaceutical 'cluster' and the RUB500 million – RUB1.5 billion through the government's Russian Venture Company) on the whole significant challenges remain in terms of incentives for foreign companies with R&D capabilities and know-how to invest in facilities and conduct biopharmaceutical R&D in Russia.²²⁵ In particular, government policies providing preferential treatment to domestic manufacturers and locally-produced products (detailed below) have made it difficult for companies to establish more than manufacturing and production facilities in Russia. Indicative of this broader trend Russia's clinical research environment remains limited. The number of clinical trials conducted in Russia is still

on an absolute and per capita basis fairly small. As of 2015 the aggregated number of clinical trials taking place (or having taken place) was 2,661.²²⁶ Looking at more recent trends in clinical research, most of the trials taking place in Russia are late-stage. In 2013 out of 266 total new trials taking place only 25 were the more complex Phase I trials.²²⁷

Intellectual property protection

As a WTO member Russia offers a standard 20 year patent protection term. However, while the protection has been available for biotechnological and biopharmaceutical inventions (with the exception of biological processes), the actual protection afforded to biopharmaceutical inventions is at times uncertain.²²⁸ For example, there is no guarantee that the drug regulator will not approve a biosimilar product for market despite an active patent on the reference biopharmaceutical, and remedies through the judicial system are slow and ineffective.²²⁹ Under its WTO commitments and the 2010 Law of Medicines, Russia has committed to implementing a regulatory data protection term of 6 years.²³⁰ This was a positive step and has significantly strengthened the existing framework and protection mechanisms for pharmaceutical innovation. However, there remains a lack of progress in implementing this commitment and developing a fully functioning form of RDP. As described in the main report recent amendments to the Law of Medicine will hopefully contribute to the introduction of a comprehensive regulatory framework.

2014 saw a number of key changes to Russia's IP environment directly relating to biotech patenting. President Putin in March 2014 signed into law a new set of amendments to the Russian Civil Code, including Part IV which covers all major forms of intellectual property rights offered in Russia.²³¹ The package of amendments was far-ranging and touched on patents, copyrights, trademarks as well as trade secrets. The overall impact of the amendments are somewhat mixed. For example, positive action has been taken with regards to setting pre-established damages for patent infringement.²³² However, other changes, such as the imposition of new process and application requirements with regards to the application for patent term restoration for

pharmaceuticals and agrochemicals, may end up causing confusion and effectively limit the availability of this protection for rights holders.²³³

The regulatory environment

Russia's regulatory system is evolving towards a system in line with international standards. For instance, one positive step involves efforts to ensure all biopharmaceutical, biomedical and microbiology production facilities comply with GMP. Although still in the process of implementation – the deadline for compliance is now reportedly set at 2016 – mandatory GMP and similar international standards in the regulatory process will help drive improvements to R&D and manufacturing sites in Russia, enabling further innovative activities by both multinational and local companies.²³⁴ Still, both in the biopharmaceutical and ag-bio sectors a number of challenges remain.

First, the market approval process in relation to biopharmaceuticals is quite onerous and lacks transparency. There are currently no specific regulations for registering both biologics and biosimilars in Russia. The registration process is the same for chemical-based and biologic products, and higher standards for the approval of biosimilars are not necessarily applied. Moreover, since 2010 registration of biopharmaceuticals is dependent on the submission of locally-conducted clinical trial data. These factors have resulted in significant registration delays and costs for foreign innovative companies.

Second, with regards to agricultural biotechnology several challenges exist. The Ministry of Agriculture is responsible for the regulation and approval of agricultural GM products. Up until July 2014, only imported GM crops may be registered and marketed; this represents a *de facto* ban on cultivation of GM seeds and products in Russia.²³⁵ However, effective July 1, 2014, all GM organisms and GMO-containing crops may be authorized for market. Still, this pathway will have to go through a process of implementation and industry sources expect the registration process to take two to three years initially.²³⁶ In addition, technical regulations governing the Eurasian Customs Union (of which Russia is a member) that came

into force in 2013 require all food products with over 0.9% of GM lines to be labeled as such.²³⁷ Nevertheless, both the Russian government and Russian policymakers are considering reversing this approach and tightening controls on GMOs. The Ministry of Agriculture is conducting a review of existing regulations on GMOs in light of international practices which the government considers to be more stringent than in Russia.²³⁸

Technology transfer

The central legislative framework for technology transfer in Russia is somewhat unique in that it focuses mainly on enterprise partnerships as opposed to patenting and licensing agreements as platforms for technology transfer. Federal Law 217-FZ on the Commercialization of University Research (2009) provides universities with the exclusive right to market their research through launching their own SMEs or obtaining stock in companies that rely on their research. Specifically, Law 217 requires that universities have at least a 25-33% share in spin-offs, depending on the type of company, in exchange for the right to use the university invention.²³⁹ In addition, the 2010 Decree 218 "On measures of state support for the development of cooperation of Russian higher education institutions and organizations implementing complex projects on high-tech production" provides competitive subsidies (up to RUB 100million) to high-tech companies seeking to establish R&D and manufacturing facilities in Russia that would be operated jointly with a Russian university.²⁴⁰ In 2010-2012, a total of RUB19 billion was allocated to the initiative.

Private efforts at technology transfer are also ongoing, including the Russian Technology Transfer Network, which involves 60 R&D organizations and innovation centers and is aimed at linking potential academic and industry partners including from the biotech and biomedical sectors.²⁴¹

Still, looking at data on patenting activities by universities and public research organizations it confirms that patenting has not been a priority for Russian publicly funded research institutions; as of 2011 Russia represented only 4% of PCT applications by universities and 2% of public research organizations among middle-income and selected low-income countries.²⁴²

However, reflecting the public policy emphasis on direct university participation in spin-offs, joint university-firm PCT applications represent a relatively large portion of total university applications in comparison with other leading countries. At 30% of total university PCT applications, Russia is on par with China and only behind Japan vis-à-vis other high and middle-income countries.²⁴³

Market and commercial incentives

Russia offers a generous 150% R&D tax deduction on qualifying expenses. This is available generally as well as for targeted industries.²⁴⁴ In addition, entities operating in Special Economic Zones (such as the Skolkovo Innovation Centre) may qualify for additional tax credits and benefits including VAT exemption, profit tax exemption, a reduced rate of social security contributions and property tax exemptions.

Looking at the biopharmaceutical market and incentive structures Russia has introduced several policies that provide preferential treatment to local companies at the expense of foreign companies. Broadly speaking, the Pharma 2020 Strategy has as one of the key goals to increase local companies' share of the total biopharmaceutical market value to 50% by 2020 (in 2012, the share was about 20%). Several measures, including the 2010 Law on Circulation of Medicines, introduce a range of conditions intended to drive local manufacturing of pharmaceuticals. These conditions effectively represent indirect requirements for foreign companies to invest in local production in order to gain access to the market. For example, local products are given an up to 15% higher price. In terms of pricing, for products on the Essential Drugs List locally manufactured drugs are annually adjusted for inflation, whereas prices are frozen on imported products.

Legal certainty (including the rule of law)

The Russian legal environment can be challenging and several barriers exist. Problem areas include corruption in the government and judicial system, civil conflict and protection of property rights and privacy. In the 2014 *Global Rule of Law Index* Russia was ranked 80th out of 99 countries.²⁴⁵

Singapore

Human capital

The National University of Singapore and the Nanyang Technological University are generally highly regarded, ranking 25th and 61st respectively in the 2014-2015 *Times Higher Education* world university rankings. In addition, the National University is also internationally praised for its life science program, ranking 34th globally.²⁴⁶

In terms of the number of researchers in full-time employment, Singapore in 2011 had over 32,000 researchers, scientists and engineers (excluding full-time postgraduate research students).²⁴⁷ Out of this number, 26% of those employed had obtained doctoral degrees and 24% had obtained Master's degrees.²⁴⁸ Looking at the proportion of researchers in relation to the total work force Singapore has one of the highest rates in the world. In 2011 Singapore had 10.4 total researchers in full-time equivalent per thousand of total employment.²⁴⁹ This is considerably higher than the OECD average of 7.7.

Infrastructure for R&D

Singapore is a big investor in research and development. Measured as a percentage of GDP 2012 R&D spending was 2.04%.²⁵⁰ Internationally, this is just below the 2012 OECD average of 2.40%, and still behind the biggest R&D spenders such as Korea and Israel.²⁵¹ R&D spending in Singapore is made up slightly more of the private sector than government. The latest data from 2012 shows industry expenditure on R&D at 53.4% of the national total.²⁵²

Singapore's innovation infrastructure and services are extremely well developed. The Government's One North infrastructure initiatives, which comprise of R&D facilities; campuses for new higher education institutions; living amenities for researchers and offices for VCs and IP specialists; are highly regarded.²⁵³ The initiative consists of two major research hubs or clusters: Biopolis is the biomedical hub and Fusionopolis is aimed at ICT, engineering and the physical sciences.

Looking at high-quality patents filed under triadic patenting, Singapore's share of the global total is

0.19% at 2012 figures which is considerably higher on an absolute and per capita basis than many OECD economies as well as the BRICS.²⁵⁴ With regards to biotechnology patenting activity in 2012 the number of patents filed by Singaporean residents under the PCT was 112.²⁵⁵

Biomedical research makes up a substantial part of the overall R&D expenditure in Singapore. In 2011 Biomedical Sciences R&D accounted for SGD1,509 million of which SGD573.8 million came from the private sector and SGD 935.2 million from the public sector.²⁵⁶ Singapore's high level of biomedical R&D capability is also illustrated by the number of researchers and scientists employed in the biomedical sector. In 2011 biomedical researchers and scientists (private and public sectors including in A*STAR) made up 22% of the overall number of researchers and scientists.²⁵⁷ Biopharmaceutical R&D has been supported by public-private partnerships promoted by A*STAR in order to accelerate drug discovery and development. Some concrete results and examples include Bayer Healthcare's partnership with five research institutions in Singapore to set up a new Translational Oncology Network.²⁵⁸ There is also the example of Menicon which developed the world's thinnest one-day disposable contact lens in Singapore.²⁵⁹

Singapore is an attractive market for venture capital and private equity. According to the IESE 2014 VC and PE Attractiveness Index, Singapore ranked third.²⁶⁰

Intellectual property protection

Singapore has a robust system of IPRs. Standard patent terms are issued for 20 years and Singapore also provides for a five-year patent term restoration.²⁶¹ Singapore also offers a five year term of regulatory data protection. Additionally, Singapore introduced legislation relating to the development of orphan drugs in 1991, which includes marketing exclusivity and subsidies as incentives for OD development.²⁶² Trade secret protection is generally strong and relevant mechanisms are in place. Singapore placed highly in the OECD Trade Secrets Protection Index.²⁶³ Singapore also reformed its protection of plant varieties in 2014.²⁶⁴ The new amendments provide protection for all genera and species. The new law came into effect July 30 2014.

The regulatory environment

Singapore has a strong clinical and regulatory environment administered by the Health Sciences Authority. For biopharmaceuticals the Health Products regulation Group is responsible for the authorisation and safety supervision of pharmaceuticals. Additionally, this group is responsible for clinical trials in Singapore. The agency is highly regarded and is involved in the regulation of western medicinal products as well as Chinese proprietary medicines and cosmetic products.²⁶⁵ However, generally speaking the regulatory authorities in Singapore require new products and technologies to be approved in other jurisdictions prior to approval in Singapore.²⁶⁶

GM foods are regulated by the Genetic Modification Advisory Committee. This committee regulates the import and commercialization of biotech products and services. Singapore's regulations are science-based and the registration process is generally viewed as efficient. Approval for food imports (GM and non-GM) is contingent on the product having been approved as safe in the exporting country.²⁶⁷

Technology transfer

Singapore has a strong tradition of technology transfer with governmental bodies as well as academic institutions being closely involved in transfer activities. For example, the Biomedical Sciences Industry Partnership Office liaises between universities, public research institutes and industry. It promotes partnerships and links commercialization partners with public sector research.²⁶⁸

Singapore's main bioclusters host domestic and international firms, biomedical research institutions and are also integrating governmental R&D bodies. Technology transfer is also being promoted and is made accessible by the close proximity of these bioclusters to the Singapore Science Park and the National University of Singapore.²⁶⁹ In 2011, Singapore set up the Intellectual Property Intermediary to help local enterprises enhance innovation capacity through technology transfer. This initiative is backed by collaboration and support from the Government. From 2011 to 2012, the IPI had engaged 95 companies.²⁷⁰

From the technology transfer office administered by the National University of Singapore, over 700 patent applications, 84 licensing agreements and equity in lieu of royalties reaching USD4.85 million had been managed from the period of its inception in 1990 till the mid-2000s.²⁷¹

Market and commercial incentives

Singapore offers a generous R&D tax credit of up to 400% on qualifying R&D expenditure.²⁷² The majority of this relief is available on R&D performed in Singapore.

With regards to the biopharmaceutical market this is relatively free with government subsidies in place only for pharmaceuticals included on the Standard Drug List.

Legal certainty (including the rule of law)

The legal environment in Singapore is considered stable and certain. Legal redress, enforcement of contracts and administrative justice is generally available and viewed as effective. Singapore is ranked 10th on the 2014 *Rule of Law Index*.²⁷³

South Africa

Human capital

Globally, South African Universities have been gaining in prestige; *Times Higher Education* ranked University of Cape Town as the 126th best university in the listing and two other South African universities ranked in the top 400.²⁷⁴ Further, University of Cape Town ranks third in the *Times Higher Education* rankings of top universities in the BRICS and emerging market economies and overall five South African universities are included in the top 100.²⁷⁵

As a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, South Africa had a 2012 rate of 6% which is far below the OECD average of 32%.²⁷⁶ In terms of students graduating with degrees in science and technology, South Africa had 42,760 graduates in 2010, up from 24,136 in 2000.²⁷⁷

Looking at the number of researchers in full-time equivalent South Africa had over 18,720 in 2010, the latest year for which OECD figures are available.²⁷⁸ However, in relation to the total work force, South Africa was behind the OECD average of 7.5. In 2010 South Africa had 1.4 total researchers in full-time equivalent per thousand of total employment.²⁷⁹

Infrastructure for R&D

South Africa is a moderate investor in research and development; 2011 figures show R&D spending as a percentage of GDP at 0.76%.²⁸⁰ Internationally, this was below the OECD average of 2.37% for that year.²⁸¹ According to the most recently available statistics from 2011, 39% of South African R&D spending is made up of private sector and industry spending.²⁸²

South Africa's clinical research environment remains limited. The number of clinical trials conducted is still on an absolute and per capita basis fairly small. As of 2015 the aggregated number of clinical trials taking place (or having taken place) was 2,010.²⁸³ Looking at more recent trends in clinical research, most of the trials taking place in South Africa are late-stage. In 2013 out of 144 total new trials taking place only 14 were the more complex Phase I trials.²⁸⁴

South African patenting activity is substantially lower than other large economies. Looking at high-quality patents filed under triadic patenting, the South African share of the global total was 0.06% at 2012 figures.²⁸⁵ In the biotechnology field South African inventors filed 14 patents under the PCT route in 2012.²⁸⁶

Intellectual property protection

South Africa faces some significant challenges in the realm of protecting IP, particularly for biopharmaceuticals. A wide-ranging patent reform package is being discussed and consulted on by the South African Government and developed by the Department of Trade and Industry.²⁸⁷ At the time of research, the reform bill is still under discussion. This package contains a number of measures that are not encouraging for rights holders, particularly in the life sciences. For example, it includes a more expansive use of compulsory licensing and the introduction of

pharmaceutical patentability requirements in the style of Section 3(d) of the Indian Patent Act. The reform package also does not address the issue of patent term restoration or introduction of a regulatory data protection framework.

The regulatory environment

For biopharmaceuticals, the Medicines Control Council is responsible for the authorisation and safety supervision of pharmaceuticals. The Council has gained a reputation internationally for taking an exceptionally long time to approve medications with a current application backlog in excess of 2,900.²⁸⁸ The South African government is considering new legislation that would replace the MCC with a new regulator the South African Health Products Regulatory Agency.²⁸⁹

South Africa is a major producer of ag-bio crops with a clear regulatory framework in place. In 2013 it was the ninth largest producer of biotech crops in the world with 2.7million hectares under cultivation.²⁹⁰ Crops under cultivation include corn, soybean and cotton.²⁹¹ The 1997 GMO Act and the 2011 Consumer Protection Bill regulate the production and consumption of GE food. The GMO Act allows regulatory authorities to address GE products on a case-by-case basis before approving them for human consumption while the Consumer Protection Bill was intended to require labelling of every food product that contained GMOs. However, concerns raised by key stakeholders has delayed the implementation of this labelling requirement.²⁹²

Technology transfer

South Africa introduced a modern technology transfer framework in 2008. The Intellectual Property Rights from Publicly Financed Research and Development Act established the parameters by which publicly funded research can be commercialized and, crucially, where ownership over the generated IP resides.²⁹³ The stated purpose of the Act has been to stimulate research and the commercialization of publicly funded research. Broadly speaking the Act and its accompanying regulations establish the principle that IP generated through publicly funded research will be retained by the recipient.²⁹⁴ Even though the Act was not put into force until 2010, the positive effects of the legislation

on rates of university technology transfer and patenting can be seen in the time leading up to the Act and following it. Data from WIPO covering PCT patenting applications by South African universities show a distinct increase from the period before promulgation of the Act and subsequent period. Between 2005-7 the five top patenting South African universities made 32 PCT applications.²⁹⁵ In the following three-year period when the Act was promulgated, 2008-2010, this more than doubled to 78 PCT applications. By the latest data period available (2011-13) the application rate had grown even further to 98 total PCT applications by the same five universities.²⁹⁶

There are dedicated government bodies to assist in technology transfer and commercialization. The Technology Innovation Agency (created in 2010) has as its mandate to facilitate and increase commercialization of research.²⁹⁷ Similarly the National Intellectual Property Management Office (created through the 2008 Act) is charged with actively assisting in tech transfer at universities and PROs. The Council for Scientific and Industrial Research works to promote technology transfer through developing policies and guidelines and by directly facilitating transfer.²⁹⁸ The Council maintains an online technology transfer portal where it runs the Instant Access Programme providing companies access to a searchable database of technologies available for licensing.²⁹⁹

Market and commercial incentives

South Africa offers generous R&D tax incentives with a super deduction of 150%.³⁰⁰ While this is a general deduction offered to all industries, certain sectors have been listed as targeted. This includes the pharmaceutical industry.³⁰¹

Biopharmaceutical prices in South Africa are currently regulated by the single exit price (SEP) mechanism was adopted in 2004. Under this law manufacturers are required to sell their drug product at the same price to all individuals in the country and caps were placed on annual price increases. In 2014 the Ministry of Health announced it would look into introducing a new pricing system based on international reference pricing.³⁰² At the time of research it was unclear if significant changes to the South African pricing system had been made.

Legal certainty (including the rule of law)

The South African legal environment is considered stable, ranking 40th on the World Justice Project's 2014 *Rule of Law Index* and highest among the BRICS. The Index noted the country has an open government system and fairly successful checks on government power. However, the justice system is slow to process cases and the country faces major security challenges.³⁰³

Switzerland

Human capital

Swiss universities are generally highly regarded, particularly in the biomedical and life sciences. For example, in the *Times Higher Education* rankings the Swiss Federal Institute of Technology Zürich is ranked 13th overall and 15th in the life sciences.³⁰⁴

As a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, Switzerland had a 2011 rate of 35% which is slightly above the OECD average of 32%.³⁰⁵ Looking at the life sciences, Switzerland had 1,913 life sciences graduates in 2012 which is an increase of over 100% since 2000.³⁰⁶

In terms of number of researchers in full-time equivalent Switzerland had over 25,000 in 2008; the latest year for which OECD figures are available.³⁰⁷ Looking at the number of researchers in relation to the total work force, Switzerland was behind the OECD average of 7.7. In 2008 it had 5.5 total researchers in full-time equivalent per thousand of total employment.³⁰⁸

Infrastructure for R&D

Switzerland is a leading investor in research and development. The latest figures from 2008 show R&D spending as a percentage of GDP at 2.87%.³⁰⁹ Internationally, this is higher than the 2012 OECD average of 2.40%, but still behind the biggest R&D spenders such as Korea and Israel.³¹⁰ Swiss R&D spending is largely made up of private sector and industry spending. The latest data from 2008 show industry expenditure on R&D at

68% of the national total.³¹¹ According to the Swiss biotech industry, biotech R&D accounted for 13% of overall industry R&D spending.³¹²

Switzerland has highly advanced medical and biomedical research facilities and its clinical research environment is world leading. The number of clinical trials conducted is on an absolute and per capita basis high. As of 2015 the aggregated number of clinical trials taking place (or having taken place) was 3,959.³¹³ Per capita this translates into Switzerland having a rate of 450 trials per million population.³¹⁴

Swiss patenting activity is substantially higher than other larger countries. Looking at high-quality patents filed under triadic patenting, the Swiss share of the global total is 1.65% at 2012 figures.³¹⁵ With regards to biotechnology patenting activity in 2012 the number of patents filed by Swiss residents under the PCT was 201.³¹⁶

In terms of public funding, The Swiss National Science Foundation provides direct grants to researchers and scientists in basic research. The Commission for Technology and Innovation (the federal body responsible for innovation) provides direct assistance to start-ups and small businesses. The Commission assists with technology transfer and linking universities and Swiss start-ups to promote and commercialise new products and technologies. The Foundation provided CHF819 million in funding for basic research in 2013.³¹⁷ 40% of this was dedicated to biological and medical research.³¹⁸ Out of this close to 60% was for basic biological and medical research.

Switzerland is also an attractive VC market. According to the IESE 2014 VC and PE Attractiveness Index, Switzerland ranked 10th.³¹⁹

Intellectual property protection

Switzerland has a very strong system and history of protecting and promoting IP. Switzerland is a member of the EPO and a signatory party to the European Patent Convention. Standard patent terms are issued for 20 years. Switzerland also provides a Supplementary Protection Certificate (SPC) of five years.³²⁰ RDP is also available at a 10 year term.

The regulatory environment

Switzerland has a strong clinical and regulatory environment. For biopharmaceuticals the DRA Swissmedic is responsible for the authorisation and safety supervision of pharmaceuticals. The agency is highly regarded internationally.³²¹

With regards to the use of biotechnology in agriculture the Swiss public in 2005 voted for a five-year moratorium on the use of GM crops in Switzerland.³²² This was later extended by the Swiss Parliament in 2010 to the end of 2013 and was recently extended again till 2017. The extensions come despite a number of scientific reports being commissioned by the Swiss Government finding that GM crops present no clear danger to human or plant health.

Technology transfer

Switzerland has a strong tradition of technology transfer with governmental bodies as well as academic institutions being closely involved in transfer activities. For example, the Commission for Technology and Innovation has as one of its core goals to promote technology transfer between universities and industry including the Swiss Biotech association. Academic institutions and professionals have their own technology transfer association through swiTT (Swiss Technology Transfer Association).³²³ The association provides support services and has its mission to help facilitate technology transfer between public institutions and private companies.³²⁴

Nevertheless, Switzerland faces some challenges. For example, like other European countries both the number of licenses agreed to and issued as well as licensing income is generally lower than in the US.³²⁵ A 2008 survey of high performing academic institutions in Europe and the US found that the proportion of universities with high-income (EUR1 million+) vs lower income (EUR0-30,000) licensing revenue was inverse between the surveyed institutions: in the US the majority of surveyed institutions were most likely to have high licensing income while the European institutions were most likely to have lower levels of income.³²⁶ Swiss institutions performed better than the European average but still appear to be behind the US.

Market and commercial incentives

Switzerland offers only a moderate amount of R&D tax incentives. Overall its tax scheme is not very favourable in comparison to other OECD countries.³²⁷ There are tax incentives in place for the use of biofuels. Qualifying biofuels are partially or wholly exempt from "mineral oil tax" which can make up a significant portion of the per litre cost of fuel.³²⁸

With regards to the biopharmaceutical market relatively strict pricing policies are in place for drugs and pharmaceuticals available through basic insurance. There are consequently a limited number of market incentives for these products which total over 2,500 medicines. However, for both supplementary insurance and all medicines not listed on the public reimbursement list there is free pricing and a relative free market.

Legal certainty (including the rule of law)

The Swiss legal environment is generally considered stable and certain. Legal redress, enforcement of contracts and administrative justice is generally available and viewed as effective.

Turkey

Human capital

Globally, Turkish universities have been gaining in prestige; the 2014-15 *Times Higher Education* identified four Turkish universities as being among the world's best. Among those four, Middle East Technical University was ranked in the top 100.³²⁹ In addition to its overall ranking, Middle East Technical University is also ranked as a top 100 university for engineering and technology. Turkey had eight universities on the *Time Higher Education* rankings of top universities in BRICS and emerging market economics, with three placing in the top ten.³³⁰

As a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, Turkey had a 2012 rate of 15% which is below the OECD average of 32%.³³¹ In terms of the life sciences, Turkey had 7,329 life

sciences graduates in 2012 which is an increase of over 250% since 2000.³³²

In terms of number of full-time researchers Turkey had over 72,109 in 2012, the latest year for which OECD figures are available.³³³ Looking at the number of researchers in relation to the total work force, Turkey was behind the OECD average of 7.7. In 2011 Turkey had 3.0 total researchers in full-time equivalent per thousand of total employment.³³⁴

Infrastructure for R&D

Turkey has a low level of R&D spending when measured as a percentage of GDP. 2012 figures show R&D spending as a percentage of GDP at 0.92%.³³⁵ Just under half of Turkish R&D spending is made up of private sector and industry spending. The latest data from 2012 show industry expenditure on R&D at 46.8% of the national total.³³⁶

Turkish patenting activity is substantially lower than other large countries. Looking at high-quality patents filed under triadic patenting, the Turkish share of the global total was 0.03% at 2012 figures.³³⁷ In the biotechnology field Turkish inventors filed 2 patents under the PCT route in 2012.³³⁸

Clinical trial activity in Turkey is quite low with a total of 1,619 aggregated clinical trials. The majority of clinical research is in later phases, with only 3 Phase I trials in operation for recent trials (registered in 2013) out of a total of 151.³³⁹

Intellectual property protection

Turkey faces a number of challenges with regards to the protection and enforcement of IPRs, particularly with regards to the life sciences. For example, while Turkey does provide for RDP in law, the actual protection afforded is quite limited. First, the term of protection is tied to an existing patent term. Second, while the exclusivity period provided by the Regulation on Licensing Human Medical Products is six years in practice the period can be as short as one or two years as the term is counted from the date of marketing authorization in any country of the European Union Customs Union.³⁴⁰ Moreover, Turkey does not provide RDP for combination products, which is incompatible with EU standards. Furthermore,

Turkey does not offer any patent term restoration despite the fact that there are generally long delays in the market authorization process.

More broadly the protection of trade secrets is problematic. Legislation does not clearly define trade secrets; reference is therefore made to the unfair competition section of the Turkish Commercial Code (Law No. 6762) for guidance, and the Court of Appeal has made efforts to provide a definition. Nevertheless, the uncertainty as to defining and establishing trade secrets as well as delays caused by the judicial system and difficulty in obtaining preliminary injunctions generally render trade secret enforcement in Turkey ineffective.

The regulatory environment

For biopharmaceuticals, the Turkish Medicines and Medical Devices Agency is responsible for authorisation and safety supervision of pharmaceuticals. The Agency has for a number of years been working to harmonize its regulatory procedures with those of the EMA.³⁴¹ Yet significant challenges remain, not least in the area of product approvals. Despite having committed to having the approval process completed within 210 days of submission, Turkish industry surveys suggest that many companies experience waiting periods in excess of 1,000 days and that the average waiting period is 539 days.³⁴² There are also significant delays caused by the requirement for on-site GMP certification by agents of the Turkish Government.³⁴³

With regards to the use of biotechnology in agricultural, the Biosafety Law passed in 2010 allows for the study and development of biotechnology in relation to agricultural under strict conditions; however, Article 5 of the law strictly forbids the production or importation of genetically modified plants.³⁴⁴ Turkey does import large amounts of GM animal feed for poultry and livestock. The Biosafety Law requires that feed importers receive approval from the Biosafety Board to import any feed that is genetically modified. As of July 2014 the Board had approved the importation of three types of soybeans and 14 types of corn. However, the Biosafety Board also rejected the approval of six types of modified corn.³⁴⁵ These rejections have reportedly created a significant barrier for feed importers because

the supply chain is not set up to differentiate each type of corn and the law identifies a feed batch as “contaminated”, thus unusable, if 0.9% of the feed is from an unapproved substance.³⁴⁶ To date, there are no modified products approved for human consumption because the government has not designated a “contamination” threshold level.³⁴⁷

Technology transfer

Technology transfer is still limited in Turkey. There is no comprehensive legal or regulatory framework in place clarifying ownership and rights with regards to publicly funded research. Traditionally, Turkish academics have operated under the ‘Professor’s privilege’ doctrine which allows for freedom of commercialization by academics provided relevant costs (e.g. use of materials, laboratory space etc.) are reimbursed to the relevant institution.³⁴⁸ Turkish patent law draws a clear distinction between “free inventions” and “service inventions”. In the context of academic research Article 41 of the Turkish Patent Law (Decree Law 551) states clearly that “...inventions made by the teaching staff of universities during their scientific studies at universities or higher schools shall be free inventions.”³⁴⁹ Only a limited number of Turkish universities have technology transfer offices and are actively engaging in licensing and tech transfer activities.³⁵⁰

In recent years Turkey has been working to improve technology transfer with local and regional partners. In conjunction with the European Union, the Turkish Government created the “Technology Transfer Accelerator Turkey”. The primary objectives of the program are to set up a fund to assist in the commercialization of technologies developed at Turkish universities and research centres, and to promote local transfers especially in less developed regions.³⁵¹ Funds for TTA Turkey are managed by the European Investment Fund and will total €30.5 million. The Fund has set a goal of selecting, at minimum, thirty projects to promote in Turkey by the end of 2017.³⁵²

In 2013 TUBITAK announced a program called the 1513 Support Program for Technology Transfer Offices. The program aims to facilitate technology transfer between local universities and industry

by providing qualified institutions with grants of up to 1 million Liras to set up technology transfer offices.³⁵³ During the first year, TUBITAK supported ten universities and ten more were added in 2014. Each university will have the opportunity to receive funding support for the next ten years if yearly performance measures are met.³⁵⁴

Market and commercial incentives

Turkey has in place a number of generous R&D incentive programs and tax benefits. There is a general 100-150% deduction for qualifying expenditure depending on the size of the company; smaller companies qualify for the larger deduction. There is also a 80-90% reduced rate of tax withholding for personnel involved in R&D activity. In addition, government grants are not considered as income. Furthermore, there are increased incentives within Turkish Technology Development Zones, including all profits derived from qualifying R&D expenditure being exempt from income and corporation tax until 2023. Additional tax incentives are in place for staff working within qualifying entities in so-called Development Zones.³⁵⁵

Looking at biopharmaceutical incentives the Turkish Government through its P&R policies bluntly restricts spending on biopharmaceutical products.³⁵⁶ From 2009 to 2010 the government’s biopharmaceutical budget was cut by 10%, which was followed by a requirement that the biopharmaceutical industry reduces prices for 2010-2011 to cover spending overruns.³⁵⁷ Subsequent budgets have also seen significant cuts.³⁵⁸

Legal certainty (including the rule of law)

Legal redress, enforcement of contracts and administrative justice can be challenging in Turkey. In the 2014 *Rule of Law Index* Turkey ranked 59th.³⁵⁹

United Kingdom

Human capital

The UK's universities are held in extremely high regard internationally with three institutions appearing in the top ten (and 45 in total) on the *Times Higher Education* rankings of the world's top 500 universities.³⁶⁰ Additionally, the country's universities are recognized as excelling in offering life science training with 17 institutions ranked in the top 100 life science universities internationally.³⁶¹

As a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, the UK had a 2012 rate of 41% which is above the OECD average of 32%.³⁶² Looking at the life sciences, the UK had 27,478 life sciences graduates in 2012 which is well above the OECD average of 9,028.³⁶³

In terms of number of researchers in full-time equivalent the UK had over 252,652 in 2012, the latest year for which OECD figures are available.³⁶⁴ Looking at the number of researchers in relation to the total work force, the UK was above the OECD average of 7.7. In 2012 there were 8.0 total researchers in full-time equivalent per thousand of total employment.³⁶⁵

Infrastructure for R&D

The UK is compared to other high-income countries a middling investor in research and development; 2012 figures show R&D spending as a percentage of GDP at 1.7%.³⁶⁶ Internationally, this is below than the OECD average of 2.40% and far behind the biggest R&D spenders such as Korea and Israel.³⁶⁷ R&D spending in the UK comes chiefly from the private sector, estimated at 45.6% in 2012.³⁶⁸

The UK is home to some of the most innovative biopharmaceutical manufacturers in the world. Clinical research is thriving and the UK conducts a large number of clinical trials with 9,556 aggregated trials to date.³⁶⁹ Looking at clinical trial intensity and the number of clinical trials to date per million population the UK has one of the highest levels in the world at 150 trials.³⁷⁰ Moreover, a high proportion of current

trials (registered since 2013) are in early phase research. Out of a total number of 694 trials with a registered start date in 2013, 187 were Phase I and 202 were Phase II trials.³⁷¹

UK patenting activity is substantially higher than in other larger countries. Looking at high-quality patents filed under triadic patenting, the British share of the global total was 3.13% at 2012 figures.³⁷² With regards to biotechnology patenting activity in 2011 the number of patents filed by UK residents under the PCT was 404.³⁷³

Biopharmaceutical research represents a large share of the British economy with pharmaceutical exports accounting for almost 10% of all goods exported in 2014.³⁷⁴ Additionally, in 2013 22% of all business R&D expenditures were focused on the pharmaceutical sector, a percentage significantly higher than any other specific sector.³⁷⁵

Venture capital in the United Kingdom is very well established and the country is globally recognized as an attractive VC market. According to the IESE 2014 VC and PE Attractiveness Index, the United Kingdom ranked 4th.³⁷⁶

Intellectual property protection

In general, the UK is seen as having a strong environment for intellectual property protection. The country has a sophisticated IP system that offers patent rights holders multiple levels of protection and avenues for recourse against IP infringements.

Regulatory Data Protection is offered under the EU standard in an 8+2+1 formula whereby companies are provided with eight years of data exclusivity followed by two years of market exclusivity. Patent term restoration is also available.

The regulatory environment

The UK has a strong clinical and regulatory environment. For biopharmaceuticals the MHRA is responsible for the authorisation and safety supervision of pharmaceuticals. The Agency works hand-in-hand with the EMA to ensure the proper dissemination of drugs approved at the EU-wide level.

Unlike many other EU countries the UK is a strong supporter of genetically engineered crops and imports a large amount of genetically engineered food products from the United States.³⁷⁷ Paradoxically, despite strong support of genetically engineered crops the country has no history of planting GE crops and does not have any in development. The country must abide by GE plants approved by the EU overall and none of the plants approved to date can be grown in the UK due to the climate.³⁷⁸ Recognizing the importance that GE crops will play in the near future the UK has developed a long-term agricultural strategy focused on agricultural innovation, livestock science and the commercialization of GE plant products.³⁷⁹

Technology transfer

The UK maintains a sophisticated and active technology transfer environment. Universities such as Oxford, Cambridge and Imperial College are active participants in transferring and commercializing research and technology. In 2013 Oxford University through its commercial enterprise ISIS Innovation Ltd generated GBP11.5 million; an increase of 13% over the previous year.³⁸⁰ Of particular note to the biotechnology field is Imperial College's success. Imperial Innovations was founded in 1986 to encourage technology transfer between Imperial College London and the general business community.³⁸¹ The group has grown considerably since that time and has facilitated the creation of a number of companies. Among the successes are RespiVert, a small-molecule drug discovery company, and Circassia, a biotech company that was listed on the London Stock Exchange in March 2014 after raising GBP200 million.³⁸²

In terms of direct central government support for technology transfer Innovate UK maintains a web portal that allows members of industry, academia, potential funders and entrepreneurs to collaborate on ideas.

Market and commercial incentives

The UK offers R&D tax incentives to both small and large companies. SMEs can qualify for a super-deduction on qualifying R&D activities of 225% and SMEs that post a yearly loss can additionally qualify for up to 32.6% cash back on

R&D related spending.³⁸³ Large companies are able to apply for a super deduction of 130% on R&D activities or receive a 10% tax credit through the Research and Development Expenditure Credit programme.³⁸⁴

Looking at biopharmaceuticals, the UK has a highly regulated pricing environment with the NHS negotiating prices with the pharmaceutical industry through the PPRS. However, as described above, in contrast to other EU Member States the UK's system of price controls is only indirect, with the PPRS only regulating the profits made on branded prescription drugs. While in comparison with the US market there are admittedly fewer market-based incentives for R&D, measured against the strict price controls in place in other European markets the UK has a relatively freer pricing market.

Legal certainty (including the rule of law)

The British legal environment is generally stable and certain. The country is ranked as the 13th most stable legal environment by the 2014 *Rule of Law Index* and receives particularly high marks for government accountability and low levels of corruption.³⁸⁵

United States

Human capital

American universities consistently top world rankings in almost all subject fields and the US remains the top destination globally for international students.³⁸⁶ In the life sciences the US dominates the *Times Higher Education* 2014-15 rankings with American universities make up 13 out of the top 20 universities.³⁸⁷

As a share of the total number of tertiary education students in the world the US has maintained its position as a world leader. In the latest year for which comparable data is available (2011) the US had a total of 70 million people in the age group 25-64 attaining some level of tertiary education.³⁸⁸ Similarly, as a percentage of the total population in the age group 25-64 that has attained some level of tertiary education, the US has one of the highest rates in the world at 42%.³⁸⁹

Looking specifically at science and engineering the US produces the second largest number of natural science and engineering university graduates in the world at almost 250,000 per year.³⁹⁰ While considerably less than China in which the total number of graduates has jumped from just under 240,000 in 1998 to over 1.1million in 2010, it is substantially higher than other countries like Japan, the UK and Korea.³⁹¹ Similarly, in the life sciences the US produced the highest number of graduates in the OECD at 109,023 for 2011.³⁹² Furthermore, the US produces the highest number of doctoral degrees in science and engineering. In 2010 this was close to 33,000 degrees.³⁹³

In terms of number of researchers the US has the second highest total of researchers in full-time equivalent at close to 1.3 million researchers in 2011.³⁹⁴ In relation to the total work force, however, the US is above the OECD average but behind countries such as Finland, Denmark and Israel. In 2011 the US had 8.8 total researchers in full-time equivalent per thousand of total employment.³⁹⁵

Infrastructure for R&D

The US is a leading investor in research and development. 2012 figures show R&D spending as a percentage of GDP at 2.79%.³⁹⁶ Internationally, this is higher than the OECD average of 2.40%, but still behind the biggest R&D spenders such as Korea and Israel.³⁹⁷

US R&D spending is largely made up of private sector and industry spending. The latest data from 2012 show industry expenditure on R&D at 59% of the national total.³⁹⁸

The US is the largest biopharmaceutical market in the world and American R&D activities is responsible for the vast majority of global clinical research. As of March 2015 close to 85,000 out of a global total of circa 189,000 clinical trials had been carried out or were taking place in the US.³⁹⁹ In terms of current trials (trials started after or during 2013) the largest number in the world were taking place in the US at 3,872.⁴⁰⁰

The US is home to the biggest proportion of private sector biopharmaceutical investment. Out of a total of USD50 billion in R&D investment by the member companies of PhRMA, USD37 billion was invested in the US.⁴⁰¹

American patenting activity is a substantial share of global patenting. Looking at high-quality patents filed under triadic patenting, the US share of the global total is the biggest at 29.74% at 2012 figures.⁴⁰² With regards to biotechnology patenting activity the US residents file more biotechnology patents than any other country. In 2012 the number of patents filed under the PCT were 4,174 which was close to half of the OECD total.⁴⁰³

Government funding and support for biomedical and biotech R&D comes through both direct support and tax credits. At the federal level the NIH is one of the main sources of funding for biotech and biomedical research. The NIH funds over 300,000 researchers at 2,500 universities, medical schools and research institutes.⁴⁰⁴ NIH's current 2015 budget is just over USD30.3 billion.⁴⁰⁵ Historically, the NIH has allocated over 50% of its budget to basic fundamental research with translational and advanced research being pursued by biopharmaceutical and biomedical companies. Many commentators have noted that this has, by and large, been a successful combination.⁴⁰⁶

As detailed in the main report *Building the Bioeconomy 2015* the US has a large number of biotech and biomedical clusters. In particular, California and Massachusetts are home to a number of world-leading clusters.

Finally, the US is home to the largest private venture capital market in the world. While the market has decreased substantially since the pre-financial crisis highs of 2007, in 2014 the total size of venture capital investment in the US was USD48 billion, the highest level in a decade.⁴⁰⁷ Surveys and indexes of the top venture capital markets in the world frequently find the US as being the most attractive and dynamic place for venture capital investing. See for example the IESE's 2014 Venture Capital and Private Equity Country Attractiveness Index which ranked the US first in the world.⁴⁰⁸

Intellectual property protection

The US has one of the most sophisticated and elaborate forms of IP protection in the world. It offers standard patenting exclusivity of 20 years with data exclusivity provisions of up to 5 years for new chemical entities and 3 years for

new indications of existing drugs.⁴⁰⁹ Patent term restoration is also offered of up to a period of 5 years.

The US has a separate and distinct term of protection for biologics. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) provides 12 years of data protection to biologics (i.e. 12 years until a biosimilar can be approved), with no filing of biosimilar applications for the first four years and an extra six months (added to both the four years and the 12 years) for submission of studies on paediatric use.

Most recently the 2011 patent reforms and the change from a first-to-invent to a first-to-file system of patenting was greeted by many innovators as a positive enhancement of existing patent protection.⁴¹⁰

The importance of America's strong IP protection in encouraging biotechnology and biomedical innovation is illustrated by surveys of biomedical corporations and their leaders. For instance, when asked about the importance of IP protection, 98% of biomedical company CEOs in California stated that international and domestic IP protection were either somewhat or extremely important issues affecting their industry.⁴¹¹

Still, challenges remain even in the US. In particular in the biotech sector question marks have been raised over the patentability of basic biotech inventions due to the Supreme Court decisions in the 2013 *Molecular Pathology v Myriad Genetics* and 2012 *Prometheus Laboratories, Inc v Mayo Collaborative Services* cases. The former ruling has raised uncertainties over the patentability of DNA molecules that mimic naturally-occurring sequences as well as other patented products and technologies isolated from natural sources.⁴¹² The latter ruling has made the field of personalized medicines and the patentability of biotechnologies and products that make use of the application of natural laws highly uncertain.⁴¹³ In April 2014 the USPTO issued new guidelines on the patentability of biotechnology inventions aimed at providing further clarification and interpretation of these decisions.⁴¹⁴ These guidelines extended the holdings from these decisions by introducing restrictions on patenting of naturally occurring substances (including genomic DNA, proteins

and stem cells), even if isolated and purified, if there is not sufficient distinction shown between a claim and the substance as found in nature. In a break from its typical approach of providing guidance on certain gray areas and leaving it to the courts determine specific limits on wider issues, the new guidelines placed broad restrictions on key areas of biotechnology. The guidelines generated significant uncertainty as to the scope of patentable subject matter for biotechnology inventions and risk widening the gap between current US practice and that in other jurisdictions, such as the EU, Australia and Japan where, for instance, purified genomic DNA and proteins are patentable. In December 2014 revised guidelines were issued. These remained under public consultation at the time of research. Broadly speaking the guidelines did provide some needed revisions and clarifications. However, it is still uncertain as to how this new guidance (and the underlying court rulings) will shape future biotech innovation and patenting.⁴¹⁵ Some analysis suggests that a high number of patent applications have been rejected following the 2012 and 2013 court rulings.⁴¹⁶

The regulatory environment

The American clinical and regulatory environment is highly regarded and internationally well recognised. With regards to the regulation of products and technologies developed using modern biotechnology, the Coordinated Framework for Regulation of Biotechnology is generally viewed as being successful. Since its announcement in 1986 the policy and subsequent sector-specific regulations are seen as having been instrumental in promoting the development of the American biotechnology industry and bringing a wide array of biotechnology products and technologies to consumers.

With regards to biopharmaceuticals the FDA sets and enforces rigorous standards. The FDA plays a leading role in efforts to harmonise regulatory standards through the International Conference on Harmonisation. Moreover, the regulatory standards of the FDA are frequently emulated and recognised as a gold standard amongst clinicians, health economists and the academic community.⁴¹⁷ Nevertheless, the FDA is not immune to criticism. Biomedical companies frequently point to deficiencies in the approval

system and specifically time spent on approvals. Recent data suggests that FDA approval times have increased substantially.⁴¹⁸

With regards to the regulation of biotechnology crops, the USDA has in recent years taken steps to cut the approval time by half for petitions for nonregulated status for genetically engineered organisms including biocrops.⁴¹⁹ Approval times have increased from six months to 3-5 years since the mid-1990s. Key changes include streamlining internal USDA review processes, setting timeframes for the completion of specific review steps, and expedited internal review and decision-making procedures.⁴²⁰ Reports suggest that there has not been a notable improvement in approval times.⁴²¹

Technology transfer

One of the key drivers of American biotech innovation and commercialisation has been the success of technology transfer in the US. The Patent and Trademark

Law Amendments Act of 1984 and 1986 (commonly referred to as the Bayh-Dole Act) and the Stevenson-Wydler Technology Innovation Act, which was later amended by the Federal Technology Transfer Act of 1986 and the Technology Transfer Commercialization Act in 2003 have all been instrumental in incentivizing technology transfer. These laws gave institutions that received federal support (such as American universities, small businesses and non-profits) control and the rights to any resulting intellectual property of their inventions or research.

Studies have found a significant correlation between increased patenting activities at US universities following the Act. For example, a 2004 study found that university share of total patenting in the US increased from 0.69% of total patents at the time of legislation to just under 5% in 1996. Moreover, in a range of 117 industries (including drugs) the increase was from a decrease of 87% in 1969 to an increase of 1,648% in 1996.⁴²² Using fifteen years of data from the annual Association of University Technology Managers (AUTM) survey a 2012 study estimating the economic contribution of licensing activity by academic institutions found that in the US the contribution of academic licensing to gross

industry output ranged from USD199-836 billion (2005 USD).⁴²³ Contributions to GDP were equally significant estimated at between USD86-388 billion (2005 USD).⁴²⁴ The latest results from the AUTM annual survey (2013) show that executed licenses and options grew by 8.2%, the number of new commercial products increased by 20%, and there was an 11% increase in the number of patents issued.⁴²⁵

The life sciences play a critical role for universities and account for the vast majority of licensing income at American universities. Figures calculated by Nature magazine for a sample of the major research institutions in the US showed how, out of the USD1 billion of licensing income received in 2013, over USD900million came from the life sciences.⁴²⁶

Market and commercial incentives

The US provides a number of R&D tax credits, both at the federal and state level. The federal Research and Experimentation Tax Credit allows companies to claim a tax credit of between 14-20% of qualifying amounts.⁴²⁷ This credit is not permanent and currently expired at the end of 2014. The Obama administration has proposed to both simplify and make permanent this rather convoluted and complicated credit.

In addition, 38 US states offer R&D tax credits at varying rates; Iowa, for instance, offers a credit of up to 6.5% of qualifying expenditure, which may be doubled for bioscience firms.⁴²⁸ Many states also offer additional incentives and tax credits such as seed capital tax credits, state venture capital investments and state sales tax exemptions for R&D equipment.⁴²⁹

By international standards, the US has a relatively free market in the purchase and sale of biopharmaceutical products. There are no national price regulations or national reimbursement agencies. Instead, private health insurers and public payers (such as Medicare, the VHA and Medicaid) negotiate prices with manufacturers and only indirectly set reimbursement limits and influence prescribing and patient usage through the use of formularies. Drug formularies (which often include therapeutic interchange or so-called switching mechanisms) and differential cost-sharing (such as tiered

co-payments) are two of the more commonly used techniques to influence prescribing practices. Arguably, one of the strongest drivers of biopharmaceutical innovation in the US has been the existence of this relatively free market in the pricing of pharmaceuticals. For example, a 2004 study of 11 OECD countries by the US Chamber of Commerce and the International Trade Administration found that under market conditions similar to those in the US, global R&D by biopharmaceutical corporations would increase by 11-16% and would result in the development of 3-4 new molecular entities annually.⁴³⁰

Legal certainty (including the rule of law)

The US legal environment is generally considered stable and certain. Legal redress, enforcement of contracts and administrative justice is generally available and viewed as effective. However, the US faces challenges as is reflected in its ranking on a number of international indices measuring the rule of law. In the 2014 *Rule of Law Index* the US ranked 19th.⁴³¹



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