

HOW MARKET-BASED POLICIES COULD SPUR BIOTECHNOLOGY GROWTH IN RUSSIA

by

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The development and maintenance of vibrant high-technology industries has been a major driver of economic growth and financial stability for the United States as a nation, and many of its individual states as well. The establishment of one critically important high-tech industry, biotechnology, had its genesis nearly three decades ago in the U.S, thanks to two major factors – cooperative work among private businesses, universities, and government, and the protection of intellectual property. Such an approach to establishing a strong high-tech industry is now emerging in the Kirov region of Russia, a development which, if managed correctly, could offer substantial creation of jobs, know-how and other economic benefits.

Since the early 1980s, the U.S. government has focused on promoting public and private investments in science and high technologies, including space, energy, biotechnology, information technology, and electronics. During this time, the U.S. government, the academic community, and the private sector have also been working cooperatively. The priority of the government has been to encourage the transfer from the government of publicly-funded research and development (R&D) into private hands within universities and companies that can most capably commercialize such know-how into market-relevant *end-user products and processes* that benefit society as a whole.

To this end, the U.S. Congress, in recognition of the economic, legal and social (i.e., the U.S.

¹This LEGAL BACKGROUNDER arose from the author's presentation made in Kirov, Russia on June 28, 2007. See Lawrence A. Kogan, "Basic Directions of Modern Biotechnology: Biotechnology – A Scientific Practical Priority of the Kirov Region Development", at <http://www.itssd.org/Programs/BasicDirectionsofModernBiotechnology-KOGANPresentationKirovConferenceJune26-28,2007.ppt>, presented at the International Conference of the Government of the Kirov Region, Vyatka State University, Yu. A. Ovchinnikov Russian Society of Biotechnologists (June 26-28, 2007). The conference was convened by Vyatka State University and the International Science and Technology Center (ISTC), Moscow Russia.

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constitutional) significance of temporary but exclusive private (tangible as well as intangible) property ownership,² enacted laws that both stimulated the creation of small businesses (1980) and small innovative companies (1982) and helped them to compete for government contracts, thus promoting the development of high technologies, including biotechnology.

First, The Small Business Act of 1958, which has since been amended many times, initiated a program to assist domestic small businesses in competing for Federal procurements. The SBA required that small business concerns be afforded the maximum practicable opportunity to participate in Federal contracts and subcontracts. The Act's declared policy purpose was to promote a high level of entrepreneurship, free markets and open competition which were deemed essential to preserving U.S. national security.³

Second, the Regulatory Flexibility Act of 1980 went a long way towards reducing the unnecessary burdens of regulation on small businesses. Through the Act, Congress endeavored "to establish as a [general] principle of regulatory issuance" that federal agencies, "consistent with the objectives of the rule and of applicable statute [in question]...fit regulatory and informational requirements to the scale of the businesses... subject to regulation. To achieve this principle, agencies were required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals [were] given serious consideration."⁴ This act was subsequently amended in 1996⁵ and again in 2007.⁶

Third, the Small Business Innovation Development Act of 1982 (SBIDA),⁷ encouraged, harnessed and facilitated governmental funding of small company research and development.⁸ The Small Business Innovation Research (SBIR) Program⁹ was established through SBIDA to: "stimulate small business

²See Lawrence A. Kogan, "Brazil's IP Opportunism Threatens U.S. Private Property Rights", 38 U. MIAMI INTER-AM. L. REV. 1, 23-24 (2006) at 16-19, at [http://www.itssd.org/Publications/IAL105-II\(frompublisher\)%5B2%5D.pdf](http://www.itssd.org/Publications/IAL105-II(frompublisher)%5B2%5D.pdf). See also O. Lee Reed, "Exclusive Private Property is Indispensable to Brazil's Economic Development", International Journal of Economic Development Volume Eight, Numbers 1-2 (Sept. 2006) at 5-10, at 7 (2006), at <http://www.itssd.org/White%20Papers/ijed-8-1-2-reed.pdf>, Introduction to, Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, International Journal of Economic Development Volume Eight, Numbers 1-2 (Sept. 2006) at <http://www.itssd.org/White%20Papers/ijed-8-1-2-kogan.pdf>; http://www.spaef.com/IJED_PUB/v8n1-2.html.

³"The essence of the American economic system of private enterprise is free competition. Only through full and free competition can free markets, free entry into business, and opportunities for the expression and growth of personal initiative and individual judgment be assured. The preservation and expansion of such competition is basic not only to the economic well being but to the security of this Nation. Such security and well being cannot be realized unless the actual and potential capacity of small business is encouraged and developed. It is the declared policy of the Congress that the Government should aid, counsel, assist, and protect, insofar as is possible, the interests of small business concerns in order to preserve free competitive enterprise, to insure that a fair proportion of the total purchases and contracts or subcontracts for property and services for the Government (including but not limited to contracts or subcontracts for maintenance, repair, and construction) be placed with small business enterprises, to insure that a fair proportion of the total sales of Government property be made to such enterprises, and to maintain and strengthen the overall economy of the Nation." See "Small Business Act," (Public Law 85 536, as amended), at <http://www.hubzonecouncil.org/application/sbaact.doc>.

⁴See 5 U.S.C. § 601-612; See "Congressional Findings and Declaration of Purpose - The Regulatory Flexibility Act", United States Small Business Administration, Office of Advocacy at <http://www.sba.gov/ADVO/laws/regflex.html>.

⁵See "Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121)," *Id.*

⁶See "Title II—Small Business Regulatory Fairness", P.L. 110-28, (May 25, 2007), at United States Small Business Administration, Office of Advocacy at <http://www.sba.gov/advo/laws/sbrefa.html>.

⁷See 15 U.S.C. § 638, as amended.

⁸"[The SBIR program] encourages small business to explore their technological potential and provides the incentive to profit from its commercialization. By including qualified small businesses in the nation's R&D arena, high-tech innovation is stimulated and the United States gains entrepreneurial spirit as it meets its specific research and development needs." See "Description of the Small Business Innovation Research Program (SBIR)", SBA Office of Technology at <http://www.sba.gov/SBIR/indexsbir-str.html>.

⁹SBIDA requires the SBA to "issue Policy Directives for the general conduct of the SBIR programs within the Federal Government." (15 U.S.C. § 638(j)(1)). During December 2000, Congress enacted the Small Business Innovation Research Program Reauthorization Act of 2000 (Reauthorization Act) (P.L.106-554), amended section 9 of the Act (15 U.S.C. § 638), and extended the SBIR Program through September 30, 2008. See also SBA Policy Directive No. 65-01 (47 FR 52966, Nov. 24, 1982). The last SBIR Policy Directive amendments were published on September 24, 2002 (SBIR PD 2002, 67 FR 60072-60098). See "SBIR Contracting & Payment Desk Reference – Annex A – Small Business Innovation Research Program Policy Directive (Sept. 24, 2002) at http://www.dodsbir.net/deskreference/annex_a.asp; "SBIR PD 2002 PD Section-by-Section Analysis - Section 3 Definitions" at

innovation, use small businesses to meet federal R&D needs, foster and encourage participation in technological innovation by minority and disadvantaged persons, and to increase private sector commercialization of innovations derived from federal R&D.” SBIDA and SBIR, as amended, have [] served as the primary vehicle through which the federal government funds research and development (R&D) projects at small technology companies.”¹⁰ Since its enactment the SBIR program “has helped thousands of small businesses to compete for federal research and development awards. Their contributions have enhanced the nation's defense, protected our environment, advanced health care, and improved our ability to manage information and manipulate data.”¹¹

Beyond these laws, two additional major pieces of American legislation played a pivotal role in facilitating scientific and technological development in the U.S. First, with the passage of the Stevenson-Wydler Technology Innovation Act (1980)¹² Congress declared that “Technology and industrial innovation are central to the economic, environmental, and social well-being of citizens of the United States.” This law called upon the executive branch to: promote technology development through establishment of cooperative research centers; stimulate better use of federally-funded technologies by state and local governments and the private sector; encourage technological development through greater recognition of inventors (both individuals *and* companies); encourage the exchange of scientific and technical personnel among academia, industry and federal laboratories; and secure the protection of intellectual property rights in laboratory innovations with commercial promise and the management of such innovations to benefit the competitiveness of U.S. industry.

Second, with the passage of the Bayh-Dole Act (1980)¹³ Congress sought to stimulate the economy by providing federal executive agencies with the means of shifting legal title to federally funded ideas and patents from the government to those private hands (approved universities, small businesses and non-profit organizations) most capable of securing the monies and expertise needed to commercialize them. Congress recognized that the public would benefit from a uniform patent policy that permitted universities and non-profits to elect ownership of legal title to federally-funded inventions and to work with companies to bring them to market.

The Bayh-Dole Act encouraged universities and non-profits to become directly involved in the commercialization process by allowing them to *exclusively license* such R&D to private companies. This promoted technology transfer by creating economic incentives for university researchers to consider the practical applications of their discoveries and for universities to search out potential companies to develop them. The licensing of inventions also stimulated the economy to the extent those businesses then manufactured and distributed the resulting products in America. Of course, in order to obtain title to such federally-funded R&D, the Bayh-Dole Act required research organizations to commit to a number of important procedural and substantive conditions.¹⁴

The key feature underlying both the Stevenson-Wydler Technology Innovation Act and the Bayh-Dole Act is the government’s recognition of *the fundamental right to exclusive private property, including intellectual property*. Without the prospect for private property ownership, there would have been little incentive for small businesses and innovative companies and, now, a growing number of inventors, to participate in the R&D commercialization process.

The use of intellectual property under U.S. government subsidization is continually being reviewed. Yet, the government’s goal has always remained the development of a method by which innovation is turned into

<http://www.zyn.com/sbir/sbres/sba-pd/pd02-SSA-3.htm>.

¹⁰See Charles W. Niessner, “Small Business Innovation Research Program”, Public Roads, (Mar.-Apr., 1998) at http://findarticles.com/p/articles/mi_m3724/is_n5_v61/ai_20853502.

¹¹See “Description of the Small Business Innovation Research Program (SBIR)”, *supra*.

¹²P.L. 96-480, enacted Oct. 21, 1980.

¹³P.L. 96-517, Patent and Trademark Act Amendments of 1980, enacted Dec. 12, 1980.

¹⁴See Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil’s Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, *supra* at 200-209..

commercialization with the participation of small businesses. The federal government has an interest in securing the constant transference of innovation from energy, space, and defense to that of the private sector, and moreover, this process is periodically being updated. To this end, the American experience in innovation and intellectual property may be advantageous to use in Russia.

According to the chairman of the Commonwealth of the Kirov Region, Kirov has the necessary potential for the innovation of technology, intensive economic development, the balancing of the region's budget and the protection of intellectual property within the high tech arena.

The main body of intellectual property law in Russia consists of the Russian Citizens' Code of 1964, as well as the Patent Law of Russia (1992) and the Law for the Rights of Innovators. Russia has recognized that these laws are outdated and no longer serve the interests of the Russian people or its economy. Thus, the Russian government has canceled 54 older laws, and has committed itself to the preparation of a new intellectual property legal regime which would include four laws and sixteen governmental decrees.

Furthermore, the Vatsky Regional University has begun development of the Center for the Collective Use of Biotechnology and Microbiology. It currently has on staff 32 PhD's, four of whom are Laureates of the Soviet Medal for Science. The university's long-term plan is to diversify the specialization of the techno-park in every primary direction for the education of engineers. The anticipated goals are to: increase the rate of scientific development; create facilities that would enable scientific and biotechnological research; create, support, and expand the collection of micro-organisms for educational and scientific process; form a scientific and manufacturing infrastructure with a focus on the market; create modern biotechnology which would fight infectious diseases; and create diagnostic tools for chemical and biotechnological synthesis of GMO (genetically modified organisms); create recombinant vaccines for the protection of plants and animals. In a national competition, the Vatsky Regional University was a finalist. It developed and showcased a program for the Center for Biotechnology and Microbiology.

The domestic market for biotechnology in Russia is just forming. To date, its key segments include biotechnological pharmaceuticals, fermentation, microorganisms, yeasts, biotechnology in the sphere of resources, agricultural biotechnology, and biotechnology in climate protection. The potential of the biotechnological market in the future is substantial, but it is yet unclear which sector will expand the most. According to an analysis by Abercade Consulting in 2005, about 2/3 of Russia's biotech market was pharmaceutical.

The current demand for such products comes mostly from the government rather than from the market. Despite government decisions, the demand for pharmaceutical production in the near future will continue to grow. The primary factors for growth are the continuation of government subsidies, the expected increase in income of the population, and the aging and expansion of the population. The prognosis is that by 2010 the market for pharmaceutical products will be \$17.2 billion, as compared to 2006, when the market was \$10.4 billion.

Given these circumstances, the biotechnology market in Kirov has a chance of developing and influencing the Kirov Region. A vibrant biotechnology sector is vital to spurring innovation, higher education and economic growth. It is important to realize that biotechnology innovation has the potential to impact agriculture, the production of food, and the forestry industry.

The Kirov Region has the potential to develop effective innovation systems supported by the investment and protection of privately owned intellectual property in the sphere of modern high tech technology. It is encouraging to see policy makers and other leaders following a path similar to that the United States took, beginning in the late 1970s, to inspire cooperation among the public and private sectors, and to strengthen protection of intellectual property rights. As a result, there will be an increase in employment and income, an increase in the spending of the region and the creation of new markets, as well as, an increase in the viability and prestige of the region.