

**PUBLISH AND NOT PERISH: JAPAN'S UNIVERSITIES  
DESIGNATED TO ENJOY PATENT NOVELTY GRACE  
PERIOD AMIDST PROMETHEAN CHANGES IN  
BIOTECHNOLOGY & UNIVERSITY PATENTING**

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## I. INTRODUCTION

Since the 1980s, biotechnology was heralded as one of America's promising new high tech, science-stamped tickets to greater prosperity<sup>1</sup> in the rapidly advancing knowledge-based world economy.<sup>2</sup> America's love affair with biotechnology was formally consummated, as it usually does, with an adulatory *Time* magazine front cover story<sup>3</sup> and it was crowned as another “fast, light, networked, knowledge-intensive field of endeavor” at which Americans excelled.<sup>4</sup> In 2007, biotechnology is still viewed as

<sup>1</sup> See Robert Reinhold, *There's Gold in Them Thar Recombinant Genetic Bits*, N.Y. TIMES, June 22, 1980, at E8; Lee Dembart, *Potential of Profit from Genetics Is Lure to Colleges*, L.A. TIMES, Nov. 19, 1980, at 1; Kathryn Christensen, *Labs and Ledgers, Gene Splicers Develop a Product: New Breed of Scientist-Tycoons*, WALL ST. J., Nov. 24, 1980, at 1.

<sup>2</sup> LESTER THUROW, BUILDING WEALTH: THE NEW RULES FOR INDIVIDUALS, COMPANIES AND NATIONS IN A KNOWLEDGE-BASED ECONOMY xv (1999) (declaring that “knowledge is the new basis for wealth”); see also G. Pascal Zachary and Robert Frank, *The Global Battle --- High-Tech Hopes: Countries Are Pinning Their Economic Dreams These Days on a New Truism: Innovation Can -- and Does -- Happen Anywhere*, WALL ST. J., Sep. 25, 2000, at R4.

<sup>3</sup> See Frederic Golden, *Shaping Life In The Lab & Profiting From Gene Splicing*, TIME, Mar. 9, 1981, at 50 (describing Herbert Boyer, a co-patentee of the Cohen-Boyer recombinant DNA technique and one of Genentech's founders, as a new breed of millionaire-scientists, who commercialized their discoveries and helped establish a new industrial sector).

<sup>4</sup> THOMAS FRIEDMAN, THE LEXUS & THE OLIVE TREE 376 (1999).

“hotter than ever”<sup>5</sup> as it is responsible for a new wave of DNA-based therapeutic drugs.<sup>6</sup> It is in the area of innovative therapeutic products<sup>7</sup> that fueled the ascension of biotechnology's star at the expense of the traditional pharmaceutical industry in terms of commercializable research and development.<sup>8</sup>

Biotechnology has transformed into a global business,<sup>9</sup> fundamentally driven by patents.<sup>10</sup> Just as the language of

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<sup>5</sup> Bernadette Tansey, *Biotech Gathering Celebrates 25 Years; 'H & Q,' Begun with About 14 Presenters, Now Has About 310*, S.F. CHRON. Jan. 7, 2007, at F1.

<sup>6</sup> Genetically engineered forms of therapeutic substances like insulin, human growth hormone and therapies like Enbrel, for rheumatoid arthritis and Gleevec, a startlingly effective treatment for chronic myelogenous leukemia. See Nicholas Wade, *A Revolution at 50; DNA Changed the World. Now What*, N.Y. TIMES, Feb. 25, 2003, at F1. Both of these biotech-based therapies are already available in Japan with Takeda jointly marketing. *Takeda Assigns MRs to Specialize in Single Drug*, NIHON KEIZAI SHIMBUN, June 25, 2005. Gleevec is marketed in Japan by Novartis Pharma KK. *Institute To Study Gene Test On Cancer Drug's Side Effects*, NIKKEI BUS. DAILY, Jan. 31, 2006.

<sup>7</sup> ERNST & YOUNG, BEYOND BORDERS GLOBAL BIOTECHNOLOGY REPORT 2005 25 (2005) (reporting that “there are approximately 230 biotech derived therapeutics on the market, 55 under review, and 365 in Phase III clinical trials.”), available at [http://www.ey.com/Global/download.nsf/International/Industry\\_Biotechnology\\_Beyond\\_Borders\\_Report\\_2005/\\$file/BeyondBordersFullReport2005.pdf](http://www.ey.com/Global/download.nsf/International/Industry_Biotechnology_Beyond_Borders_Report_2005/$file/BeyondBordersFullReport2005.pdf).

<sup>8</sup> Ronald Lindsay, *Innovation and the Biopharmaceutical Industry - Crisis or Crossroads?* in INNOVATE OR PERISH: MANAGING THE ENDURING TECHNOLOGY COMPANY IN THE GLOBAL MARKET 247 (Edward Khan, ed. 2006). Big pharmaceutical companies' research efforts to replenish their pipelines are underachieving. See Peter Landers & Joann S. Lublin, *Merck's Big Bet on Research By Its Scientists Comes Up Short* WALL ST. J., Nov. 28, 2003, at A1; see also Denise Gellene, *Lure Of Products Lead Drug Firms to Biotechs*, L.A. TIMES, June 23, 2005, at C1 (reporting that “faced with patent expirations on highly profitable drugs, big pharmaceutical firms are turning to small biotechs to restock their medicine chests”).

<sup>9</sup> Karen Lowry Miller et al., *The Biotech Boom*, NEWSWEEK, Oct. 30, 2000, at 47 (noting that the biotechnology field long dominated by the United States, is now getting awfully crowded with global players).

<sup>10</sup> John J. Doll, *The Patenting of DNA: Concerns That Practice May Impede Innovation and Cooperation*, 280 SCIENCE 689, 690 (1998) (noting that “it is only with the patenting of DNA technology that some companies, particularly small ones, can raise sufficient venture capital to bring beneficial products to the marketplace or fund further research.”).

biotechnology research and discovery is universal all over the world,<sup>11</sup> significant scientific innovations have fueled biotechnology companies on a global basis<sup>12</sup> in the world's major developed and even developing economies like China<sup>13</sup>, India<sup>14</sup>, Singapore, and other Asian countries.<sup>15</sup>

## II. JAPANESE BIOTECHNOLOGY - PROMISING BEGINNINGS

Since the 1970s, there had already been pressure from Japan's powerful trade lobby, *Keidanren* - Japan's Federation of Economic Organizations, to explore the commercial possibilities inherent in the life sciences,<sup>16</sup> but biotechnology only took off in a big way when it received the imprimatur of the Japanese government as a strategic area for Japanese industry.<sup>17</sup>

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<sup>11</sup> “Wherever you go in the world, whatever plant, animal, bug or blob you look at, if it is alive, it will use the same dictionary and know the same code . . . . We all use exactly the same language.” MATT RIDLEY, *GENOME: THE AUTOBIOGRAPHY OF A SPECIES IN TWENTY-THREE CHAPTERS* 21-22 (1999).

<sup>12</sup> A realistic snapshot of the global reach of the current biotechnology industry is manifested from the record-setting “19,479 attendees from 62 countries” that descended upon Chicago to attend BIO 2006, the annual meeting hosted by Biotechnology Industry Organization, the American biotechnology trade organization. See Biotechnology Industry Organization, *BIO 2006 in Chicago Surpasses Records* (Apr. 14, 2006), [http://www.bio.org/events/2006/media/pr2.asp?id=2006\\_0414\\_01](http://www.bio.org/events/2006/media/pr2.asp?id=2006_0414_01) (last visited Jan. 26, 2007). Nearly “one-third of the attendees were international participants.” *Id.*

<sup>13</sup> Evidently dissatisfied with being typecast as the world's consumer goods manufacturer of choice, China is also making the great leap forward into a higher value, knowledge intensive biotechnology player. See Jehangir S. Pocha, *Beijing Eyes Biotech Business - Scientists Are Returning to China After Working in the United States*, S.F. CHRON., Sep. 16, 2006, at C1; Bruce Einhorn et al., *A New Lab Partner For the U.S.?*, BUS. WK., Aug. 22, 2005, at 116.

<sup>14</sup> India has also tossed its hat into the biotechnology business ring. See K. S. Jayaraman, *Biotech Boom*, 436 NATURE 480, 480 (2005).

<sup>15</sup> Hannah Beech, *Asia's Great Science Experiment*, TIME ASIA, Oct. 30, 2006, at 46 (reporting biotechnology hubs being established in Singapore, China and India); see also Cris Prystay, *Malaysia's Ambitions in Biotech Get Native Entrepreneur's Backing*, WALL ST. J., Feb. 5, 2003, at B7C; Takeshi Kamiya, *For South Korea, the Future Is All About Biotechnology*, ASAHI SHIMBUN, Nov. 1, 2006.

<sup>16</sup> IAN INKSTER, *THE JAPANESE INDUSTRIAL ECONOMY* 71 (2001).

<sup>17</sup> In 1981, Japan's Ministry of International Trade & Industry (MITI), currently known as the Ministry of Economy, Trade & Industry (METI), announced that “biotechnology along with microelectronics and new materials was a key technology for future industries.” OFFICE OF TECHNOLOGICAL ASSESSMENT,

By 1990, some nine years after the first successful American biotechnology IPO,<sup>18</sup> there were already “more than 800 Japanese companies involved in biotechnology commercialization,” but this “count includes Japanese companies that are involved in biotechnology in some way; a large number of these companies have their primary business in some other area.”<sup>19</sup> As a result of this interest in biotechnology by Japanese industry, Japan became a popular business destination for many American startup biotech companies<sup>20</sup> and many business deals were struck with Japanese partners<sup>21</sup> eager to learn and commercialize this exciting new technology which was pioneered by American science.

In light of such industrial interest from Japan, American apprehension of Japanese competition in biotechnology began to coalesce to the consensus “fear that biotechnology may go the way of semiconductors, with Japanese and other foreign based firms reaping most of the economic benefits generated by a high technology industry in which the breakthroughs and pioneering

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U.S. CONGRESS, BIOTECHNOLOGY IN A GLOBAL ECONOMY, OTA-BA-494, 19 (1991), available at [http://govinfo.library.unt.edu/ota/Ota\\_2/DATA/1991/9110.pdf](http://govinfo.library.unt.edu/ota/Ota_2/DATA/1991/9110.pdf).

<sup>18</sup> Genentech's place in biotechnology history is secure as it was the first biotech IPO in the world. See TOM ABATE, THE BIOTECH INVESTOR: HOW TO PROFIT FROM THE COMING BOOM IN BIOTECHNOLOGY 11 (2004) (noting Genentech's launch of its IPO a few months after the seminal Chakrabarty U.S. Supreme Court decision was not serendipitous since “Wall Street had been waiting for proof that biotech companies would be able to patent their inventions and protect their medical discoveries.”).

<sup>19</sup> See NATIONAL RESEARCH COUNCIL, U.S.-JAPAN TECHNOLOGY LINKAGES IN BIOTECHNOLOGY: CHALLENGES FOR THE 1990S 6-7 (1992).

<sup>20</sup> Amgen's legendary Founder-CEO, George Rathmann recounted Amgen's early startup days when he had “two person teams heading to Japan and Europe monthly” in search of new corporate partners in 1982 when Amgen's start-up money was running out and “unfortunately the Japanese market was unwilling to take the chance.” CYNTHIA ROBBINS-ROTH, FROM ALCHEMY TO IPO: THE BUSINESS OF BIOTECHNOLOGY 40 (2000). Today Amgen is the largest and most successful biotechnology company in the world. See Robert Langreth, *Company of the Year - Biotech Behemoth*, FORBES, Jan 10, 2005, at 128.

<sup>21</sup> OFFICE OF TECHNOLOGICAL ASSESSMENT, *supra* note 17, at 60 (reporting that between 1982 to 1988, a staggering 94% of the 195 deals between Asian and American companies involved a Japanese partner and in 1988 “a record 52 US-Japanese deals” were struck).

commercialization largely occurred within the United States.”<sup>22</sup> Given the Japanese government's industrial policy track record<sup>23</sup> in driving the country's pre-1990 stellar economic performance against the underwhelming American economy, there appeared to be legitimate grounds for American fears of Japan.<sup>24</sup> Mirroring the anxieties that bedeviled much of the beleaguered American industry, it was noted that America's world leadership in biotechnology was “unequivocally being threatened by the Japanese.”<sup>25</sup> In fact, these

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<sup>22</sup> NATIONAL RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND US-JAPAN COMPETITION IN BIOTECHNOLOGY: REPORT OF A WORKSHOP 1 (1991).

<sup>23</sup> MITI played a key role in guiding Japan's economic growth in the postwar period. Cf. Kazuyoshi Matsuura et al., *Institutional Restructuring in the Japanese Economy since 1985*, 37 J. ECON. ISSUES, 1013 (2003) (reporting that “the twin shocks of the completion of the catching-up with other advanced economies and growing internationalization resulted in a reduction of MITI’s ability to coordinate industry behavior. As part of a wider reform of government departments MITI was reorganized in 2001 into the new Ministry of Economy, Trade and Industry (METI)”). See generally CHALMERS JOHNSON, *MITI AND THE JAPANESE MIRACLE: THE GROWTH OF INDUSTRIAL POLICY, 1925-1975* (1982) (offering a classic account of MITI's formidable achievements); S. CALLON, *DIVIDED SUN: MITI AND THE BREAKDOWN OF JAPANESE HIGH-TECH INDUSTRIAL POLICY, 1975-1993* (1995) (providing a post-mortem of how the mighty had fallen).

<sup>24</sup> The sum of all American fears of the seemingly unstoppable Japanese economic juggernaut was amply illustrated by a relentless flow of mass media stories and books documenting Japan's economic and industrial rise in the midst of American decline. E.g. Christopher Bryon, *How Japan Does It - The World's Toughest Competitor Stirs A U.S. Trade Storm*, TIME, Mar. 30, 1981, at 54; Sam Jameson, *The Pacific Rim: Japan Seen Overtaking U.S. in '85*, L.A. TIMES, May 24, 1985, at 3; Theodore White, *The Danger from Japan*, N.Y. TIMES MAG., July 28, 1985, at 18; David Sanger, *How Japan Does What It's Doing To Keep Its Economy in Top Gear*, N.Y. TIMES, Nov. 27, 1988, at 1; Jay Mathews Date, *East Buys West: Foreign Ownership on Rise Record Japanese Speculation in Real Estate Inflates Values, Threatens a Political Backlash*, WASH. POST, May 29, 1988, at H1; EZRA VOGEL, *JAPAN AS NUMBER ONE: LESSONS FOR AMERICA* (1979); CLYDE PRESTOWITZ, *TRADING PLACES: HOW WE ALLOWED JAPAN TO TAKE THE LEAD* (1988); STEPHEN D. COHEN, *COWBOYS AND SAMURAI: WHY THE UNITED STATES IS LOSING THE BATTLE WITH THE JAPANESE, AND WHY IT MATTERS* (1991); WILLIAM DIETRICH, *IN THE SHADOW OF THE RISING SUN: THE POLITICAL ROOTS OF AMERICAN ECONOMIC DECLINE* (1991); WILLIAM ZIEMBA, & SANDRA SCHWARTZ, *POWER JAPAN: HOW & WHY THE JAPANESE ECONOMY WORKS* (1992).

<sup>25</sup> This was Leroy Hood's, one of the world's leading gene sequencing experts, blunt warning during the U.S. Senate hearings regarding the funding of The Human Genome Project. See RODNEY LOEPPKY, *ENCODING CAPITAL: THE POLITICAL ECONOMY OF THE HUMAN GENOME PROJECT* 86 (2005).

publicly voiced US worries about Japan were apparently so effective that it was even proffered as one of the reasons why Japan was “noticeably absent” from the current global biotechnology boom.<sup>26</sup> Notwithstanding the 1980s’ American paranoia<sup>27</sup> of Japan economically overtaking the U.S., from the early 1990s onwards, Japan underwent a painfully demoralizing<sup>28</sup> lengthy recession<sup>29</sup> -- the lost decade<sup>30</sup> -- where the Japanese economy suffered a spectacular reversal of fortune.<sup>31</sup>

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<sup>26</sup> Miller, *supra* note 9, at 51 (quoting the director of the Genomic Sciences Center in Yokohama as saying that in the early 1990s, the Japanese “government may have been overly sensitive to America’s fears of Japanese industrial domination” and that “[we] did not want Americans to feel that way, and that’s why we fell behind”).

<sup>27</sup> The American media obsession with the Japanese economic threat in the 1980s crested to a high water point in 1992 when Michael Crichton’s hugely successful novel *Rising Sun* and the resulting eponymous Hollywood film, faithfully fanned the flames of Japan’s perilous image. See Narrelle Morris, *Paradigm Paranoia: Images of Japan and the Japanese in American Popular Fiction of the Early 1990s*, 21 JAPANESE STUDIES 45, 45-59 (2001).

<sup>28</sup> One infamous low point was when ratings agency Moody’s dropped Japan’s credit rating to A2, putting Japan’s debt level just below that of Hungary and Botswana. Many industrialized nations, including the United States and Britain, enjoy Moody’s top credit rating, called triple-A, five notches above Japan’s. See Akiko Kashiwagi, *Japan’s Credit Rating Cut by Two Notches*, WASH. POST., June 1, 2002, at E1.

<sup>29</sup> See Irene Kunii, *Technology: Giants On The Ropes*, BUS. WK., Nov. 30, 1998 (noting the grim and severe economic outlook that Japanese electronics giants faced); *What ails Japan?* ECONOMIST, Apr. 18, 2002 (reporting that “Japan has lurched from recession to recession - the current one is the fourth in ten years - and since the 1990s have been called ‘the lost decade’ for several years now”).

<sup>30</sup> Takatoshi Ito, *Retrospective on the Bubble Period and Its Relationship to Developments in the 1990s*, in JAPAN’S LOST DECADE: ORIGINS, CONSEQUENCES AND PROSPECTS FOR RECOVERY 18, 18 (Robert M. Stern et al. eds., 2004).

<sup>31</sup> Bill Emmott, *The Sun Also Rises*, ECONOMIST, Oct. 8, 2005 (reporting that “[n]o country in modern history has moved so quickly from worldwide adulation to dismissal or even contempt as did Japan”). A sampling of the titles of the media stories and books show Japan’s fall from grace. E.g. RICHARD KATZ, *JAPAN, THE SYSTEM THAT SOURED: THE RISE AND FALL OF THE JAPANESE ECONOMIC MIRACLE* (1998); Brian Bremner, *All Eyes on a Teetering Economy: A Diving Nikkei, Shrinking GDP: How Bad Can Things Get?*, BUS. WK., Sep. 17, 2001, at 54; WILLIAM W. GRIMES, *UNMAKING THE JAPANESE MIRACLE: MACROECONOMIC POLITICS, 1985-2000* (2001); William H. Overholt, *Japan’s*

### A. Japan's Biotechnology Lost Decade

Japan's lost decade saw not only a collapse of asset prices but biotechnology commercialization stumbled “into a full retreat” as Japanese companies “pulled back significantly” from international deals.<sup>32</sup> Past Japanese biotechnology efforts did not develop in a manner that was necessarily to Japan's advantage, where, in spite of the “rosy glow that had imbued American's vision of biotechnology in Japan,” it was a “shock” when Japan did not turn out to be that promised “land of tPA milk and recombinant honey.”<sup>33</sup> In order to overcome the “prolonged structural recession,”<sup>34</sup> Japan made “science and technology (S&T) activity a top strategic priority”<sup>35</sup> amongst other measures. Many commentators urged reform of Japan's innovation system to rehabilitate Japan's sputtering economy.<sup>36</sup> These calls have been translated into extensive statutory

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*Economy at War with Itself*, 81 FOREIGN AFFAIRS 134 (2001); S. JAVED MASWOOD, JAPAN IN CRISIS (2002).

<sup>32</sup> STEVEN W. COLLINS, THE RACE TO COMMERCIALIZE BIOTECHNOLOGY: MOLECULES, MARKET AND THE STATE IN JAPAN AND THE US 137 (2003).

<sup>33</sup> OFFICE OF TECHNOLOGICAL ASSESSMENT, *supra* note 17, at 148.

<sup>34</sup> Kazuyuki Motohashi, *Spotlight on Japan's Competitiveness Part 3: Rebuilding Japan's Innovation System to Meet the Challenges of the IT Revolution*, J. JAPANESE TRADE & INDUSTRY, Jan.-Feb. 2003, at 1, 2 (noting that “in stark contrast to the strong economic growth in the United States in the 1990s, the same period in Japan was bleak enough to win the label of the 'lost decade.' The average 4.1% economic growth of the 1980s plunged to 1.4% in the 1990s, and the unemployment rate climbed above 5% to the worst-ever postwar level.”). JAPAN'S LOST DECADE: POLICIES FOR ECONOMIC REVIVAL (Tim Callen & Johnathan D. Ostry eds., 2003).

<sup>35</sup> Yoshiko Okubo & Shinichi Kobayashi, *Japan, in UNESCO SCIENCE REPORT 2005* 203, 208-214, 222 (2005) (reporting that Japan's “paradigm shift since the late 1990s “from science, technology and society to science, technology for society” by enacting a furious spate of statutory, institutional and administrative reforms and restructuring its S&T system).

<sup>36</sup> Akira Goto, *Japan's National Innovation System: Current Status and Problems*, 16 OXFORD REV. OF ECON. POL'Y, 103-113 (2000) (Japan's national innovation system that was so successful in the 1980s seemed to have lost its competitiveness in the 1990s and fundamental reform had to take place). *See generally* Toshiko Takenaka & Ichiro Nakayama, *Will Intellectual Property Policy Save Japan from Recession? Japan's Basic Intellectual Property Law and Its Implementation Through the Strategic Program*, 35 INT'L REV. INDUS. PROP. & COPYRIGHT L. 877, 878 (2004).



amendments and policy initiatives<sup>37</sup> to Japanese S&T policy, university, intellectual property and other laws, and this has brought a “second wind” to Japanese biotechnology as it was “linked in part to Japan's economic revitalization.”<sup>38</sup>

### B. *Japanese Economic Quagmire*

However, if the “Japanese quagmire” was just a matter of economics, it would have been fixed long ago.<sup>39</sup> “Like many economic riddles, its roots lie in the murkier realms of sociology and psychology”<sup>40</sup>, and it appears that there was a realization that the solution to Japan's prolonged economic slump required something more than the usual dithering and ineffective Japanese government responses like the clumsy fiscal policy tools of massive public spending on road construction.<sup>41</sup> Japanese society “seemed frozen into a passivity that bordered on anomie”<sup>42</sup> but it quietly underwent an

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<sup>37</sup> See HISAMITSU ARAI, OECD CONFERENCE ON INTELLECTUAL PROPERTY VALUATION AND EXPLOITATION - SUMMARY REPORT, 24-25 (OECD ed., 2005). (reporting a summary of the current Japanese IP strategic program which comprised about 450 action items that the Japanese government had developed in Japan since 2003 following Prime Minister Koizumi's 2002 announcement of the goal to make Japan an intellectual property based nation). A detailed account of the Japanese government's efforts is explained in annual IP strategic programs that have been compiled since 2003. See SECRETARIAT OF INTELLECTUAL PROPERTY STRATEGY HEADQUARTERS, [http://www.ipr.go.jp/e\\_materials.html](http://www.ipr.go.jp/e_materials.html) (last visited January 26, 2007).

<sup>38</sup> COLLINS, *supra* note 32, at 137.

<sup>39</sup> David Ignatius, *Reviving a Sleepwalking Japan*, WASH. POST, Feb. 21, 2001, at B7.

<sup>40</sup> *Id.*

<sup>41</sup> The Japanese government's previous failed economic revival efforts included numerous special interest driven pork-barrel road construction works projects, an ill-timed and advised consumption tax increase, a persistent failure to transparently rehabilitate the financial sector laden with potentially disastrous nonperforming loan problems - all led to a mistrust of government bureaucrats to deliver solutions in the public interest. See EISUKE SAKAKIBARA, STRUCTURAL REFORM IN JAPAN: BREAKING THE IRON TRIANGLE 23-27, 70-86 (2004); see also Makoto Itoh, *Japan's Continuing Financial Difficulties and Confused Economic Policies*, in ECONOMIC REFORM IN JAPAN: CAN THE JAPANESE CHANGE? (Craig Freedman ed., 2001).

<sup>42</sup> Frank B. Gibney, *Reinventing Japan...Again*, 119 FOREIGN POL'Y 74, 79 (2000).

appreciable fundamental attitudinal shift<sup>43</sup> with an evolved outlook.<sup>44</sup> A metamorphosed entrepreneurial spirit emerged, symbolized by a Japanese venture fund manager, Yoshito Hori, who doubles as the founding dean of a business school (an occupational profile that was neither probable nor plausible some 10 years ago), observing that “Japan had a very rigid, stable society [ten years ago],” but “the mentality now is so much different. Entrepreneurs are respected.”<sup>45</sup>

After 15 long years, Japan finally appears to be pulling out of its economic slump.<sup>46</sup> Some credit has been given to Japanese government reforms<sup>47</sup> with the recent economic recovery “supported

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<sup>43</sup> Ideologically, there was “a swing from faith in social contract institutions and practices toward market-based solutions, often led by U.S.-trained academics and an increasingly receptive media.” D.H. Whittaker, *Crisis and Innovation in Japan: A New Future through Technoentrepreneurship?*, in *CRISIS AND INNOVATION IN ASIAN TECHNOLOGY* 57, 83 (William W. Keller & Richard J. Samuels eds., 2003).

<sup>44</sup> See JEFF KINGSTON, *JAPAN'S QUIET TRANSFORMATION: SOCIAL CHANGE AND CIVIL SOCIETY IN THE 21ST CENTURY* xvi (2004) (commenting that “Japan in 2004 is very different from the way it was in 1989; from a historical perspective fifteen years is a small blip of time and in this brief moment many of the seemingly ineradicable verities and practices of Japan have been unalterably transformed”).

<sup>45</sup> Tim Kelly, *Venture Professor*, *FORBES ASIA*, Feb. 13, 2006 (internal quotation marks omitted); see also Christian Caryl, *Turning Un-Japanese*, *NEWSWEEK*, Feb. 13, 2006, at 34 (reporting “Japan's emerging class of entrepreneurs, from salarymen who have chucked safe corporate careers to strike out on their own” to daring to have IPO dreams with many “quietly making fortunes by creating software for videogames and mobile phones” in hacker's dens).

<sup>46</sup> Popular business media appear to agree that Japan, after several false starts, has indeed started on the road to real economic recovery. See Brian Bremner & Hiroko Tashiro, *Is Japan Back?*, *BUS. WK.*, June 14, 2004, at 48; Clay Chandler, *JAPAN: Back From the Dead?*, *FORTUNE*, Dec. 13, 2004, at 145; Craig Karmin, *Japan Is Back: It Looks Real This Time*, *WALL ST. J.*, Nov. 27, 2005, at 1; *The Sun Also Rises*, *ECONOMIST*, Oct. 8, 2005, at 11; Kenneth Curtis, *It's Morning in Japan*, *TIME ASIA*, Mar. 20, 2006, at 23; Peter Tasker, *Japan is Back, So Beware*, *NEWSWEEK INT'L*, Mar. 20, 2006, at 41.

<sup>47</sup> See Jim Frederick & Toko Sekiguchi, *Here Comes the Sun*, *TIME INT'L*, Apr. 12, 2004, at 14 (reporting that Japan's changing fortunes were due to “a surprising new spirit of dynamism among policymakers in Tokyo”); Jesper Koll, *Japan is Back, For Real This Time*, *FAR EASTERN ECON. REV.* 168(9), Oct. 2005, at 11-12 (crediting “[b]ehind-the-scenes work by the government” to improve the infrastructure of capital markets, “accounting standards, legal system, labor market regulations and, ultimately, the tax system, underscor[ing] Japan[']s commitment to becoming a more free capitalist system”).

by such science-based innovations as electrically conductive plastic, now widely used in high-tech equipment such as mobile phones.”<sup>48</sup> In terms of biotechnology, currently, Japan is currently recognized to be “well advanced in plant genetics and has made breakthroughs in rice genomics, but it is lagging behind the United States in human genetics.”<sup>49</sup>

Japan's past underwhelming biotechnology endeavors, as compared to America, had been begrudgingly acknowledged.<sup>50</sup> “For a technological powerhouse with the world’s second-largest economy, Japan does not have the biotech sector it deserves . . . [nor] does [it] rank in Ernst & Young’s list of top 12 biotechnology countries.”<sup>51</sup>

The reasons for Japan's past biotech sector infirmities were attributed to constraints imposed “by several structural and cultural impediments.”<sup>52</sup> First, Japan had a weak life sciences scientific base and different academic norms; second, there was a lack of access to capital, especially venture capital; third, there was the absence of technology transfer infrastructure in Japanese universities; and fourth, was Japan's weak intellectual property system. The following is a discussion about these structural and cultural impediments and the measures that were taken to remedy these impediments, Japan's policymakers' aims to realize the potential to rejuvenate Japan's economy with a vibrant biotechnology sector fueled by technology transferred from university research to startup ventures or industry.

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<sup>48</sup> Iwao Matsuda, *Boosting S&T Innovation in Japan*, 313(5791) SCIENCE 1201, 1201 (2006). Matsuda is the Minister of State for Science and Technology Policy of Japan.

<sup>49</sup> ALBERT SASSON, *MEDICAL BIOTECHNOLOGY: ACHIEVEMENTS, PROSPECTS AND PERCEPTIONS* 13 (2005).

<sup>50</sup> Compared to the U.S., Japan's biotechnology companies were fewer and smaller with the Japanese government outspent by the U.S. government four fold producing a serious gap in the biotechnology field. Mitsuru Miyata, *Japan's Biotech Sector Has Already Lost the First Round to the U.S.*, WEEKLY ECONOMIST, Feb. 8 2000, at 36 (in Japanese).

<sup>51</sup> Ernst & Young’s list of top 12 biotechnology countries counts companies primarily engaged in biotech, and “the relative paucity of startup-based standalone biotech companies has long been a problem.” *Japan Overview - Japan Restructures to Develop a Startup-Based Industry*, in ERNST & YOUNG, *supra* note 7, at 78.

<sup>52</sup> *Id.*

### III. WEAK LIFE SCIENCES BASE & DIFFERENT ACADEMIC NORMS

There is an “inherently entrepreneurial”<sup>53</sup> aspect to U.S. academic culture and this inherent correspondence between academic and entrepreneurial cultures was “significantly reinforced in the past twenty years by both the passage of the Bayh-Dole Act<sup>54</sup> and the dramatic growth of the biotechnology industry, largely as the outcome of successful efforts to create new firms out of university research efforts.”<sup>55</sup>

Most of the world's significant biotechnology breakthroughs that increased productivity in the U.S. pharmaceutical industry have been from U.S. academic institutions conducting basic research.<sup>56</sup> “The willingness to exploit the results of academic research commercially” greatly distinguished the American academic environment<sup>57</sup> from the Japanese one.<sup>58</sup> Moreover, “links between the

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<sup>53</sup> Henry Etzkowitz, *Bridging the Gap: The Evolution of Industry-University Links in the United States*, in INDUSTRIALIZING KNOWLEDGE: UNIVERSITY-INDUSTRY LINKAGES IN JAPAN AND THE UNITED STATES 218, 230 (Branscomb et al. eds., 1999).

<sup>54</sup> The Bayh-Dole law change “accelerated the use of academic breakthroughs like gene splicing to develop biotech drugs and other products, giving rise to a three-way partnership of government, universities and startup firms that is ‘the envy of every nation.’” Bernadette Tansey, *The Building of Biotech - 25 years later, 1980 Bayh-Dole act honored as foundation of an industry*, S.F. CHRON., June 21, 2005, at D1 (quoting James Mullen, Chief Executive Officer of Biogen Idec Inc.).

<sup>55</sup> LEWIS M. BRANSCOMBE & PHILIP E. AUERSWALD, TAKING TECHNICAL RISKS: HOW INNOVATORS, EXECUTIVES, AND INVESTORS MANAGE HIGH-TECH RISK 23 (2001).

<sup>56</sup> See Lynne G. Zucker et al., *Intellectual Human Capital and the Birth of U.S. Biotechnology Enterprises*, 88 AM. ECON. REV. 290, 291 (1998); Iain M. Cockburn & Rebecca M. Henderson, *Publicly Funded Science and the Productivity of the Pharmaceutical Industry*, 1 INNOVATION POLICY AND THE ECONOMY 1, 1-34 (Jaffe et al. eds., 2001).

<sup>57</sup> See Arthur D. Levinson, *What distinguishes Biotech from Big Pharma*, in ERNST & YOUNG, *supra* note 7, at 5 (noting that “It’s no coincidence that the major biotech centers in the United States are clustered around top academic institutions. In South San Francisco, Genentech is nestled between U.C. Berkeley, U.C. San Francisco, and Stanford. Many biotechs are rooted in academic beginnings and have successfully maintained a culture that attracts top scientists”).

academy and industry, especially the relatively free exchange of personnel, appear to have been much weaker in . . . Japan.”<sup>59</sup> “Interaction between universities and industry was relatively unknown in Japan until 1990.”<sup>60</sup>

A. *Universities - The Weakest Part of Japan's Research System*

Even the Japan Science and Technology Agency admitted that Japanese “universities are often called the weakest part” of Japan's research system.<sup>61</sup> Primarily dominated by industry and the private sector, the “directed research efforts [are] towards the development of process innovations with immediate commercial applications, not towards basic scientific advances.”<sup>62</sup> Additionally, “a lot of publicly funded research is actually conducted by the private sector, as opposed to being conducted by public universities or government research institutes as is more typical in the United States and some other countries.”<sup>63</sup>

However, this Japanese industry-dominated model of innovation had inherent limitations.

Japan's innovation system, with its primary reliance on the work of central research institutes at major corporations, has been faced with a need to remake itself since the collapse of the bubble economy in the first half of the 1990s. Corporations, their performance slipping, are losing their ability to fund

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<sup>58</sup> Iain Henderson et al., *Pharmaceuticals & Biotechnology, in U.S. INDUSTRY IN 2000: STUDIES IN COMPETITIVE PERFORMANCE* 363, 389 (David Mowery ed., 1999) [hereinafter U.S. INDUSTRY IN 2000].

<sup>59</sup> *Id.*

<sup>60</sup> Okubo & Kobayashi, *supra* note 35, at 210.

<sup>61</sup> *See* OFFICE OF INTERNATIONAL AFFAIRS, *LEARNING THE R&D SYSTEM: UNIVERSITY RESEARCH IN JAPAN AND THE UNITED STATES* 3 (1989) (citing JAPAN SCIENCE AND TECHNOLOGY AGENCY REPORT, *SCIENCE & TECHNOLOGY WHITE PAPER* 1988).

<sup>62</sup> *Id.*

<sup>63</sup> DAVID FLATH, *THE JAPANESE ECONOMY* 334 (2000).

expensive basic research, and their mission is shifting back towards the development of marketable products.<sup>64</sup>

This weakness is exacerbated in academic-intensive fields like biotechnology and biopharmaceuticals where “the exploitation of genetics as a tool to produce proteins as drugs lagged considerably behind the United States [with] . . . almost all of the established . . . Japanese companies . . . slow to adopt the tools of biotechnology as an integral part of their drug research efforts.”<sup>65</sup> Compared to America, Japan has been much slower to adopt the use of “molecular biology as a research tool.”<sup>66</sup>

On a macro scale, it was observed that the Japanese education ministry's previous “implementation of poor education reforms has resulted in declining scholastic achievement, even at the university level” thereby resulting in Japanese education reaching “an appalling state.”<sup>67</sup> Exacerbating its basic education deficiency, “Japan's advanced education system has long left much to be desired”<sup>68</sup> and

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<sup>64</sup> Kazuyuki Motohashi, *The Japanese Model: Shifts in Comparative Advantage Due to the It Revolution and Modularization*, J. JAPANESE TRADE & INDUSTRY, Nov.-Dec. 2003, at 30, 34. For a more critical view see Guy De Jonquieres, *The Severe Flaws in Japan's Industrial Model*, FIN. TIMES, Nov. 29, 2005, at 19. The author commented that:

[The Japanese] excel at straight-line extrapolation, constantly doing the same things better. But they could not handle sudden bends. In the past, Japanese companies have repeatedly reinvented themselves, moving out of dying sectors by using existing skills to create new businesses. But it is unclear where the qualities that once made them winners in electronics can be profitably redeployed.

*Id.*

<sup>65</sup> U.S. INDUSTRY IN 2000, *supra* note 58, at 386.

<sup>66</sup> *Id.* at 392.

<sup>67</sup> SAKAKIBARA *supra* note 39, at 40-41.

<sup>68</sup> MICHAEL E. PORTER ET AL., CAN JAPAN COMPETE? 144 (2000). Japan's basic education strengths had “growing weaknesses” where even Tokyo University had “to offer remedial courses in math, physics and chemistry for incoming students.” Japan's “university and graduate-level training [is] uneven in quality” and “because of limited funds and antiquated research facilities, Japanese

seriously underperformed in producing enough specialized graduate students “in important disciplines, such as computer software and biotechnology.”<sup>69</sup> This paucity of biology PhDs<sup>70</sup> was even reflected at the Japanese Patent Office, but this has since been addressed.<sup>71</sup>

In the past, the Japanese government and leading Japanese companies merely recruited new bachelor's degree recipients and gave them long-term in-service training as future managers. Thus, advancing to graduate education has not been attractive leading to the low numbers of advanced graduate degree holders in Japan.<sup>72</sup>

[Japanese industry] never expected from universities training and supply of a fully skilled and talented workforce that is highly specialized [and] . . . particularly in the field of natural sciences, not only did the growth of

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universities lack strong research programs in many important fields.” *Id.* at 144, 146.

<sup>69</sup> *Id.* at 144 (citing the grim Japanese Ministry of Education statistics that in 1996, Japanese students with biology-related majors numbered 1,875 and were dwarfed by the 62,081 in the United States. In 1994, Japan's ratio of graduate students per 1,000 population was 1.3 whereas the U.S. figure was 7.7 resulting in chronic shortages of specialized skills); *see also* MINISTRY OF EDUCATION, EDUCATION POLICY OF OUR NATION 304 (1998).

<sup>70</sup> Mark Lehrer & Kazuhiro Asakawa, *Rethinking the Public Sector: Idiosyncrasies of Biotechnology Commercialization as Motors of National R&D Reform in Germany and Japan*, 33 RESEARCH POL'Y 921, 927 (2004) (noting the small number of biology PhDs Japan produced annually is 200 compared to America's 6000).

<sup>71</sup> According to an IP commentator from the Tokyo-based National Graduate Institute for Policy Studies, “there are no PhD-holders in Japan's patent office, against some 500 in the US patent office.” David Cyranoski, *Japanese Forum Urges Rethink Over Patents*, 415 NATURE 354, 354 (2002). However, this situation was remedied when more than 20 natural sciences doctorates were present in the 98-strong examiner class scheduled to start work in May 2004. David Cyranoski, *Curiosity Makes Way for Capitalism*, 429 NATURE 216, 216 (2004).

<sup>72</sup> Shinichi Yamamoto, *Graduate Education Reform & International Mobility of Scientists in Japan and Related Information for Korea*, in GRADUATE EDUCATION REFORM IN EUROPE, ASIA AND THE AMERICAS AND INTERNATIONAL MOBILITY OF SCIENTISTS AND ENGINEERS: PROCEEDINGS OF AN NSF WORKSHOP 65, 69 (Jean M. Johnson ed., 2000), available at <http://www.nsf.gov/statistics/nsf00318/pdf/c1s4.pdf>.

research budgets stagnate, but also the best talent was snatched up by corporate research centers. Basic research promptly went the way of impoverishment. The university was, in a word, abandoned by industry.<sup>73</sup>

*B. Reforming Japan's graduate education*

Massification of Japan's undergraduate education<sup>74</sup> together with the low number of advanced graduate degree holders in Japan ran counter to the developing expectations of industry and policy makers who wanted to use university teaching as an engine for economic growth and technological innovation.<sup>75</sup> There were also worries that “not all [Japanese] graduate schools have developed educational programs that offer attractive content and provide an appropriate response to current demand from the Japanese economy.”<sup>76</sup> The aforesaid combined with Japan's difficulties in academic-based research in life sciences,<sup>77</sup> were the dominant reasons why Japan's biotechnology efforts were a little off the mark<sup>78</sup>

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<sup>73</sup> Gregory S. Poole, *Higher Education Reform in Japan: Amano Ikuo on 'The University in Crisis'* 4(3) INT'L EDUCATION J. 149, 160 (2003), available at <http://ehlt.flinders.edu.au/education/iej/articles/v4n3/Poole/paper.pdf> (referring to an English translation of the introductory chapter of the influential book, IKUO AMANO, CHALLENGES TO JAPANESE UNIVERSITIES (1999), in order to provide a sample “of the constructive criticism of Japanese higher education not yet been published in English”).

<sup>74</sup> Yamamoto, *supra* note 72, at 65-67 (reporting that due to Japan's rapid economic growth period in the 1960s and 1970s, the Japanese economy demanded an undergraduate educated workforce resulting in massification, i.e. higher education was no longer for the elite few but for the masses. This massification was achieved at the expense of graduate research and research training, moreover, the quality and content of such undergraduate education was criticized as being too academic and “not useful in future jobs outside academia.”).

<sup>75</sup> *Id.* at 69.

<sup>76</sup> *Id.* at 74.

<sup>77</sup> U.S. INDUSTRY IN 2000, *supra* note 58, at 389 (surmising that “the weakness of the Japanese [biotechnology] industry may partially reflect the weakness of Japanese science”).

<sup>78</sup> See Arthur Kornberg, *Whither Biotechnology in Japan? Why Biotechnology Hasn't Yet Taken Off*, HARV. ASIA PAC. REV., Fall 2002, at 6, 7-8.



especially since biotechnology is an industry based exclusively on new knowledge.<sup>79</sup>

Japan's Ministry of Education, Culture, Sports, Science & Technology ("MEXT") bravely acknowledged that universities in Japan,

face strong criticisms, including those to the effect that education content and reform methods do not reflect changes in the student population and that the quality of education is falling, that community cooperation in education and research aspects is insufficient and that various regulations and customs prevent flexible decision making, thus making it impossible to respond to social changes.<sup>80</sup>

This formed the impetus of the late 1990s far-reaching university reforms.<sup>81</sup> These university reforms, effective from April 1, 2004, removed university staff from civil service rosters, thereby ending guaranteed lifetime employment.<sup>82</sup> Universities are now subject to frequent evaluations for competitive research grants, and permitted more freedom to pursue collaborations with industry.<sup>83</sup> The chief

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<sup>79</sup> DAVID HART, *THE EMERGENCE OF ENTREPRENEURSHIP POLICY: GOVERNANCE, START-UPS, AND GROWTH IN THE U.S. KNOWLEDGE ECONOMY* 29 (2003).

<sup>80</sup> MINISTRY OF EDUCATION, CULTURE, SPORTS, SCIENCE AND TECHNOLOGY, *FY2003 WHITE PAPER ON EDUCATION, CULTURE, SPORTS, SCIENCE AND TECHNOLOGY* 7 (2004) [hereinafter MEXT WHITE PAPER].

<sup>81</sup> *Id.* at 32-68. For a summary of the post 1996 Japanese education reforms see Okubo & Kobayashi, *supra* note 35, at 209-14.

<sup>82</sup> See Atsuko Toyama, *Japan's Minister of Education, Culture, Sports, Sciences and Technology (2001-2004), University Reforms in Japan to Usher in Century of Knowledge*, in JAPAN SOCIETY FOR THE PROMOTION OF SCIENCE QUARTERLY No. 9, 1, 2-7 (2004); see also THE 'BIG BANG' IN JAPANESE HIGHER EDUCATION: THE 2004 REFORMS AND THE DYNAMICS OF CHANGE (J. S. Eades et al. eds., 2005).

<sup>83</sup> Dennis Normile, *Japan's Universities: Reforms Would Loosen Bonds, Cut Safety Net*, 295 SCIENCE 1621, 1621-22 (2002).

hope of these university reforms is to give Japan's "scientific stars, especially the young ones, room to flourish in a system that has been crowded out by unproductive professors." The director of the Science and Technology Policy Planning division in the Cabinet of the Government of Japan candidly quipped that "there's no place as comfortable as the Japanese universities — especially for professors without talent."<sup>84</sup>

C. *Improvements in Japanese life science graduates & publication trends*

In the interim, Japanese graduate education in life sciences has marginally improved quantitatively as "the number of people acquiring a master's degree or doctoral degree in the natural sciences in Japan has been rising alongside an expansion of graduate schools." However, the "United States awards the largest number of life sciences degrees, a little over three times as many as does Japan" and "the number of graduate school students as a proportion of all university students is also lowest in Japan compared to the U.S., UK, France."<sup>85</sup>

Moreover, since 1994, the quality of Japan's life sciences research still lags behind the U.S., Britain, and Germany in terms of citation share. Japan's impact on the world research community remains modest, given that Japan's citation count is relatively small compared with its production of scientific papers. Additionally, although Japan's share had increased steadily between 1992 and 1997, it was at a rate which is still below the world average but slightly greater than the growth rate of its production share.<sup>86</sup> Lastly, in terms of relative comparative advantage (RCA),<sup>87</sup> although Japanese

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<sup>84</sup> See David Cyranoski & I-han Chou, *Winds of Change Blow Away the Cobwebs on Campus: Japan's Hidebound University System is Being Reformed*, 429 NATURE 210, 214 (2004).

<sup>85</sup> MINISTRY OF EDUCATION, CULTURE, SPORTS, SCIENCE AND TECHNOLOGY, WHITE PAPER ON SCIENCE AND TECHNOLOGY 2004 194 (2005) [hereinafter S&T WHITE PAPER], available at [http://www.mext.go.jp/english/news/2005/04/05051301/full\\_text.zip](http://www.mext.go.jp/english/news/2005/04/05051301/full_text.zip)

<sup>86</sup> See National Institute of Science and Technology Policy (NISTEP) et al., *Science and Technology Indicators: 2004 - A Systematic Analysis of Science and Technology Activities in Japan 138-39* (2005) [hereinafter S&T Indicators], <http://www.nistep.go.jp/acheiv/ftx/eng/rep073e/pdf/rep073e.pdf>.

<sup>87</sup> "Relative comparative advantage (RCA) is often used to clearly identify changes in the output of papers by field of research. This indicator can be

clinical medicine papers have shown “robust growth” since 1982, it still fell short of the world average in 2002, and in the biology and sciences field, from 1987 to 2002 Japan had lingered slightly below the world average.<sup>88</sup>

There are several who openly question the effectiveness of the recent university reforms discussed hereinabove as “many remain skeptical” that the reforms will “result in only superficial administrative reshuffling” and, according to the former director of the University of Tokyo Institute of Medical Science, “the title, cover, first page, may be changed . . . [b]ut after the third page, the real contents of the book may still be the same.”<sup>89</sup>

However, one influential Japanese university reformist had noted that “it is inevitable that various types of opposition will be born and confusion will spread” amongst the forces opposing such reforms in Japanese academia in the interim and it is not expected that one “will be able to see the image of the new university until such a period of disorder, confusion, and groping has passed.”<sup>90</sup> Even though previous abortive attempts at university education reform have not been very encouraging,<sup>91</sup> “Japan has a long history of discovering

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calculated by dividing the domestic share of the papers in a given field by the worldwide share of the papers in that field.” *Id.* at 142.

<sup>88</sup> *See id.*

<sup>89</sup> Cyranoski & Chou, *supra* note 84, at 213; *see also* Editorial, *Legislation Does Not Guarantee University Reform*, NIHON KEIZAI SHIMBUN, Jan. 27, 2003 (noting that “legislation will create a framework for reform, but the universities’ responses to the changes are casting a pall over the outlook for reform. Many universities are adopting goals and plans using their traditional decision-making process, which has often been blamed for administrative rigidities and inefficiencies”).

<sup>90</sup> AMANO, *supra* note 73, at 167.

<sup>91</sup> Previous ambitious Japanese government attempts at reforming Japan’s university education system have failed. *See* LEONARD J. SCHOPPA, *EDUCATION REFORM IN JAPAN; A CASE OF IMMOBILIST POLITICS* (1993) (noting that twice since 1967 and 1993, the Japanese government had embarked on, but then failed to see through, major reform initiatives); B. J. MCVEIGH, *JAPANESE HIGHER EDUCATION AS MYTH* (2002) (concluding that although Japan’s higher education system appears to successfully graduate students every year, it is actually a system of institutionalized mendacity that reproduces the less enviable traits of national statism).

in the darkest days of its bewilderment a source of renewal,”<sup>92</sup> and Japan should be able to rely on its “150-year tradition of doing excellent science that didn’t even stop during the war.”<sup>93</sup> The university education reforms discussed earlier have received faint praise and “mixed” responses from Japanese researchers<sup>94</sup> so the reforms are clearly a work-in-progress.

#### IV. ACCESS TO CAPITAL - VENTURE OR CORPORATE

Venture capital played a major role in the creation of U.S. biotechnology firms, as did the collaboration between newly created firms and larger more established firms.<sup>95</sup> In Japan, the situation was starkly different, “[e]specially during the initial period, from 1991 to 1997, there was almost no venture capital in Japan.”<sup>96</sup> Due to the bank-centered capital market, Japan’s mechanism for supplying risk money, which should have been undertaken by venture capitalists, was “feeble.”<sup>97</sup> All these factors contributed to the absence of biotechnology startups in Japan in the past.

Previously, the few Japanese startups that there existed could not turn to established Japanese pharmaceutical companies as a source

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<sup>92</sup> JOHN NATHAN, *JAPAN UNBOUND: A VOLATILE NATION’S QUEST FOR PRIDE AND PURPOSE* 23 (2004).

<sup>93</sup> Cyranoski & Chou, *supra* note 84, at 214 (observing that even though “the customary way of doing things might be under attack, but Japan’s long tradition of research is what will keep the country ahead”).

<sup>94</sup> Ichiko Fuyuno, *Japan’s University Shake-up Wins Faint Praise After First Year*, 435 *NATURE* 1144, 1144 (2005).

<sup>95</sup> U.S. INDUSTRY IN 2000, *supra* note 57 at 389-90.

<sup>96</sup> See Tetsuya Iizuka, *From the Lost Decade to the Age of Individuals and Intellectual Properties*, in *REPORT ON THE INTERNATIONAL PATENT LICENSING SEMINAR 2003- IP REVOLUTION: TOWARD THE ESTABLISHMENT OF AN INTELLECTUAL PROPERTY NATION* 46 (National Institute for Industrial Property Information, eds., 2003), available at <http://books.nap.edu/books/0309086361/html/219.html> - p20007f538960219001.

<sup>97</sup> Kazuyuki Motohashi, *Growing R&D Collaboration of Japanese Firms and Policy Implications for Reforming National Innovation System, Science & Technology in an Innovation Driven Economy* 2 (2005), [http://symposium.stepi.re.kr/files/2005-12-16\\_1\\_Growing%20R&D%20Collaboration%20of%20Japanese%20Firms%20and%20Policy%20Implications%20for%20Reforming.pdf](http://symposium.stepi.re.kr/files/2005-12-16_1_Growing%20R&D%20Collaboration%20of%20Japanese%20Firms%20and%20Policy%20Implications%20for%20Reforming.pdf).

of capital because many of these Japanese companies were already committed to capital, marketing, and research relationships with a “plethora”<sup>98</sup> of new U.S. and European biotechnology firms.<sup>99</sup> Larger Japanese pharmaceutical companies “had little incentive to invest in local biotechnology firms” and Japanese startups were crowded out from these capital tie-ups.<sup>100</sup> So, it was not surprising that in 2000, Japan was ranked lowest in the amount of venture capital invested amongst the major industrialized countries surveyed (0.022 percent of GDP in Japan versus 0.52 percent of GDP in the U.S.).<sup>101</sup> There were also other institutional bureaucratic impediments against the formation of venture start-ups in Japan.<sup>102</sup> Accordingly, “[i]n places like Japan and Germany, where starting new companies and quickly growing them into big companies [was] difficult, the biotechnology industry [could not] thriv[e].”<sup>103</sup>

A. *Japan: Venture Capital Wasteland*

In a revealing admission that venture conditions in Japan were far from optimal, the Japanese government, through the Japan External Trade Organization (JETRO), the Ministry of Economy, Trade, and Industry (METI), and the Japan Small and Medium Enterprise Agency, expanded its small-business programs, founded technology parks and established technology fairs in U.S. cities, including Los Angeles, but the results have been disappointing as most of the startups “couldn’t clearly explain their businesses or hadn’t done the research to show why they could succeed in the United States.”<sup>104</sup> In fact, it was noted that small startup ventures were “popping up virtually everywhere in the industrialized world

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<sup>98</sup> U.S. INDUSTRY IN 2000, *supra* note 58, at 390.

<sup>99</sup> Aya Furuta, *Japan's drug makers seek R&D remedy through foreign biotechnology ventures*, NIKKEI WEEKLY, Apr. 5, 1999.

<sup>100</sup> U.S. INDUSTRY IN 2000, *supra* note 57, at 390.

<sup>101</sup> Paul D. Reynolds et al., GLOBAL ENTREPRENEURSHIP MONITOR 2000 - EXECUTIVE REPORT, 4 (2000).

<sup>102</sup> See Sebastian Moffett, *Japan's Entrepreneurs Say Hawaii Offers a Better Business Climate --- Tired of Red Tape at Home, Smaller Companies Register In U.S. and Start to Prosper*, WALL ST. J., Oct. 15, 2002 at A16.

<sup>103</sup> THUROW, *supra* note 2 at 232.

<sup>104</sup> Evelyn Iritani, *Japan Giving Its Start-Ups a U.S. Education, with Limited Success*, L.A. TIMES, Sep. 10, 2000, at C1.

with the exception of Japan, ‘where such small businesses are rapidly declining in number’” with the start-up rate in Japan an abysmal 4 percent, well below the U.S. startup rate of 14 percent.<sup>105</sup> Interestingly, in response to the prolonged economic decline, more Japanese have displayed stirrings of that crucial entrepreneurial spirit of individualism<sup>106</sup> and “if this nascent trend persists and spreads, it could ensure the future vitality of that industry, in spite of the rigidities in the larger society.”<sup>107</sup>

In 1998, the typical Japanese startup was not fronted by the stereotypical young, restless, highly educated, “underemployed but energetic”<sup>108</sup> entrepreneur, like in the U.S., but rather a fifty-five year old retiree, without a technical background in science or engineering, some not even possessing a four year college degree. Most worryingly, however, was that the majority of these new startups were affiliated in some way with a larger established Japanese company and the Japanese 'startup' was merely a fig leaf since these pseudo-startups were “inward looking networks that are thus closed to new sources of information [and opportunities] from the outside.”<sup>109</sup>

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<sup>105</sup> Walter Hatch, *Japanese Production Networks in Asia: Extending the Status Quo*, in Whittaker, *supra* note 42, at 54.

<sup>106</sup> See Bill Spindle, *Japan Becomes a Mecca for Venture Capitalists: U.S. Firms Invest Heavily As Prospects Improve For Entrepreneurship*, WALL ST. J., Feb. 24, 2000, at A13; Yumiko Ono and Bill Spindle, *Standing Along—Japan’s Long Decline Makes One Thing Rise: Individualism*, WALL ST. J., Dec. 29, 2000, at A1.

<sup>107</sup> RICHARD HUNDLE ET AL., *THE GLOBAL COURSE OF THE INFORMATION REVOLUTION: RECURRING THEMES AND REGIONAL VARIATIONS* 89 (2003) (although this work relates to the IT industry, its observation of “the rigidities of the Japanese society, economy, and government” stifling risk-taking, and entrepreneurship are applicable across the technology spectrum including biotechnology ventures).

<sup>108</sup> JERRY KAPLAN, *STARTUP: A SILICON VALLEY ADVENTURE* 8 (1996).

<sup>109</sup> Whittaker, *supra* note 42, at 27. See also *id.* at 23, 54-56 (opining that these 'startups' were a “legacy of relationalism” where there is a “dense web of longstanding and mutually reinforcing relationships between nominally independent firms.” Drawing data from 1998-1999 surveys conducted by the Japanese business newspaper, the NIHON KEIZAI SHIMBUN and the Japanese government-affiliated National Institute of Science and Technology Policy, it was found that the typical Japanese “venture businessmen” was a, presumably sprightly, fifty-five year old who either “retires from a firm but intends to maintain a business relationship with his former employer [affiliates or *norenwake*] or set up a new firm under the direction of his old employer” (directed affiliate or *bunsha*)).

Naturally, there have been notable exceptions to this typical surveyed profile as “Japan's young entrepreneurs convey vitality, excitement, and hopefulness about the future”<sup>110</sup> with some of these venture businesses even gaining mainstream credibility in Japanese society.<sup>111</sup> A promising recent development is the Japanese university graduates' blossoming interest in venture businesses as a career route where such university graduates “want to challenge their own abilities, even if it means failing, and to engage in work that will hold and further ignite their interests.”<sup>112</sup> The appetite of budding university venture entrepreneurs<sup>113</sup> appears to have successfully weathered the early 2006 spectacular fall from grace of Japan's most famous venture entrepreneur Takafumi Horie, the former CEO of Japanese internet portal Livedoor.<sup>114</sup> This is an important attitudinal change can only augur well for the future of Japanese venture business endeavors.

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<sup>110</sup> NATHAN, *supra* note 92, at 99 (naming Ikuo Nishioka - former CEO of Intel Japan - who left the company to found his own venture capital firm, Oki Matsumoto, founder of MONEX Beans online brokerage firm and Softbank owner Mayayoshi Son as the new entrepreneurial vanguard). *See also* Chisaki Watanabe, *Japan Looks to Internet Entrepreneurs to Jolt Economy*, L.A. TIMES, July 10, 2000, at C7.

<sup>111</sup> Two leading Japanese Internet companies which had venture startup beginnings, Softbank and Rakuten, currently own Japanese professional baseball teams and there is nothing more mainstream than owning a part of one of Japan's favorite pastimes, *Rakuten Baseball Business May Make Profit In 2nd Year*, NIHON KEIZAI SHIMBUN, Nov. 13, 2004; *Fukuoka Softbank Hawks Get Green Light*, JAPAN TIMES, Dec. 25, 2004.

<sup>112</sup> ROSS MOUER & HIROSUKE KAWANISHI, *A SOCIOLOGY OF WORK IN JAPAN* 131(2006).

<sup>113</sup> Futoshi Kuwamoto, *Entrepreneurial Wave Hits Campus*, NIKKEI WEEKLY, Aug. 21, 2006 (reporting that university courses taught by private sector venture-firm executives and venture capitalists have a “strong appeal” amongst many Japanese students judging from expanding class enrollment and more Japanese universities are setting up “Entrepreneur Dojos” to teach students about angel investors, burn rate, business plan writing, cashflow and IPOs).

<sup>114</sup> From 2004 to late 2005, Horie was lionized by the Japanese media and public as the poster boy of the new breed of young dynamic Japanese entrepreneur hero when he had taken on the flinty old Japanese business establishment in several high media profile business encounters which even included an unsuccessful run for political office. This adulation abruptly ended when Horie was arrested and detained by Japanese prosecutors without bail, and indicted with a litany of Enronesque high corporate crimes including accounting fraud, stock market manipulation and money laundering in a corporate scandal that even forced the Tokyo Stock Exchange to suspend trading after a deluge of

B. 1000 University Venture-based Companies by 2005

The Japanese government also sought to aggressively nurture and encourage this venture startup environment by a series of legislative and deregulation reforms, which is summarized in the following table:

Summary of Japanese Legislation Supporting Venture Businesses<sup>115</sup>

1989	Law on Temporary Measures to Facilitate Specific New Businesses	Credit guarantees by Industrial Structure Improvement Fund, etc. and funding from New Business Investment Co., Ltd.
1995	Temporary Law concerning Measures for the Promotion of the Creative Business Activities of Small & Medium Enterprises enacted	Expansion of investment regulations by Tokyo Small and Medium Business Investment & Consultation Co., Ltd. and credit guarantees by Credit Guarantee Corporations.
1995	Law on Temporary Measures to Facilitate Specific New Businesses Revised	Japan's first stock option system.

panicked sell orders of Livedoor shares occurred immediately after his arrest. *See Japan after Livedoor - From Hero to Zero*, ECONOMIST, Feb. 12, 2006; 'Livedoor Shock' Brings TSE Trading to a Halt, ASAHI SHIMBUN, Jan. 19, 2006.

<sup>115</sup> Dai Higashino, *Special Report: Changing Environment for Japanese Venture Businesses*, JAPAN ECON. MONTHLY, May 2005, at 1, 2 (reporting that “[t]he old framework has been changing drastically, however, as the result of deregulation that has taken place since around 2000. In addition, several important regulations scheduled to be introduced in the future could create room for considerable growth and proliferation of venture businesses”).



1997	Temporary Law Concerning Measures for the Promotion of the Creative Business Activities of Small and Medium Enterprises revised	Individual investors who suffer losses on investments in certain small or midsize enterprises (research expenditure exceeds 3% of sales and firm is less than 5 years old) can carry over the losses ("angel tax" regulations)
1998	Limited Partnership Act for Venture Capital Investment enacted	For partnerships investing in small and midsize enterprises, which had been subject to unlimited liability in the past, members who do not take part in management can qualify for limited liability under certain conditions.
1998	Law for Facilitating the Creation of New Business enacted	Financial support for inauguration and inaugurators of new enterprises, credit guarantees and establishment of region-by-region platforms.
1999	Law for Facilitating the Creation of New Businesses revised	Improvement of legislation by providing exceptions to Commercial Law provisions for stock options, issuance of preferred stock and ex post facto inspection by auditors after establishment.

2003	Special Regulations Governing Minimum Capital Requirements enacted	Exemptions from minimum capital requirement (10 million yen for joint-stock companies and 3 million yen for limited liability companies) under certain conditions for five years from founding.
2004	Limited Partnership Act for Venture Capital Investment revised	Investment methods drastically liberalized and rules for the protection of investors introduced under the Securities and Exchange Law.
2006	Corporation Law enacted	Would unify limited-liability companies as joint-stock companies, abolish minimum capital requirements and introduce merged company regulations.

In 2001, METI announced a plan to realize 1,000 university-based venture companies by March 2005<sup>116</sup> and it is clear that the Japanese government has hit this numerical target as it was reported that there were 1141 such startups by 2005.<sup>117</sup> The short term results were indeed promising given the spread of university-based venture businesses, which are helping to link technology and business.<sup>118</sup> “The economic effects of these ventures, including indirect spin-offs, were 21,000 employees and 300 billion yen in annual sales” where

<sup>116</sup> MINISTRY OF ECONOMY, TRADE AND INDUSTRY, PLAN FOR THE CREATION OF NEW MARKETS AND NEW JOBS HIRANUMA PLAN (OUTLINE) (2001) (last visited Apr. 9, 2007), <http://www.meti.go.jp/english/information/data/cPlan010525e.html>.

<sup>117</sup> See MINISTRY OF EDUCATION, CULTURE, SPORTS, SCIENCE AND TECHNOLOGY, FY2005 WHITE PAPER ON EDUCATION, CULTURE, SPORTS, SCIENCE AND TECHNOLOGY 28 (2006).

<sup>118</sup> Higashino, *supra* note 112, at 3.

twelve such venture companies have gone public and “another 180 or so are expected to do so sometime in the future.”<sup>119</sup>

More promisingly for the biotechnology ventures, venture capital firms invested 28 billion yen in biotechnology and medical start-ups in fiscal 2004, more than double the amount in 2003,<sup>120</sup> although Japan still has to work harder in order to shake off its reputation as a “venture capital wasteland” because “Japan, with an economy half the size of the U.S., consumed one-twelfth as much venture capital. Singapore got \$1 billion from U.S. venture capitalists, ten times what Japan got.”<sup>121</sup> Nevertheless, there appears to be positive developments in the right direction.<sup>122</sup>

## V. TECHNOLOGY TRANSFER

Patents are the cornerstone of any successful biotechnology venture anywhere in the world, especially so in the cradle of the world's biotechnology industry, the United States of America, where the ability to harness biotechnology breakthroughs through the establishment of patent rights is fundamental to its very existence.<sup>123</sup> The importance of patenting to biotechnology cannot be overstated, as Japanese companies have expressed that one of the keys to the success in biotechnology business in Japan is the “possession of key basic patents in relevant fields.”<sup>124</sup> In fact, the second highest ranked issue confronting any decision to enter into the biotechnology

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<sup>119</sup> *Id.*

<sup>120</sup> *Venture Capitalists Double Investment in Bio/Medical Sectors*, NIHON KEIZAI SHIMBUN, Jul. 5, 2005.

<sup>121</sup> Kelly, *supra* note 45.

<sup>122</sup> *Venture Capital Firms Ramp Up Private Equity Investment In FY06*, NIHON KEIZAI SHIMBUN, Dec. 5, 2006.

<sup>123</sup> “[T]he biotechnology industry would not have emerged ‘but for the existence of predictable patents.’” See FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3, 17 (2003).

<sup>124</sup> JAPAN EXTERNAL TRADE ORGANIZATION, BIOTECHNOLOGY-RELATED PRODUCTS, JAPANESE MARKET REPORT NO. 47, 31 (2000).

business in Japan is that “basic patents are already held by other companies.”<sup>125</sup>

A. *Weak and Almost Nonexistent Infrastructure*

Although the Japanese business community always had a direct appreciation of the importance of patents in its business affairs, Japanese academia had an “anti-patent mentality” where “the climate surrounding intellectual property was anything but hospitable in Japanese universities.”<sup>126</sup> There was also weak or almost nonexistent university infrastructure<sup>127</sup> to transfer such university-based intellectual property rights<sup>128</sup> to industry. Again, the disparity between the American<sup>129</sup> and Japanese university venture environments is demonstrated by the inability of Japanese universities to leverage ideas into new companies. Japanese universities played an insignificant role in the startup community as it was observed that while 2,624 startups emerged from American universities between 1980 and 2000, Japanese universities produced a paltry 240 startups between 1980 and 2001.<sup>130</sup>

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<sup>125</sup> *Id.* at 39.

<sup>126</sup> See Hisamitsu Arai, *National Intellectual Property Strategy and Industry Academic Collaboration*, 1 ACTEB REV. 15, 15-16 (2003).

<sup>127</sup> One main reason why Japan's past biotechnology efforts had persistently underperformed was Japan's late recognition of the role of universities in technology transfer of research fruit in biotechnology sciences. See generally Robert Kneller, *University-Industry Cooperation and Technology Transfer in Japan Compared with the U.S.: Another Reason for Japan's Economic Malaise?*, See 24 U. PENN. J. INT'L ECON. L. 329 (2003); Leonard Lynn & Reiko Kishida, *Changing Paradigms for Japanese Technology Policy: SMEs, Universities, and Biotechnology*, 3 ASIA BUS. & MGMT. J. 459 - 478 (2004); See William A. Blanpied, *Technology Transfer in Japan: An Overview and Sampling of Current Activities*, in NAT'L SCI. FOUND. TOKYO SPEC. SCI. REP. NO. 03-03 (2003), available at <http://www.nsfkyo.org/ssr03-03.html> (last visited Jan. 26, 2007).

<sup>128</sup> See Lynne Zucker & Michael Darby, *Capturing Technological Opportunity via Japan's Star Scientists: Evidence from Japanese Firms' Biotech Patents and Products*, 26 J. TECH. TRANSFER 37, (2001) (reporting that Japanese universities had generally low levels of basic research in molecular biology and that scientific knowledge at universities was inadequately transferred and applied toward industrial innovation).

<sup>129</sup> See Anita Sharpe, *A Biotech Deal Maker Stalks Ventures in Groves of Academe*, WALL ST. J., June 8, 1998, at B1.

<sup>130</sup> *Business Looks to Academia for Ideas*, NIKKEI WEEKLY, May 27, 2002.

From the late 1980s to early 1990s, at “the end of steep economic growth, international economic competition, and concomitant rivalry in cutting-edge technologies and generally feeling apprehensive about the future,” Japanese industry actually turned to Japanese universities as it “could not ignore the importance of universities’ roles in terms of developing human resources and basic research;” leading to stern industry calls “for more openness and transparency in both the institution and academics and, secondly, the hope for the training of highly specialized talent, rich in originality and creativity,” but Japanese industry was faced with a university system that could not meet these expectations.<sup>131</sup> University and government “bureaucratic red tape” inhibited the development of Japanese university-industry collaborations to such an extent that “Japanese companies found it easier and more fruitful to conduct collaborations with overseas universities, especially U.S. ones, who were naturally aggressive in pursuing links with industry.”<sup>132</sup>

The Japanese government sought to modify this dysfunctional university-industry relationship with the centerpiece of its university-industry reform effort to transform Japanese universities into venture company incubators<sup>133</sup> by improving “the universities’ ability to manage IP, including evaluation of inventions, technology marketing.” “[C]lear rules and regulations enabl[ed] universities to own the IP generated by their researchers . . . [with] funding . . . secured for filing patent applications and prosecuting them.” The Japanese government chose “34 universities and provided them with subsidies to encourage IP activities.”<sup>134</sup> As part of the reforms to encourage more university-industry exchanges, Japanese national university academics were allowed to take up side jobs or consulting positions with private sector companies.

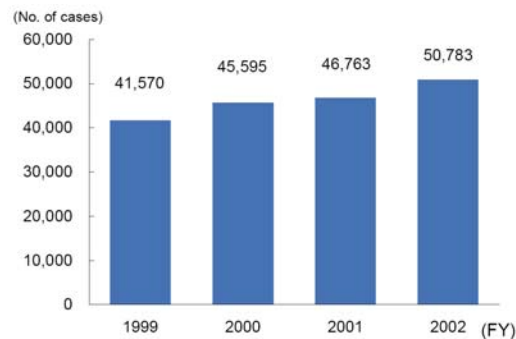
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<sup>131</sup> AMANO, *supra* note 73, at 161.

<sup>132</sup> Whittaker, *supra* note 43, at 78 (noting that in fiscal 1999, Japanese companies spent ¥154 billion on research in overseas institutions compared with ¥73 billion for domestic institutions).

<sup>133</sup> MEXT WHITE PAPER, *supra* note 80, at 93 (reporting that a National Incubator Center was established in order “to support the nurturing of start-ups at universities”).

<sup>134</sup> See Ichiro Nakayama, *Intellectual Property Strategy in Japan: Towards an IP-based Nation*, in PATENTS, INNOVATION AND ECONOMIC PERFORMANCE, OECD PROCEEDINGS 301, 301-308 (OECD ed. 2005).



Trend in number of side job approvals by national universities<sup>135</sup>

The response has been overwhelming for the period FY1999 to FY2002 as over 180,000 authorizations were issued by national universities, as illustrated in the preceding graph. The scales have also fallen from the eyes of the Japanese business media who, in the early 1980s, disparagingly ridiculed American academics who by selling “out to business had threatened the free flow of scientific information and corrupted the mission of basic research enterprise.”<sup>136</sup> Japanese universities have now even made the “pot sweeter” for inventor-professors in order to attract top quality researchers.<sup>137</sup>

#### B. Japan Adopts Bayh-Dole University Technology Transfer Model

In order to facilitate technology transfer from Japanese universities to industry,<sup>138</sup> Japan emulated the successful American Bayh-Dole model<sup>139</sup> of university technology transfer. “Section 30 of

<sup>135</sup> S&T WHITE PAPER, *supra* note 85, at 356 fig. 3-3-14.

<sup>136</sup> COLLINS, *supra* note 32, at 132.

<sup>137</sup> Japanese universities were raising the amount that a professor could earn from a patent to, on average, 30% of royalties or licensing fees and “Kyushu Institute of Technology will give an attractive 56 per cent,” CURIOSITY *supra* note 68 at 218.

<sup>138</sup> Keisuke Isogai, *The University's Role in Industry-Academia Collaboration and Related Government Policies*, 1 ACTEB REV. 6 (2003).

<sup>139</sup> Lita Nelsen, *The Rise of Intellectual Property Protection in the American University*, 279 SCIENCE 1460 (1998) (noting that “intellectual property scarcely existed in the vocabularies of U.S. academic researchers and administrators even 15 years ago. Now it is an ever-present part of discussions on research policies and directions” and that “the phrase 'Bayh-Dole' is heard frequently in Japan and Germany as their educational ministries seek to emulate the U.S. university technology transfer system”).

the Industrial Revitalization Law- the so-called Japan version of the U.S. Bayh-Dole Act - was put into force in October 1999, which allows the researcher to whom government-sponsored research has been commissioned to fully own patent rights, etc, gained through research.”<sup>140</sup> The Japanese government introduced the following legislative reforms to achieve these goals:

Summary of Japanese Government Measures Supporting University-Industry Co-operation<sup>141</sup>

1998	Law Promoting University-Industry Technology Transfer Enacted	Promotes development of TLOs.
1998	Law for the Promotion of Research Exchanges Revised	Permits use of state-owned land at low cost for joint research by industry and academia.
2000	Law to Strengthen Industrial Technology Eacted	Ban on holding side jobs or business by national university academics lifted and free use of national universities’ facilities by licensed, authorized TLOs permitted.
2001	Priority Plan for Creation of New Markets and Employment	A “three-year, 1,000 university-based venture companies plan” announced.
2004	National Universities Incorporated	Flexible personnel system based on ability and performance & other deregulation measures to ensure autonomy of university administration

<sup>140</sup> S&T WHITE PAPER, *supra* note 85, at 349.

<sup>141</sup> Higashino, *supra* note 115, at 3.

2004	Patent Law Partly Revised	Patent-related fees for universities and TLOs lowered.
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Japanese university administrations began to enact transparent university intellectual property policies in regards to inventions made by their respective academics.<sup>142</sup> Ownership of such academic-originating inventions reside with the universities, instead of personally with the professors, which was the case in the past.<sup>143</sup>

As is common with many reform efforts, the beneficiaries of said reform had some initial trepidation because the government, industry and university all realized that:

[C]loser collaboration between universities and businesses would definitely boost Japan's competitiveness, [although] the psychological and legal barriers that exist between university researchers and those in business circles are formidable. There is still a strong belief among university scientists that they should focus on academic research and keep their distance from the profit-oriented business sector.<sup>144</sup>

<sup>142</sup> See Kazumi Matsushige & Hisateru Oku, *Dealing with Intellectual Property Issues at Kyoto University After Its Incorporation*, 29 BIMONTHLY A.I.P.P.I. 335 (2004) (spelling out the terms and conditions of how Kyoto University handles compensation distribution with industry or academic partners, ownership of intellectual property, confidentiality, intellectual property management and other relevant issues concerning university IP management and regulation).

<sup>143</sup> ERNST & YOUNG, *supra* note 7, at 78 (noting that this change in ownership “gives universities the incentive to commercialize the invention, much like the Bayh-Dole Act did in the United States”); see also Robert Kneller, *Transformation of Japan's National Universities into Administratively Independent Corporations*, 34 LES NOUVELLES (Canada) 1 (2004) (reporting that “despite recent progress, the ability of many TLOs to make expeditious, rational technology management decisions is still doubtful”).

<sup>144</sup> Sachiko Hirao, *Top Schools Eye Uneasy Alliance with Private Sector*, JAPAN TIMES, Dec. 27, 2001.



Benefits of the university-industry policy reforms began to appear,<sup>145</sup> as according to a METI survey, when thirty-nine technology TLOs earned 2.9 billion yen in licensing income in 2004, about 5.2 times more than in 2003, an amazing achievement by any measure.<sup>146</sup> One immediate effect of this increased university-industry co-operation is the opening up of research conducted by Japanese universities to foreign companies, a proposition which would have been unthinkable unless these university TLO reforms had been enacted.<sup>147</sup>

As such, Japanese universities appear to have successfully made the transition into university/industry technology transfer, even though Japanese university technology licensing offices<sup>148</sup> (TLOs) are a relatively recent phenomenon.<sup>149</sup> The robust upward trend of patent

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<sup>145</sup> ERNST & YOUNG, *supra* note 7, at 78 (noting that “Tokyo University stands to make about ¥3.5 billion (\$32 million)” if it sells a stake of one of its startups which had a successful IPO).

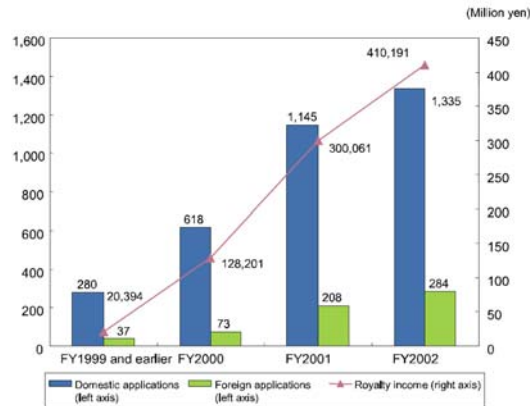
<sup>146</sup> *Univ-Related Tech Licensing Groups Earn 5.2 Times More In FY04*, NIHON KEIZAI SHIMBUN, May 24, 2005. For a less sanguine view see Robert Kneller, *The New Japanese System of Technology Transfer: Concerns Related to the Role of University IP Centers*, 39 LES NOUVELLES 69 (2004).

<sup>147</sup> Uta Harnischfeger, *Schering to Research Aging in Japan*, FINANCIAL TIMES, Sep. 15, 2003 (reporting that Berlin-based pharmaceutical maker, Schering AG, decided to establish a research center in a biotechnology cluster in Kobe where the Japanese Riken Center for Developmental Biology, a research institute, was also situated); *see also* Whittaker, *supra* note 43, at 59 (reporting the 2001 successful acquisition by an Australian materials company, Silex Systems Ltd., of worldwide patents relating to new semiconductor material technology originating from Keio University).

<sup>148</sup> S&T WHITE PAPER, *supra* note 85, at 346 (The Law for Promoting University-Industry Technology Transfer came into force in August 1998, with “the aim of pioneering new business fields, improving industrial technology, and revitalizing research activities at universities by promoting the patenting of university research results.” The law defines the desired TLO operations as (1) Discovery, evaluation, and screening of research activities that can be commercialized, (2) Filing patents of university research results, managing granted patents, (3) Licensing of patents and other intellectual property rights to companies and (4) Recycling of royalties and other relevant incomes. The law asserts that approved TLOs are eligible for support from the Japanese government through subsidies and preferential treatment in fees and government industrial support programs.).

<sup>149</sup> Japan's first TLO was only formed on December 4, 1998. *See* MINISTRY OF ECONOMY, TRADE & INDUSTRY, TASK FORCE ON INDUS. COMPETITIVENESS & INTELL. PROP. POL'Y REP. 7 (2002).

application filings and patent royalty revenue streams of Japanese universities' TLOs, as evidenced from the following chart, demonstrates that at least some Japanese universities appear to be shedding their past anti-patent inhibitions.



Trend in TLO patent applications & royalty revenue<sup>150</sup>

However, Japanese academia's relative inexperience and unfamiliarity with patent law arcana coupled with the eternal fear of being scooped by a rival research group, means that Japanese scientists may hastily publish their research prior to filing patent applications. This haste limits patent protection for potentially lucrative university based inventions when such subject matter irretrievably enters into the public domain. Fortunately, Japan has a statutory six month safe harbor against such (novelty destroying publication) under its patent law that can salvage all Japanese patent rights.

## VI. PUBLISH AND NOT PERISH

### A. *Sisyphean Academic Dilemma of Publishing or Perishing*

There is an almost Sisyphean task for any worthy academic who, on one hand, is almost genetically encoded to promptly publish the fruits of his/her scientific research, since such academic publications are the primary basis for “promotion, tenure and research

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S&T WHITE PAPER, *supra* note 85, at 348 fig. 3-3-10.

funding.”<sup>151</sup> On the other hand, publication before filing a patent application leads to the inevitable perishing of one's potentially lucrative patent rights, as the novelty requirement of various national patent laws “discourage early publication.”<sup>152</sup>

Recently, U.S. universities and research institutes have developed a voracious appetite for filing patent applications for inventions created by their academic faculty and students<sup>153</sup> and consequently, there has been a paradigm shift in attitudes resulting in academics resorting to publication delays<sup>154</sup> in light of such patenting and commercialization activities.<sup>155</sup> The reasons for this upward spike in U.S. university patenting and commercialization is better explained elsewhere<sup>156</sup> but such U.S. academic research has been

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<sup>151</sup> NATIONAL RESEARCH COUNCIL, ISSUES FOR SCIENCE AND ENGINEERING RESEARCHERS IN THE DIGITAL AGE 42 (2001).

<sup>152</sup> *Id.*; cf. Rachel Teitelbaum & Mark S Cohen, *Publish and Perish: What Constitutes a Bar Under the Patent Laws* 22 NATURE BIOTECHNOLOGY 1149 (2004); John E. Vick, Jr., *Publish and Perish: The Printed Publication Bar to Patentability*, 18 AIPLA Q. J. 235, 237 (1990).

<sup>153</sup> See Stuart J. H. Graham & David C. Mowery, *Intellectual Property Protection in the U.S. Software Industry*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 245 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (noting the number of patents issued to U.S. universities and colleges more than doubled between 1979 and 1984, more than doubled again between 1984 and 1989, and doubled yet again between 1989 and 1997 with the increasing majority of university inventions being directed to biomedical technologies and software inventions actually saw a decline during the same period).

<sup>154</sup> David Blumenthal et al., *Withholding Research Results in Academic Life*, 277 J. AM. MED. ASS'N 1224, 1224 (Apr. 16, 1997) (stating that approximately 20% of life science researchers delayed publication of their studies more than six months at least once for reasons associated with patents and commercialization considerations).

<sup>155</sup> WESLEY M. COHEN ET AL., INDUSTRY AND THE ACADEMY: UNEASY PARTNERS IN THE CAUSE OF TECHNOLOGICAL ADVANCE, IN CHALLENGES TO RESEARCH UNIVERSITIES 188, 188-89 (Linda R. Cohen et al. eds., 1998) (finding in a survey of industry-university research centers that over half of the centers permitted firms to request publication delays and 35% of the institutions allowed researchers to delete information prior to publication. At those centers with a mission to improve industrial products and processes, 63% allowed publication delays and 54% permitted the deletion of information).

<sup>156</sup> SHEILA SLAUGHTER & LARRY L. LESLIE, ACADEMIC CAPITALISM: POLITICS, POLICIES, AND THE ENTREPRENEURIAL UNIVERSITY 6 (1997) (noting that U.S. corporations turned increasingly to research universities in this period for “science-based products and processes to market in a global economy.”) See also

recognized as a significant factor in the development of new products and processes in the biotechnology, pharmaceutical and medical device industries.<sup>157</sup> Therefore, given that academia in Japan emulates their U.S. counterparts in patenting the fruits of research, it is not surprising that these academics will face similar dilemmas: the risk of destroying possible patent rights by publishing their potentially lucrative patentable academic fruits before securing any patent application rights.

*B. Japan's Novelty Grace Period - Statutory Provisions*

Fortunately, the patent fruits of Japanese academic research may not be lost by such pre-patent filing disclosures due to the Japanese patent law safe harbor. The six-month safe harbor provides that even though an inventor publishes the contents of a patentable invention prior to filing a patent application, there is a grace period offering protection for such pre-filing disclosures subject to the applicant satisfying several conditions under Japanese patent law.<sup>158</sup>

Not only is Japan the second largest biotechnology market in the world, it is also the world's second largest economy.<sup>159</sup> Japanese patent law will impact a global biotechnology company's patent assets because, notwithstanding the noble aspirations of those that

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David Mowery, et. al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RESEARCH POL'Y 99-119 (2001). It was observed that the "basic economic truth underlying research performed by large universities — it is a business, and universities derive substantial commercial value from that research." Stephen G. Kunin & Linda S. Therkorn, *Workshop on Future Public Policy and Ethical Issues Facing the Biotechnology Industry* 86 J. PAT. & TRADEMARK OFF. SOC'Y 501, 503 (2004).

<sup>157</sup> Edwin Mansfield, *Academic Research and Industrial Innovation: An Update of Empirical Findings*, 26 RESEARCH POL'Y 773, 774 (1998) (reporting that between 1986 and 1994, 15% of new innovations would not have been developed without substantial delay in the "absence of academic research").

<sup>158</sup> Tokkyo Hō [Patent Law], Law No. 121 of 1959, art. 67-2-2; see also John A. Tessensohn & Shusaku Yamamoto, *Japan's Novelty Grace Period Solves the Problem of Publish and Perish*, 25 NATURE BIOTECHNOLOGY 55 (2007).

<sup>159</sup> See STATISTICS BUREAU, MINISTRY OF INTERNAL AFFAIRS AND COMMUNICATION, STATISTICAL HANDBOOK OF JAPAN 2005 25 (2005); cf. PANOS MOURDOUKOUTAS, *NEW EMERGING JAPANESE ECONOMY: OPPORTUNITY AND STRATEGY FOR WORLD BUSINESS 1* (2005) (noting "Japan's 127 million people with stable jobs, a high per capita income and savings, crowded into a land area equal to California, and a growing appetite for western products makes it the world's second largest market after the US. Which company wouldn't be reaching for it?").

prophesize about global patent harmonization,<sup>160</sup> amongst the respective national patent laws in the United States, Europe and Japan (the three main industrial economies of the world), there are many impediments on this long rocky march to international patent harmonization.<sup>161</sup> Although Japan's six month grace period is not widely utilized,<sup>162</sup> the fact that Japan has a grace period is one example of the lack of harmonization amongst the three major patent jurisdictions in the world. In Europe, there is no such grace period.<sup>163</sup> In the United States there is a one year grace period against such inventor's own publications.<sup>164</sup>

Japan's six month grace period is only applicable where the "person having the right to obtain a patent" has (1) conducted an experiment, (2) made a presentation in an online or printed publication, (3) made a presentation in writing at a Japanese Patent Office (JPO) designated study meeting or (4) at an international exhibition held in the territory of a country party to the Paris Convention or of a Member of the World Trade Organization by its government, or by a person authorized thereby, or at an international

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<sup>160</sup> See Donald S. Chisum, *The Harmonization of International Patent Law*, 26 JOHN MARSHALL L. REV. 437, 437 (1993); Gerald J. Mossinghoff & Vivian Ku, *World Patent System Circa 20XX, A.D.*, 38 IDEA 529, 535 (1998); Heinze Bardehle, *A New Approach to Worldwide Harmonization of Patent Law*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 303, 303 (1999).

<sup>161</sup> See Anthony D. Sabatelli & J.C. Rasser, *Impediments to Global Patent Law Harmonization*, 22 N. KY. L. REV. 579, 579 (1995); Anneliese M. Seifert, *Will the United States Take the Plunge into Global Patent Law Harmonization? A Discussion of the United States' Past, Present, and Future Harmonization Efforts*, 6 MARQ. INTEL. PROP. L. REV. 173, 187 (2002).

<sup>162</sup> Only 0.42% of all patent applications filed in Japan in 1999 invoked the provisions of the Japanese law concerning the grace period. See JAPANESE PATENT OFFICE, *THE SURVEY ON THE USAGE OF THE GRACE PERIOD IN JAPAN*, WIPO Doc. GP/CE/I/3, no. 28 (2000) (on file with author).

<sup>163</sup> Joseph Straus, *Expert Opinion on the Introduction of a Grace Period in the European Patent Law*, available at <http://www.european-patent-office.org/news/pressrel/pdf/straus.pdf> (last visited January 26, 2007); see also Joseph Straus, *Grace Period and the European and International Patent Law - Analysis of Key Legal and Socio-Economic Aspects*, 20 IIC STUDIES: STUDIES IN INDUS. PROP. & COPYRIGHT L. 1, 3 (Gerhard Schrickler ed., 2001).

<sup>164</sup> 35 U.S.C. §102(b) (an invention is not patentable if it was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States).

exhibition held in the territory of a country not a party to the Paris Convention nor a member of the World Trade Organization, or by a person authorized thereby where such country has been designated by the Commissioner of the Patent Office.<sup>165</sup> It should be noted that Japan's novelty destroying statutory bars are far wider in scope<sup>166</sup> than the acts that are entitled to Japan's grace period are limited to these four prescribed instances. Therefore, if there was a prior sale of the invention before it was filed as a patent application, such act of sale is not covered by Japan's grace period.<sup>167</sup> If the product embodying the claimed invention was publicly disclosed at a trade show or a scientist's presentation of research findings at a university symposium, where there is no duty of confidentiality on the attendees of such trade show or university symposium (anywhere in the world), such act of making the product public knowledge will destroy the novelty of the invention.<sup>168</sup>

C. *Japanese Patent Office Designation of Japanese Universities*

In order to assist Japanese academia and researchers' new mission to avoid the loss of potential lucrative patent rights as a result of pre-filing disclosures of scientific research at Japanese universities or research institutes, the JPO (an agency under METI's umbrella) amended its standards in December 2001 and April 2002 to more easily designate universities and public research institutes as scientific bodies entitled to the statutory grace period protection.<sup>169</sup>

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<sup>165</sup> Tokkyo Hō, art. 30, para. (1).

<sup>166</sup> Tokkyo Hō, art. 29, para. (1). Japan's novelty destroying provisions are article 29, paragraph (1)(i) inventions which were publicly known in Japan or abroad prior to the filing of the patent application; article 29, paragraph (1)(ii) inventions which were publicly worked in Japan or abroad prior to the filing of the patent application, and article 29, paragraph (1)(iii) inventions which were described in an online or printed publication distributed in Japan or elsewhere prior to the filing of the patent application.

<sup>167</sup> Tokkyo Hō, art. 29, para. (1).

<sup>168</sup> Tokkyo Hō, art. 29, para. (1).

<sup>169</sup> Tokkyo Hō, art. 29, para. (1). As of July 1, 2001, 62 universities, 3 technical colleges, 2 institutions for joint use among universities, 12 independent administrative agencies, and 29 public laboratories were designated as scientific bodies. JAPAN PATENT OFFICE, ANNUAL REPORT 2002, 31 (2003).

Therefore, as a result, designated universities or research institutes can now enjoy the benefit of this six month grace period protection against its academic or researchers' own pre-filing publication or disclosures. This would eliminate the possibility of any loss of important Japanese patent rights as a result of pre-filing disclosures or publications at scientific seminars or lectures held at these designated universities or research institutes. Since 2001, many Japanese universities and research institutes have been designated by the JPO Commissioner as scientific bodies that are entitled to enjoy the grace period.<sup>170</sup>

The designation of such universities will be helpful in view of the greatly increased international research collaboration between academics from Japanese and foreign universities, as evidenced by the rising trend of international co-authorship of Japanese scientific papers.<sup>171</sup> More importantly for Japanese biotechnology, the fields that showed the most robust rate of increase in international co-authorship collaboration were clinical medicine and biology, life sciences and agriculture.<sup>172</sup>

The fields of Japanese science and research are becoming more internationalized in Japan,<sup>173</sup> therefore, if Japan's own patent-destroying disclosure regarding discoveries or research occurs at any

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<sup>170</sup> As of March 31, 2006, 157 universities, 25 technical colleges, 30 technical colleges, 12 inter-university research institute corporations, 26 independent administrative institutions, 56 public testing laboratories and 593 academic societies have been designated. JAPAN PATENT OFFICE, ANNUAL REPORT 2006, 67 (2006).

<sup>171</sup> There has been a phenomenal increase in international co-authorship of Japanese scientific papers relating to biology/, life sciences/, agriculture (an increase of 271 to 2751) and clinical medical fields (435 to 3184) between 1981 to and 2003. As impressive as these Japanese numbers are, they are still dwarfed by the increase in U.S. international co-authored papers (1,946 to 14,513 and 3,236 to 13,363) for the same scientific fields over the same time period. See S&T INDICATORS, *supra* note 86, at 248, 251-253.

<sup>172</sup> *Id.* (reporting in the international co-authorship ranking, that Japan remained the lowest among the nine countries, like the U.S., U.K., France, Germany and even China, throughout the period from 1981 to 2001).

<sup>173</sup> Kenji Tamura, *Japanese Scientists Use English or Get the Silent Treatment*, ASAHI SHIMBUN, Nov. 11, 2005 (reporting on efforts by Japanese scientists to reach a wider audience by authoring their research in English, "the standard language in the world of science" and if Japanese research institutes adopted English speaking environments, Japan would be able to attract "more competitive researchers from abroad.").

designated Japanese universities or research institutes before filing a patent application, such pre-filing disclosure would not lead to a total loss of Japanese patent rights. Foreign scientists can utilize Japan's six month grace period and salvage their Japanese patent rights.

So, this designation will offer a big advantage to international scientific research conducted with Japanese universities and research institutes. The current list of these grace period designated bodies is maintained by the JPO and is composed exclusively of Japan-based research institutes, without inclusion of a single foreign university, research institute or scientific body.<sup>174</sup> However, the JPO has indicated that it is open to accepting applications from overseas scientific bodies, subject to satisfaction of certain requirements, and to grant them JPO-designated status in order to to enjoy the six month grace period protection.<sup>175</sup>

#### D. Requirements of Japan's grace Grace Period

The Japanese grace period application can *ONLY* only be filed (1) as an international PCT patent application designating Japan *OR* or (2) directly with the Japanese Patent Office within six months from date of novelty destroying publication. It is not possible to claim the benefit of Japan's six month grace period by filing a Paris Convention priority application in a member country within six months of publication and then file a Japanese national application or international PCT patent applications designating Japan within one year claiming the benefit of the Paris Convention application's priority date.<sup>176</sup> The grace period can only be claimed by filing either (1) or (2) as explained earlier.<sup>177</sup> When filing the international PCT application designating Japan, the applicant should indicate the circumstances leading to the claim of the grace period claim in the

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<sup>174</sup> Japan Patent Office, Patent Law Section 30 Designated Scientific Bodies List, Feb. 28, 2007, <http://www.jpo.go.jp/torikumi/30jyou/30jyou2/dantai.htm> (last visited March 22, 2007) (in Japanese).

<sup>175</sup> Japan Patent Office, Procedures for Designation of Scientific Bodies and Exhibitions under Section 30 of the Patent Law, Dec. 18, 2001, [http://www.jpo.go.jp/torikumi\\_e/hiroba\\_e/toku30e\\_0117.htm](http://www.jpo.go.jp/torikumi_e/hiroba_e/toku30e_0117.htm) (last visited January Feb. 24, 2007).

<sup>176</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as last revised at Stockholm, July 14, 1967, art. 28, 21 U.S.T. 1583, 828 U.N.T.S. 305.

<sup>177</sup> Tessensohn & Yamamoto, *supra* note 158, at 56.



PCT Request.<sup>178</sup> When the applicant is entering into the Japanese National Phase, the grace period claim must be made.

Within thirty days from the date of entering into the Japanese National Phase at the JPO, a copy of the presentation of the invention (*e.g.* a copy of the publication of the abstract of the invention - this copy need not be certified) must be filed. The presentation copy must include the name of the publication, the date of issuance of the publication (publication or online availability date), the name(s) of the person(s) who presented the abstract, the persons who are the inventors; and an abstract which indicates the claimed invention. If the aforesaid person(s) who presented the abstract are not the same as the inventors of the subject patent application, a reason must be provided.<sup>179</sup>

It should be noted that not all printed publications are eligible to enjoy Japan's grace period as it has been held by Japan's Supreme Court that the phrase "printed publication" excludes the applicant's counterpart foreign patent publication.<sup>180</sup> In interpreting Section section 30(1), the Supreme Court held that it does not apply to disclosures in a foreign patent gazette (in that case, it was the U.S. patent gazette). This is another instance of lack of harmonization between the United States and Japan, because in the United States, it is possible to exclude the applicant's own patent publication in the United States, but such publications are not eligible for grace period

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<sup>178</sup> Patent Cooperation Treaty, June 19, 1970, 9 I.L.M. 978 [hereinafter PCT]; *see also* PCT, R. 4.17(v), R. 51.1(a)(v); WORLD INTELLECTUAL PROPERTY ORGANIZATION, NOTES TO THE REQUEST FORM (PCT/RO/101) 3 (2006); U.S. DEPT. OF COMMERCE, PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE, app. AI, 15-16 (2006) [hereinafter MPEP].

<sup>179</sup> Tokkyo Hō, art. 30, para. (4).

<sup>180</sup> The Supreme Court of Japan interpreted the term "printed publication" as:

an act whereby the person having the right to obtain a patent (*i.e.* an inventor or an applicant) makes an invention public or known, with his active intention to make it public or known. However, in a disclosure through a patent gazette, there is merely his passive intention of admitting a third person's act of making the invention public or known. Therefore, the disclosure in a patent gazette does not fall within the term *printed publication*.

Hoechst AG v. Commissioner of JPO, 1337 HANREI JIHŌ 117 (Sup. Ct., Nov. 10, 1989) (emphasis added).

protection in Japan.<sup>181</sup> Furthermore, if disclosure of the applicant's invention was made against the will of the inventor, it is possible to file a Japanese grace period patent application within six months of such novelty destroying disclosure.<sup>182</sup>

In summary, it would be far better to secure patent filing rights prior to any publication of the contents of the patent application, but in the event that publication before filing had occurred, patent rights in Japan are not absolutely lost as there is a six month grace period that can be used subject to satisfying certain conditions. This safety net against pre-filing inventors' disclosures is especially useful in light of the fact that Japanese universities are expected to be the incubators of patent-based enterprises.

The Japanese government's designation of Japanese universities and research institutes to be entitled to Japan's novelty grace period is part of a contemporary pro-owner, pro-patentee ferment in the overall attitude and spirit of Japan's intellectual property laws in the last 10 ten years or so.

## VII. INTELLECTUAL PROPERTY REFORM

The stated statutory purpose and spirit of Japanese patent law is to "encourage inventions by promoting their protection and utilization so as to contribute to the development of industry."<sup>183</sup> Historically, it was accurate to characterize that Japan's patent system was operated more in favor of the users of the patent file (in doing research and development)<sup>184</sup> than the patentee.<sup>185</sup> Japan's patent system was well suited to Japan's historical position as a late

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<sup>181</sup> It is possible for the applicant to overcome the printed publication novelty statutory bar under 35 U.S.C. § 102(b) in the United States by filing affidavits or declarations submitted under 37 C.F.R. § 1.131 to "swear behind" a reference. MPEP, *supra* note 178, app. R, 92.

<sup>182</sup> Tokkyo Hō, art. 30, para. (2).

<sup>183</sup> Tokkyo Hō, art. 1.

<sup>184</sup> Toshiko Takenaka, *The Role of the Japanese Patent System in Japanese Industry*, 13 UCLA PAC. BASIN L. J. 25, 25 (1994).

<sup>185</sup> NATIONAL RESEARCH COUNCIL, *supra* note 22, at 14 (arguing that the American system gives "stronger protection for the patentee and the Japanese system [is] more focused on teaching industry new innovations and diffusing technology").

developer (in terms of Japan developing from feudal isolation after the 1868 Meiji Restoration and emerging from the rubble of defeat after World War II). Japan started off as a borrower and adaptor of foreign technology, rather than a technology leader.<sup>186</sup> This borrower-adaptor innovation model became one of the crucial pillars in Japan's industrial prowess. For example, the Japanese invented neither robots nor photocopiers, but in a just a few years they became leaders in both technologies because the Japanese strategy was to spend two thirds of its R&D money on "improving products and processes, whereas the United States spent two-thirds of its money on developing new products."<sup>187</sup>

One notable Japanese borrower-adaptor innovation model was Sony's storied license of the transistor patent from U.S. Bell Labs.<sup>188</sup> However, there were daunting technological difficulties to overcome and improvements to be made in commercializing such patented transistor technology.<sup>189</sup> Japanese industry has an unparalleled improvement innovation skill.<sup>190</sup> Japan's improvement innovation model is in stark contrast to America's current global leadership<sup>191</sup> in

<sup>186</sup> See Janusz Ordover, *A Patent System for Both Diffusion and Exclusion*, 5 J. ECON. PERSPECTIVES 212-229 (1991).

<sup>187</sup> LESTER THUROW, *FORTUNE FAVORS THE BOLD* 196 (2003).

<sup>188</sup> JOHN NATHAN, *SONY: THE PRIVATE LIFE* 32 (1999).

<sup>189</sup> TESSA MORRIS-SUZUKI, *THE TECHNOLOGICAL TRANSFORMATION OF JAPAN: FROM THE SEVENTEENTH TO THE TWENTY-FIRST CENTURY 171-72* (1994). Sony's rapid conquest of the transistor radio market was not accomplished by simply implanting transistors into the existing technology of the radio because early transistors could not deal with the high frequencies necessary to broadcast human voices. Sony had to research further technical improvements in order to successfully implement the transistor technology into radios.

<sup>190</sup> *The Future of Japanese Business: Competing Through Innovation*, *ECONOMIST*, Dec. 17, 2005, at 60 [hereinafter *Future Japanese*]. The Economist reports that Japanese companies are focusing on "making things first and only then pausing to think about how to improve them or put them to new uses." *Id.* When done right, Japanese companies "can innovate so quickly that they leave western competitors grasping for air." *Id.*

<sup>191</sup> DOMESTIC POL'Y COUNCIL, OFF. OF SCI. & TECH. POL'Y, *AMERICAN COMPETITIVENESS INITIATIVE: LEADING THE WORLD IN INNOVATION* 4-5 (2006) (noting that "[b]y nearly every relevant metric, the U.S. leads the world in science and technology" and "[w]ith only about five percent of the world's population, the U.S. employs nearly one-third of all scientists and engineers and accounts for approximately one third of global R&D spending . . ."), available at <http://www.whitehouse.gov/stateoftheunion/2006/aci/aci06-booklet.pdf>.

breakthrough basic science.<sup>192</sup> Science and technology will determine the continued success of the U.S. economy,<sup>193</sup> which is indisputably the world's most innovative market.<sup>194</sup>

Previously, it was feared that Japan could translate this 'industrial improvement' innovation strategy into biotechnology. One of the legendary founders of Genentech had warned that:

In Japan, the biggest share of every research dollar is funneled into bioprocess engineering rather than into basic research. The Japanese have relied on the United States and other countries to provide the breakthroughs. Then, by rapidly applying considerable expertise in process development and scale-up, they can jump well ahead and

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<sup>192</sup> DONALD E. STOKES, PASTEUR'S PASTEUR'S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION 4, 61-68, 103-106 (1997) (arguing that biotechnology research is simultaneously fundamental and commercially useful as most inquiry in biotechnology is "use-oriented" basic research). Not surprisingly, biotechnology is one of the rare fields that in which one can typically find journal publications disclosing discoveries that also are patented, which explains America's business dominance in the field. See generally Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177, 177-231 (1987); Philippe Ducor, *Intellectual Property: Coauthorship and Coinventorship*, 289 SCIENCE 873, 873-75 (2000).

<sup>193</sup> Lamar Alexander, *Nurturing the Next Einsteins*, 307 SCIENCE 1013, 1013 (Feb. 18, 2005) (noting that Americans' "future economic competitiveness and quality of life depend on [their] ability to stay ahead of the scientific and technological curve").

<sup>194</sup> However, there are growing fears that the U.S. may lose its leadership position in science and technology in the future. See COMMITTEE ON SCI., ENGINEERING, & PUBLIC POL'Y, *RISING ABOVE THE GATHERING STORM: ENERGIZING AND EMPLOYING AMERICA FOR A BRIGHTER ECONOMIC FUTURE* 61 (2006). The authors were "deeply concerned that the scientific and technological building blocks critical to our economic leadership are eroding at a time when many other nations are gathering strength." *Id.*, see also William J. Broad, *Top Advisory Panel Warns of an Erosion of the U.S. Competitive Edge in Science*, N.Y. TIMES, Oct. 13, 2005, at A22; Rick Weiss, *Our Incredible Shrinking Curiosity*, WASH. POST, Apr. 10, 2005, at B1 (questioning the wisdom of several U.S. government agencies' recent "shift in "focus away from blue-sky research and toward goal-oriented . . . endeavors").

capture a large share of the world market for biotechnology products.<sup>195</sup>

This did not happen because some 30 years later, while Japan still leads the world in patent applications, “almost all are for new uses or derivatives of existing technologies.” The United States still “holds a tremendous lead in many high-tech fields such as aerospace, energy, advanced medical care and pharmaceuticals and biotechnology” as a result of America’s “strong structure for basic science making it possible for Americans to get the basic patents for the new areas.”<sup>196</sup>

Apparently, “Japan’s style of innovation failed it in biotechnology and software and biotechnology in the 1990s” as Japanese companies “have not counted for much in software, the internet, and biotechnology and other high high-growth industries of the past decade” because of “a lack of creativity, flexibility and risk taking.”<sup>197</sup> Its “method of management and organization,” was “no match for the rapid rate of change in cutting-edge industries” like biotechnology, software and the internet.<sup>198</sup> This lack of “risk taking” in biotechnology was glaringly illustrated by Japanese industry’s missed opportunity in spurning biotech behemoth Amgen’s early efforts to find a Japanese partner when Amgen was but a struggling startup.<sup>199</sup>

#### A. Dishonorably Regarded As Lenient to Infringement

In any event, the Japanese government’s overall approach to intellectual property has altered dramatically<sup>200</sup> as there was a

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<sup>195</sup> See Robert A. Swanson, *Entrepreneurship and Innovation: in Biotechnology*, in THE POSITIVE SUM STRATEGY 429, 431 (Ralph Landau & Nathan Rosenberg eds., 1986).

<sup>196</sup> Fujio Mitarai, *My Agenda: Innovate Japan*, JAPAN ECHO, Oct. 2006, 28, 28-29. Mitarai is the CEO of Canon Corporation. Canon Corporation, no innovation slouch, “has been consistently in the top three in terms of patent registrations for the past 14 years.” *Id.*

<sup>197</sup> *Future Japanese*, *supra* note 190.

<sup>198</sup> *Future Japanese*, *supra* note 190, at 59.

<sup>199</sup> See Langreth, *supra* note 20.

<sup>200</sup> See Takahiko Kondo, *Roles of the Intellectual Property Rights System in Economic Development in the [sic] Light of [sic] Japanese Economy*, 25 AIPPI 28, 28-37 (2000).

realization that Japan's ways had to change fundamentally.<sup>201</sup> The goal was to transform Japan from "a market that is dishonorably regarded as lenient towards infringement where one can infringe on whatever patent he likes because court proceedings are slow and compensation insignificant," to an innovation/patent patent-based "system that that goes beyond mere egalitarianism to secure suitable rewards for superior corporate performance."<sup>202</sup> The primary reason for this change in mindset was that from the late 1990s "many copied Japanese products, made in China and other Asian countries, have been imported into the country, dealing a blow to [Japan's] domestic companies."<sup>203</sup>

Therefore, many Japanese companies showed an increased readiness, and even sophistication, when they had to resort to litigation within Japan to solve business conflicts,<sup>204</sup> effectively dispelling the myth of the reluctant Japanese litigant.<sup>205</sup>

It was noted that "in a globalized business world marked by a battle with time, companies have come to seek judicial systems and choose battlegrounds beneficial to their own interests" and given the

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<sup>201</sup> See Hisamitsu Arai, *The Road of an Intellectual Property-Based Nation*, in NAT'L CENTER FOR INDUS. PROP. INFO., REPORT ON THE INTERNATIONAL PATENT LICENSING SEMINAR 2004, 116 (2004) (observing that if all Japan did "was making prototypes—if US comes up with some basic invention, Japan produces a prototype, improves it, then sends it to China or some other countries in Asia to have it mass-produced—[Japan] can never hope to feed [its] 120 million people").

<sup>202</sup> See Takeshi Isayama, Commissioner, Japan Patent Office, Keynote Address at the Annual Meeting of Intellectual Property Owners, (Nov. 16, 1998), in 13 WORLD INTELL. PROP. L. REP. 31, 31-32 (1999), available at [http://www.jpo.go.jp/shiryou\\_e/toushin\\_e/kouenroku\\_e/0916ipo.htm](http://www.jpo.go.jp/shiryou_e/toushin_e/kouenroku_e/0916ipo.htm).

<sup>203</sup> Morio Koyama, *Patent, Copyright Reform Eyed*, DAILY YOMIURI, May 23, 2003.

<sup>204</sup> *Corporations Take Shine to Legal Action*, NIHON KEIZAI SHIMBUN, Oct. 25, 1999 (reporting that a whopping 95% of 168 surveyed Japanese companies have "been involved in legal disputes" with 83% having sued other firms in Japan, with one-third saying they had initiated legal action against concerns overseas and "many of the cases stem from the collapse of the bubble economy, the globalization of commercial activity and technological innovation.").

<sup>205</sup> John A. Tessensohn, *Reluctant Patent Litigants - Breaking the Myth in Japan*, 20 ABA-IPL NEWSL. 1, 5 (2002). See generally John Haley, *The Myth of the Reluctant Litigant*, 3 J. JAPANESE STUDIES 359 (1978); Carl F. Goodman, *The Somewhat Less Reluctant Litigant: Japan's Changing View Towards Civil Litigation*, 32 LAW & POL'Y INT'L BUS. 769 (2001); Thomas Ginsburg & Glenn Hoetker, *The Unreluctant Litigant? Japan's Japan's Turn Toward Litigation*, 35 J. LEGAL STUDIES 31 (2006).

slow turning of the wheels of justice in Japan, many Japanese plaintiffs have enforced their patent rights in overseas courts, particularly in the United States, so that the Japanese judiciary experienced “a hollowing out, of sorts, leaving the courts in a sense of crisis.”<sup>206</sup>

*B. Japan Inspired by American Pro-Patent Policy*

The patent law transformation was also spurred by Japan's adoption<sup>207</sup> of the American inspired pro-patent policy<sup>208</sup> where such a pro-patent policy<sup>209</sup> was seen as a crucial part of improving Japan's economic productivity.<sup>210</sup> The pace of IP legislative reform was

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<sup>206</sup> Isayama, *supra* note 202, at 32. This hollowing-out was characterized as “legally undermining of Japan's Japan's patent system” as well, *See* HISAMITSU ARAI, POL'Y ADVISORY COMMISSION, WORLD INTELL. PROP. ORG., INTELLECTUAL PROPERTY POLICIES FOR THE TWENTY-FIRST CENTURY: THE JAPANESE EXPERIENCE IN WEALTH CREATION 27-31 (1999), *available at* [http://www.wipo.int/export/sites/www/freepublications/en/intproperty/834/wipo\\_public\\_834.pdf](http://www.wipo.int/export/sites/www/freepublications/en/intproperty/834/wipo_public_834.pdf) (noting the disturbing trend of Japanese companies that are suing their Korean and Taiwanese rivals in overseas courts, rather than Japanese courts even when the Japanese plaintiffs possess counterpart patents within Japan).

<sup>207</sup> *See* John A. Tessensohn & Shusaku Yamamoto, *Reaping the Fruits of a Pro-Patentee Era*, 85 MANAGING INTELL. PROP. 28, 28-35 (1999).

<sup>208</sup> The inspiration for Japan's pro-patent policy is John A. Young, *Global Competition - The New Reality: Results of the President's Commission on Industrial Competitiveness* [hereinafter Young Report], in THE POSITIVE SUM STRATEGY 501, *supra* note 195, at 501-510 (Ralph Landau & Nathan Rosenberg eds., 1986).

<sup>209</sup> Japanese policy makers have singled out the Young Report as helpful background in formulating their own Japanese pro-patent policy. *See* PLANNING SUBCOMM. OF THE INDUS. PROP. COUNCIL, REP. OF THE PLANNING SUBCOMM. OF THE INDUS. PROP. COUNCIL TO THE BETTER UNDERSTANDING OF PRO-PATENT POLICY 10 (1998) (reporting that “since the Young Report, the U.S. has been pursuing pro-patent policy in order to enhance the value of intellectual property”).

<sup>210</sup> *See* Q. Todd Dickinson, Acting USPTO Commissioner, Remarks Before the Section on Intellectual Property of the American Bar Association (June 24, 1999), *available at* <http://www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/624aba.pdf> (remarking that in pointing to a “prescient” but “relatively obscure report from the mid-1980's” - the so-called Young Report - “the Japanese are seeking to increasingly emulate our (U.S.) systems. They see the success of the U.S. economy, the productivity gains that are resulting from increased automation and the information age, and they

especially feverish in the last several years<sup>211</sup> as amendments to Japan's patent and other intellectual property laws have become a "regular annual event."<sup>212</sup> Last year, 2006, a high level of intellectual property activity on the legislative calendar was sustained.<sup>213</sup>

IP law reforms became a focal part of the Japanese government's goal of being an "intellectual-property based nation."<sup>214</sup> These IP law reforms are a paradigm example of domestic pressure (*naiatsu*).<sup>215</sup> Even though the United States Trade Representative (USTR)<sup>216</sup> had long called for numerous deregulation changes to

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firmly believe that our IP systems, as they have developed over the last two decades are one of the key factors in this current success").

<sup>211</sup> Nakayama, *supra* note 134, at 888.

<sup>212</sup> See Matsuo Nonaka, *Japanese Legislative Updates on Intellectual Property in 2004*, UNIV. OF WASH. CASRIP NEWSL., Spring/Summer 2004, at 7, available at <http://www.law.washington.edu/Casrip/Newsletter/Vol11/newsv11i2.pdf>. See also Hiroshi Kawamata, *Japanese Legislative Updates on Intellectual Property in 2005*, UNIV. OF WASH. CASRIP NEWSL., Fall 2005, available at <http://www.law.washington.edu/Casrip/Newsletter/Vol12/newsv12i2Japan1.html> (last visited January 26, 2007) which reported another busy legislative year for intellectual property in 2005 at the Japanese Diet.

<sup>213</sup> *METI Seeks Stiffer Penalties For Intellectual Property Violations*, NIHON KEIZAI SHIMBUN, Feb. 28, 2006. See also JAPANESE PATENT OFFICE, *supra* note 170, at 52-58 (detailing the 2006 legislative changes made to Japan's intellectual property laws aimed to "increase the international competitiveness of Japanese industry through the creation of designs, the establishment of brands (trademarks), and the creation of innovative inventions (patents), while also giving consideration to international harmonization of these systems").

<sup>214</sup> JAPAN PATENT OFFICE, ANNUAL REPORT 2003 17 (2004) ("In order to realize the 'Intellectual Property Based Nation', it is essential and indispensable to establish the pro-patent policy which enables granting patents to excellent techniques without missing the timely opportunities for commercialization as well as protecting and exploiting such techniques.").

<sup>215</sup> It appears that domestic pressure (*naiatsu*) from Japanese interest groups, and to a lesser extent institutions, have more of an effect than the international pressure (*gaiatsu*) exerted by the United States in deregulation attempts in opening up the various sectors of the Japanese economy. See Robert Bullock, *Market Opening in Japan: Deregulation, Reregulation, and Cross-Sectoral Variation*, in *NEW PERSPECTIVES ON U.S.-JAPAN RELATIONS* 42 (Gerald Curtis ed., 2000).

<sup>216</sup> The U.S. Government, through the offices of the United States Trade Representative, has a notorious international trade policy tool for motivating foreign countries, especially Japan, to reform their intellectual property regimes or



Japan's many laws, including its IP laws, these USTR calls were politely denied or clarified by the Japanese government.<sup>217</sup> Meanwhile, away from the rarefied diplomatic niceties, Japanese industry had been in the forefront<sup>218</sup> in urging the Japanese government to reform Japan's domestic intellectual property and patent laws so that they would be able to have effective legal/IP litigation tools within Japan to deal with counterfeit or patent infringing products from China, Taiwan and Korea. More importantly, Japanese companies are increasingly "going to court to protect their patents on technologies pertaining to computer microchips and flat-panel displays" after its "bitter experience in the semiconductor industry. Japan, once the leader in dynamic random access memory (DRAM) chips, was unseated by Asian neighbors in the 1990s because they failed to control the key patents."<sup>219</sup>

Some of these far-reaching pro-patent legislative reforms and judicial developments included: 1) changing Japan's patent laws to make Japan a pro-patent environment<sup>220</sup> by allowing applicants to obtain their patent rights quicker through expedited examination of

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any other national practices, if they are prejudicial to American trade interests. See Donald G. Beane, THE UNITED STATES AND GATT - A RELATIONAL STUDY 217-18, 231-35 (2000); see generally MANUAL FOR THE PRACTICE OF U. S. INTERNATIONAL TRADE LAW (William K. Ince ed., 2002).

<sup>217</sup> The USTR issues its annual National Trade Estimate Report which catalogs the latest trade sins of America's trading partners and the Japanese government issues its polite but firm annual rebuttal. See generally GOVERNMENT OF JAPAN, COMMENTS OF THE GOVERNMENT OF JAPAN ON 2005 NATIONAL TRADE ESTIMATE (NTE) REPORT (2005), available at <http://www.mofa.go.jp/region/n-america/us/economy/date/nte2005.pdf>.

<sup>218</sup> See PLANNING SUBCOMM. OF THE INDUS. PROP. COUNCIL, *supra* note 209, at 3; INTELL. PROP. COMM. OF THE INDUS. STRUCTURE COUNCIL, REPORT 39 (2001). In fact, the Keidanren had been one of the primary domestic voices for Japan to build up a comprehensive strategic technology policy. See JAPAN FED'N OF ECON. ORG., TOWARD THE FOUNDATION OF A STRATEGIC INDUSTRIAL TECHNOLOGY POLICY (1998), <http://www.keidanren.or.jp/japanese/policy/pol210/honbun.html> (last visited Apr. 19, 2007) (in Japanese).

<sup>219</sup> *Once Bitten, Twice Prone to Sue*, ASAHI SHIMBUN, Nov. 11, 2004 (reporting Japanese electronics companies like Toshiba, Sharp, Matsushita, Fujitsu & Renesas have sued Taiwanese, Korean and Chinese rivals for patent infringement).

<sup>220</sup> See John A. Tessensohn, *Japan Casts Off Dishonor in IP World Order*, 13 WORLD INTELL. PROP. L. REP. 315, 318 (1999).

patent applications,<sup>221</sup> 2) making it easier for patentees to enforce their patent rights against infringers,<sup>222</sup> 3) confirming the availability of patent infringement under the doctrine of equivalents,<sup>223</sup> 4) granting an *inter partes* preliminary injunction against a Japanese knockoff of Apple Computer's iconic iMAC personal computer in 28 days after the motion was filed,<sup>224</sup> 5) widening the scope of indirect infringement,<sup>225</sup> 6) expanding the scope of patentable inventions to cover software-related inventions and business methods as software related inventions,<sup>226</sup> 7) reducing the plaintiff's burden in calculation of patent infringement damages resulting in higher damage awards against patent infringers,<sup>227</sup> 8) making it easier for patentees to use streamlined Japanese customs procedures to seize imports of patent-infringing goods at the nation's ports and checkpoints,<sup>228</sup> 9)

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<sup>221</sup> See John A. Tessensohn, *Japan Speeds up Patent Reform*, 114 PATENT WORLD 25, 27 (1999).

<sup>222</sup> See John A. Tessensohn & Shusaku Yamamoto, *Purging Dishonor 2000 - A Watershed Year for Japanese Patent Litigation*, 8 INTELL. PROP. TODAY 1, 1 (2001) (reporting on the changes in the Japanese patent infringement environment and how courts have sped up their infringement hearing docket).

<sup>223</sup> See John A. Tessensohn & Shusaku Yamamoto, *Doctrine of EAT Equivalents Adds Torque to Japanese Patent Infringement*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 483, 483 (1999).

<sup>224</sup> See John A. Tessensohn, *Court Grants Preliminary Injunction Against Sale of iMac Look-Alike*, 13 WORLD INTELL. PROP. L. REP. 393 (1999).

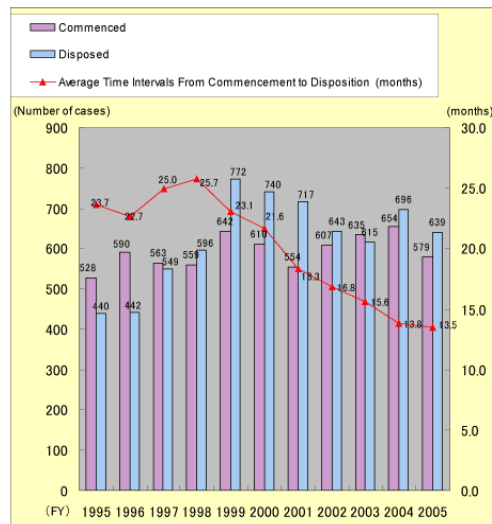
<sup>225</sup> See John A. Tessensohn & Shusaku Yamamoto, *Planning For Effective Patent Enforcement*, in MANAGING INTELL. PROP. xv (2004) (expanding the scope of what conduct constitutes indirect infringement of patent rights).

<sup>226</sup> See John A. Tessensohn & Shusaku Yamamoto, *Japanese Patent Office Confirms Patentability of Business Methods*, PATENT STRATEGY & MANAGEMENT 11 (2001).

<sup>227</sup> See John A. Tessensohn & Shusaku Yamamoto, *Slot Machine Patent Infringement Case Brings New Damages Award Record*, 16 WORLD INTELL. PROP. L. REP. 10, 10 (2002) (reporting that Japanese Courts have responded to the recent trend of Japanese companies using patent litigation to protect their business interests by granting bigger damage awards - at least by Japanese); see also Toshiko Takenaka, *Patent Infringement Damages in Japan and the United States: Will Increased Patent Infringement Damage Awards Revive the Japanese Economy?*, 2 WASH. U. J.L. & POL'Y 309 (2000).

<sup>228</sup> See Ian Rowley, *The Japan That Can Say: 'See You In Court'*, BUS. WK., Nov. 29, 2004, (reporting "the litigation genie is out of the bottle" in Japan in view of Matsushita's successful Japanese Customs action stopping LG Electronics' importation of infringing flat panel display televisions into Japan).

streamlining the Japanese Patent Office procedures by abolishing patent oppositions, 10) modifying the invalidation appeal procedure to eliminate duplicative work and achieve more prompt resolution of patent litigation disputes,<sup>229</sup> and 11) confirming the right of a Japanese venture company to obtain a preliminary injunction even though it had exclusively licensed its patent to a third party and this Japanese venture company argued the matter all the way to the Supreme Court to obtain this ruling.<sup>230</sup> One high point of these IP reforms was the April 1, 2005 establishment of a specialized appellate court, the Intellectual Property High Court of Japan, whose purpose was to “realize reinforcement and speeding up of litigations concerning intellectual property rights.”<sup>231</sup>



<sup>229</sup> See John A. Tessensohn & Shusaku Yamamoto, *New Invalidation Appeal System*, 25 EURO. INTELL. PROP. REV. N-154, N-154 (2003).

<sup>230</sup> See John A. Tessensohn & Shusaku Yamamoto, *Japan's Patentee Injunction Right Preserved*, 152 MANAGING INTELL. PROP. 29, 29-31 (2005).

<sup>231</sup> See John A. Tessensohn & Shusaku Yamamoto, *Commentary - Establishment of Japan's Intellectual Property High Court*, 19 WORLD INTELL. PROP. L. REP. 21, 21-22 (2005) (The Intellectual Property High Court of Japan, a specialized IP appellate court is similar in spirit and intent to the United States Court of Appeals of the Federal Circuit [CAFC]). The Intellectual Property High Court's homepage is available at <http://www.ip.courts.go.jp/eng/index.html>.

Number of IP litigations and Disposal Time Period<sup>232</sup>

This will add momentum to the series of administrative and policy changes to speed up hearings within the Japanese judiciary<sup>233</sup> which contributed to the statistically significant reduction in the disposal period of IP-related litigation (from 23.1 months in 1994 to 13.5 months in 2005) as the aforesaid graph demonstrates.

C. *Extensive IP Law Reforms Enacted*

The aforementioned, extensive IP law reforms have transformed the Japanese legal and business attitudes and operating environment. Even large Japanese electronics companies are “abandoning their traditional reticence and moving to fight patent infringement” and enforce their hard-earned patent rights in Japan, thereby confirming the success of Japan's pro-patent policy.<sup>234</sup> It is worthwhile to note that the IP law and judicial reforms were a small part of the larger wave of legal reform that swept Japan from the late 1990s,<sup>235</sup> introducing a jury-like system of lay judges set to come into force in 2009.<sup>236</sup> This reformist pro-patent attitude is now deeply

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<sup>232</sup> See INTELLECTUAL PROPERTY HIGH COURT, STATISTICS, NUMBER OF INTELLECTUAL PROPERTY CASES COMMENCED AND DISPOSED, AND AVERAGE TIME INTERVALS FROM COMMENCEMENT TO DISPOSITION, [http://www.ip.courts.go.jp/eng/documents/stat\\_03.html](http://www.ip.courts.go.jp/eng/documents/stat_03.html) (last visited January 26, 2007).

<sup>233</sup> Judge Ryosuke Yasunami, *Trend of Lawsuits over Intellectual Property Rights & Measures Taken by Courts for Faster Proceedings*, 26 AIPPI 135, 135-45 (2001).

<sup>234</sup> See Andrew Morse, *Japan's Firms Do More Duels in Court*, WALL ST. J., Mar. 14, 2005, at A15; Todd Zaun, *Japanese Discover the Art of the Lawsuit*, N.Y. TIMES, Dec. 3, 2004, at W1; *Patents a Retail Issue Too, Sharp Case Shows*, ASAHI SHIMBUN, June 15, 2004; *Fujitsu Uses Suits to End Patent Fight*, NIKKEI KEIZAI SHIMBUN, June 8, 2004; Phred Dvorak, *Japan Intellectual-Property Fights Heat Up*, WALL ST. J., Mar. 14, 2005, at B4.

<sup>235</sup> John O. Haley, *Heisei Renewal or Heisei Transformation: Are Legal Reforms Really Changing Japan?*, 10 J. JAPAN L. 5, 5 (2005) (reaching a pessimistic conclusion about the impact that these legal reforms have on Japanese corporate governance and finding that organizational autonomy “remains as before . . . [there is no] fundamental change”).

<sup>236</sup> *Id.* at 6; see also Masami Ito, *Lay Judgment In Practice - Workings of a Watershed*, JAPAN TIMES, Feb. 27, 2005; Fumio Tanaka, *Tribunals to Shorten Work Feuds*, DAILY YOMIURI, Mar. 3, 2006 (reporting the Japanese Supreme Court's appointment of 997 people as the first generation of lay labor

ingrained in the Japanese management lexicon, philosophy and practice.<sup>237</sup> Notwithstanding these remarkable short-term developments, Japan has a 10 year IP reform plan, recognizing that it may be difficult to change the mindset of those over-40s, therefore Japan “must wait for the growth of the younger generation in their 20s and 30s to revamp the system.”<sup>238</sup>

### VIII. BIOTECHNOLOGY POLICY CHANGES

In light of the constraints imposed by Japan's past structural and cultural impediments discussed hereinabove, it was not surprising that the Japanese domestic biotechnology market has been labeled as “very immature”<sup>239</sup> compared to the U.S., U.K. and German markets. Notwithstanding its alleged immature status, Japan's biotechnology market was valued at ¥1.66 trillion, (about USD11.6 billion) in 2003,<sup>240</sup> “making it the second largest [national biotechnology market] in the world [after] the United States.”<sup>241</sup> This calculation is based on including the value of the respective biotechnology contributions of Japanese companies that are not stand alone biotechnology entities but also have other areas of specialization within the company such as pharmaceuticals, chemicals or even beer.

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judges for the system, which will be implemented before the lay judge system starts in 2009).

<sup>237</sup> See Yoshinori Mori, *Form Practice: IP Management in Japanese Companies*, in *MANAGEMENT OF TECHNOLOGY AND INNOVATION IN JAPAN* 374 (Cornelius Herstatt et al. eds., 2006) (confirming “the increasing role of patents as weapons in the struggle to compete” in the current business environment).

<sup>238</sup> This candid admission was from Hisamitsu Arai, Secretary General of the Intellectual Property Strategy Headquarters, the Cabinet Secretariat. See *Intellectual Property Must Be Managed Like Valuable Asset - Nurture Creativity; Reward Japan's Risk-Takers*, JAPAN TIMES, Dec. 26, 2005, at 8-9.

<sup>239</sup> *Global Value Chains in the Pharmaceuticals Industries, Technologies, and Value Chain*, in *RECOVERY FROM SUCCESS: INNOVATION AND TECHNOLOGY MANAGEMENT IN JAPAN* 91 (D.H. Whittaker et al. eds., 2006).

<sup>240</sup> JAPAN EXTERNAL TRADE ORGANIZATION, *ATTRACTIVE SECTORS - BIOTECHNOLOGY 1* (2005), available at <http://www.jetro.go.jp/en/market/attract>.

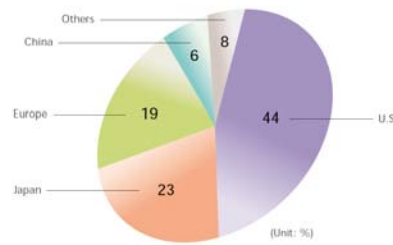
<sup>241</sup> *Id.*

This feature is a unique trait of Japan's biotechnology industry. Even though Kirin Brewery Co. Ltd.'s core business is primarily the production and sale of beer, it also possesses a formidable diversified biotechnology business encompassing transgenic animal biotechnology.<sup>242</sup>

A. *World's Second Largest National Biotechnology Market Growing*

In any event, the Japanese biotechnology sector is growing<sup>243</sup> as Japanese applicants file the second highest number of biotechnology patent applications after the United States, as demonstrated by the following graph, which shows the biotechnology patent applications filed at the Japanese Patent Office (JPO) by country share.<sup>244</sup>

Biotechnology patent applications by country share



As part of a larger reform program to pull Japan out of the persistent economic downturns in the late 1990s, the Japanese government began to “piece together” a “multiagency initiative” aimed at bolstering the country's biotechnology industry by spring 2000.<sup>245</sup> The Japanese government matched its rhetoric by digging

<sup>242</sup> See Rathin C. Das, *Antibodies: The Comeback Kids of the Biotech World*, 32 AM. BIOTECH. LABORATORY 18, 18 (2000) (reporting the global alliance between Kirin, which would provide US \$12 million to Medarex for the right to exclusive distribution of Medarex's HuMab - Mouse technology in Asia. Kirin also granted the exclusive distribution right of its Transchromosomal Mouse to Medarex outside of Asia).

<sup>243</sup> Akemi Nakamura, *Businesses Bustle to Board Biotech Bandwagon*, JAPAN TIMES, Aug. 7, 2001 (reporting that “many Japanese companies are running to catch the bandwagon for the emerging biotech business.”).

<sup>244</sup> JAPAN EXTERNAL TRADE ORGANIZATION, *supra* note 240, at 4.

<sup>245</sup> Dennis Normile, *Japan Readies Huge Increase in Biotech*, 285 SCIENCE 183, 183 (1999).

deep into its pocketbook.<sup>246</sup> Consequently, METI earmarked Japan's biotechnology industry as one of seven focus areas in its strategy for Japan's future economic well being.<sup>247</sup>

Historically, Japan's successful industrial policy consisted of Japan's leaders setting "strategic goals at the highest levels of state power" where the Japanese government bureaucrats in the ministries like MITI/METI, Ministry of Finance and other economic bureaucracies, like a military command, "devise plans, announce their goals, and then expect industries to develop their own tactical plans." Therefore, although "in some aspects, the Japanese economy can be said to be planned, the ministries are very flexible and harness the power of market forces to achieve their strategic ends."<sup>248</sup>

*B. Past abortive Japanese government biotechnology policies*

As admirable as these contemporary biotechnology plans were, there was a curious sense of *déjà vu* because the Japanese government had carried out a similar multiagency biotechnology effort in March 1991.<sup>249</sup> Unfortunately, at that time, the Japanese government's biotechnology plans were "not greatly respected by many Japanese executives in biotechnology-related companies,"<sup>250</sup> and most of the Japanese corporate "diversification into biotechnology was a disappointment. Commercialization has taken longer, been more technically difficult, and been more dependent on factors unique to

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<sup>246</sup> Asako Saegusa, *Japan Declares Five-year Plan to Double Genome Research Funds*, 400 NATURE 389, 389 (1999); see also Asako Saegusa, *Japan Banks on Budget to Boost Biotechnology*, 18 NATURE BIOTECHNOLOGY 142, 142 (2000).

<sup>247</sup> Biotechnology was one of seven technology fields that the Japanese government will give priority in providing assistance to boost the nation's global competitiveness and drive the future growth of the Japanese economy. See *Govt. To Name 7 Key Industrial Fields In New Initiative*, NIHON KEIZAI SHIMBUN, Mar. 23, 2004.

<sup>248</sup> BRIAN MCVEIGH, *THE NATURE OF THE JAPAN STATE: RATIONALITY AND RITUALITY* 119 (1998).

<sup>249</sup> See NATIONAL RESEARCH COUNCIL, *supra* note 19, at 17 (reporting that "the most striking aspect of Japanese government support for biotechnology is its commercial orientation and the number of agencies involved"). As of March 1991, there were five Japanese government agencies involved in biotechnology. *Id.*

<sup>250</sup> OFFICE OF TECHNOLOGICAL ASSESSMENT, *supra* note 17 at 157.

each industrial sector than expected. Biotechnology has not achieved the spectacular success that other fields have for Japanese industry,” and the Japanese industry “had become too powerful to be unwillingly guided into targeted investments” by the Japanese government<sup>251</sup> and such a top down approach is actually anathema to the root of biotechnology – basic scientific research – especially in America.<sup>252</sup>

The Japanese government has taken the lead in transforming Japan's moribund biotechnology sector with its very ambitious plans and a prediction that the domestic biotechnology market will grow to 25 trillion yen by 2010.<sup>253</sup> The current measures are different in spirit and substance from the previous failed biotechnology efforts<sup>254</sup> and other doomed government deregulation policies, where until 1997 (an impressive 1797 deregulation programs in 11 economic sectors were listed by the Japanese government) just listing items did “not actually deregulate Japanese systems,” the Japanese government “could mandate as many exceptions to the liberalization as they would like” and the new plans “still left a lot of leeway in the implementation of the deregulation measures,”<sup>255</sup> thereby

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<sup>251</sup> OFFICE OF TECHNOLOGICAL ASSESSMENT, *supra* note 17, at 150, 158.

<sup>252</sup> Komberg, *supra* note 78, at 6-7 (observing that the system of direction of research “from the top down has operated in Europe and Japan” but it does not work as well in the U.S. where it is a “bottom up system” where “the individual scientist “assumes full responsibility and can commit the passion needed to achieve and gain recognition for that achievement.”).

<sup>253</sup> *Can the Biotech Market Hit 25 Trillion Yen?*, NIKKEI WEEKLY, Oct. 11, 2005 (reporting that Japanese industry survey respondents were skeptical of the “government's rosy scenario” and that “personalized medical care tailored to each patient's genetic makeup” and “regenerative medicine” are not likely to be commercializable until 2020 in view of the absence of a legal framework regulating the use of such genetic-based therapies).

<sup>254</sup> OFFICE OF TECHNOLOGICAL ASSESSMENT, *supra* note 17, at 245 (reporting that in 1981, MITI boldly “announced its goal of matching U.S. biotechnology within 5 years” but it would appear that the quest for world biotechnology supremacy did not exactly turn out the way Japan had envisaged).

<sup>255</sup> See MAYUMI ITO, GLOBALIZATION OF JAPAN: JAPANESE SAKOKU MENTALITY AND U.S. EFFORTS TO OPEN JAPAN 182-183 (1998) (listing the deregulated economic fields ranging from housing and land, distribution, information and telecommunications, finance, securities and insurance, employment and labor, importation of housing products, taxi business, abolition of licenses for retail salt sales, altering cellular phone rates from an approval system to an advance notification system).



undermining the overall effectiveness of these reforms.

### C. *Avoiding Past Policy Failures*

Presumably to avoid the previous underachieving coordination efforts amongst government ministries<sup>256</sup> and the bureaucratic infighting that hamstrung Japan's first generation genomic activities,<sup>257</sup> the Biotechnology Strategy Council was established in 2002, with the Japanese Prime Minister's involvement lending some *gravitas* to it.<sup>258</sup> The finalized 2002 Biotechnology Strategy Guidelines issued by the Biotechnology Strategy Council called for unified planning, drafting and comprehensive coordination of "budgetary allocation policies and their execution," for all budgets biotech-related science and technology budgets (amongst the Council for Science and Technology Policy, related ministries and agencies), and to build up and improve the funding functions of budget-allocating institutions with competitive research funds and transparent evaluation criteria.<sup>259</sup>

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<sup>256</sup> Robert Triendl, *New Biotech Council in Japan*, 20 NATURE BIOTECHNOLOGY 763, 763 (2002) (reporting that Japan's "past experiences suggest that policy co-ordination will not come easily - despite a series of efforts and committees over the past few years, little has been achieved thus far").

<sup>257</sup> OFFICE OF TECHNOLOGICAL ASSESSMENT, *supra* note 17, at 156.

<sup>258</sup> S&T WHITE PAPER, *supra* note 85, at 251 (reporting a Cabinet-level initiative of Japanese Prime Minister Junichiro Koizumi, the Japanese Biotechnology Strategy Council, which provided a blueprint titled "Strategies for Development of Biotechnology" in December 2002); *see also* JAPAN EXTERNAL TRADE ORGANIZATION, JAPANESE MARKET REPORT - BIOMEDICAL 27 (2004) (highlighting Japan's efforts to undertake "considerable improvement of research and development [more than doubling the R&D budget over five years, etc.], drastic strengthening of the industrialization process (expanding tax measures to support startups, reviewing regulations on startups, etc.), and thorough public understanding (drastically stepping up the government's efforts to provide information concerning safety of genetically modified food, etc.)"). *See generally* Prime Minister of Japan, Concerning the Biotechnology Strategy Council (July 5, 2002), available at [http://www.kantei.go.jp/foreign/policy/bt/konkyo\\_e.html](http://www.kantei.go.jp/foreign/policy/bt/konkyo_e.html) (last visited January 26, 2007).

<sup>259</sup> *See* BIOTECHNOLOGY STRATEGY GUIDELINES 32-33 (2002); *see also* John A. Tessensohn & Shusaku Yamamoto, *Recent Landmark Changes in Japanese Biotechnology & University Patenting (Part II)*, 3 J. INT'L BIOTECHNOLOGY L. 152 (2006).

In the past, Japanese government biotechnology policy and funding has been the subject of non-productive turf battles<sup>260</sup> between the differing government ministries and agencies (e.g., METI, MEXT, Ministry of Labor, Health and Welfare) and their respective broad portfolios. It was observed that “eventually the bureaucrats walk off and follow the particular interest of their ministry,” resulting that “the Japanese scientific community does not have very much influence on research funding.”<sup>261</sup> It remains to be seen whether the unified planning, drafting and comprehensive coordination will improve the implementation of the 2002 Biotechnology Strategy Guidelines discussed earlier.<sup>262</sup>

Perhaps more importantly, realizing that “the government's job is not to identify promising technologies but to improve the overall environment for innovation,”<sup>263</sup> the current structural reforms described earlier were targeted to facilitate more fundamental systemic and attitudinal changes to Japan's university and academic, judicial, patent, venture company, corporate restructuring and industrial environments – all major inputs of innovation. These inputs were not even touched in the underachieving 1990s government biotechnology measures. On a macro level, it has been observed that the Japanese government, which formulates and executes reforms, is often part of the problem,<sup>264</sup> rather than the solution.<sup>265</sup>

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<sup>260</sup> ROBERT COOK-DEEGAN, *THE GENE WARS: SCIENCE, POLITICS AND THE HUMAN GENOME* 226, 229 (1994).

<sup>261</sup> See Robert Triendl, *Japanese Council Urges Reform of Funding System*, 20 *NATURE BIOTECHNOLOGY* 1176, 1177-1178 (2002).

<sup>262</sup> See *BIOTECHNOLOGY STRATEGY GUIDELINES*, *supra* note 259.

<sup>263</sup> PORTER ET AL., *supra* note 68, at 153.

<sup>264</sup> HIROSHI KATO, *KANRYOSHUDO KOKKA NO SHIPPAI* [THE FAILURE OF A BUREAUCRACY DOMINATED NATION] (1997). For the seminal English language work on Japan's omnipotent bureaucracy see CHALMERS JOHNSON, *JAPAN: WHO GOVERNS? THE RISE OF THE DEVELOPMENTAL STATE* (1995). See generally FRANK GIBNEY, *UNLOCKING THE BUREAUCRAT'S KINGDOM: DEREGULATION AND THE JAPANESE ECONOMY* (1998) (reporting how the entrenched Japanese government bureaucracy, that controls the economy with a heavy thicket of regulation and guidance, has shown little willingness or ability to make the significant reforms that Japan needs to recover); Aurelia George Mulgan, *Japan: A Setting Sun?*, *FOREIGN AFFAIRS*, July 2000, at 40 (commenting that neither the Japanese politicians nor its bureaucracy are willing give up the many benefits of the status quo, so Japan's reforms and its economy are stalled permanently); EDWARD J. LINCOLN, *ARTHRITIC JAPAN: THE SLOW PACE OF ECONOMIC REFORM* (2001)

However, there are optimistic (albeit minority) views<sup>266</sup> on the nature of the Japanese bureaucracy and there is “light at the end of the tunnel” where, “in addition to the steadily growing number of combative and determined politicians, such as Prime Minister Koizumi”, the Japanese “electorate has been roused” and “public opinion might well become a major impetus” of Japanese civil service reform,<sup>267</sup> and the Japanese bureaucracy's capacity to meaningfully execute some government reforms has even begun to bear some fruit.<sup>268</sup>

Japan's government bureaucracy is not an unchanging monolith. As a sign of how times have changed the Japanese government bureaucracy, even the “infamous MITI has even become the reform minded METI” where METI has “reinvented itself as the

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(observing that the government deregulation and other aspects of systemic economic reform in Japan have proceeded so sluggishly).

<sup>265</sup> See Hirotaka Takeuchi, *The Competitiveness of Japanese Industries and Firms, in JAPAN, MOVING TOWARD A MORE ADVANCED KNOWLEDGE ECONOMY: ASSESSMENT AND LESSONS* 47 (Tsutomu Shibata ed. 2006) (commenting that “the much celebrated Japanese government model is not the cause of Japan's post-war economic success. In fact, it is more closely associated with the nation's failures.”).

<sup>266</sup> See THE JAPANESE CIVIL SERVICE AND ECONOMIC DEVELOPMENT: CATALYSTS FOR CHANGE (T.J. Pempel & Michio Muramatsu et al. eds., 1995); Peter F. Ducker, *In Defense of Japanese Bureaucracy*, FOREIGN AFFAIRS, Sept. 1998, at 68, 68-80 (counseling that in Japan, where society's stability takes precedence over the economy, the bureaucrats' caution, bred by past traumas, is not as foolish as many Westerners think. Defending the bureaucrats is wiser than trashing them).

<sup>267</sup> Akira Namakura, *The Debilitating Power of Japan's Central Bureaucrats, in PUBLIC SERVICE REFORM IN EAST ASIA: REFORM ISSUES AND CHALLENGES IN JAPAN, KOREA, SINGAPORE AND HONG KONG* 37 (Anthony B. L. Cheung ed., 2005).

<sup>268</sup> RICHARD KATZ, *JAPANESE PHOENIX: THE LONG ROAD TO ECONOMIC REVIVAL* (2002); see also M. Diana Helweg, *Japan: A Rising Sun?*, FOREIGN AFFAIRS, July 2000, at 26 (commenting that the revolutionary changes to Japan's economy will take time and will recreate the nation from the inside out); William Horsley, *The Liberation of Japan*, 63 PROSPECT 55 (2001) (observing that the past ten years of economic stagnation in Japan has been a period of creative destruction and sets the stage for a new era of economic growth and that the “Japanese are freer than ever before from the chains of company loyalty, dependence and conformity”).

champion of deregulation.”<sup>269</sup> In fact, METI had radically transformed its “mission, character, and strategy”<sup>270</sup> for two reasons: increasing internationalization and economic globalization brought about a loss of regulatory power, and a new generation of METI officials with graduate training from the U.S. now determine its policies.<sup>271</sup> Weakened, METI has taken up the cause of deregulation, “mostly in opposition to other ministries which have cross-cutting jurisdiction over many of the service industries.”<sup>272</sup> As a result, the current METI-driven reforms generally differ in scope and spirit to previous Japanese bureaucratic reforms.<sup>273</sup>

D. *Early Fruits of University-Industry Cooperation*

METI's centerpiece of this transformation was the industrial cluster, where Japanese universities and research institutes formed cluster developments<sup>274</sup> with regional industry or university venture start-ups on the great hope that they will “become key players in industrial development”<sup>275</sup> of Japan's economy. To date, there are

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<sup>269</sup> See C. FRED BERGSTEN ET AL., NO MORE BASHING: BUILDING A NEW JAPAN-UNITED STATES ECONOMIC RELATIONSHIP 246, 264 (2001).

<sup>270</sup> Masaru Kohno, *A Changing Ministry of International Trade & Industry*, in JAPANESE GOVERNANCE: BEYOND JAPAN INC. 97 (Jennifer Amyx & Peter Drysdale eds., 2001).

<sup>271</sup> *Id.* at 109.

<sup>272</sup> *Id.* at 102.

<sup>273</sup> For an accessible, albeit opinionated, description on Japanese bureaucratic reform attempts see ALEX KERR, DOGS AND DEMONS: TALES FROM THE DARK SIDE OF MODERN JAPAN 366-367 (2002) (characterizing the Japanese bureaucracy reform efforts as “half-hearted” and “highly deceptive” with the psychology underlying them as “Epimethean” - Prometheus' brother - backward looking and valuing precedent. “[F]orced by public opinion, bureaucrats make minimal, often purely symbolic changes, while exerting most of their energies to protect the status quo. Reforms look backward, toward shoring up established systems, not forward to the new world”).

<sup>274</sup> S&T WHITE PAPER, *supra* note 85, at 362-65 (both cluster projects have the aim to create “new technology seeds by promoting joint research among industry, academia, and government in fields of creative basic research, focusing on universities and public research institutions in regional areas” and “to open up new fields for businesses, and to create start-ups and new products by promoting collaboration projects among industry, academia, and government, such as technology development that leads to practical applications, focusing on business enterprises” respectively).

<sup>275</sup> Okubo & Kobayashi, *supra* note 35, at 213.

nineteen such university startup clusters situated all over Japan<sup>276</sup> and much hope and effort has been placed on this cluster strategy.<sup>277</sup> Unfortunately, METI's past "sincere efforts" in the 1990s in designing and implementing similar industrial "network creating" have "largely failed" and "fared poorly."<sup>278</sup>

Such national government involvement has even been unflatteringly characterized as the "kiss of death" for some local cluster initiatives in Japan.<sup>279</sup> In fact, "it is difficult to say that these industry clusters have been able to achieve their intended results" of creating new regional industries and development of existing industries.<sup>280</sup> It has even been opined that "recent ambitious plans by the Japanese government to create biotech ventures will surely fail."<sup>281</sup> All these sentiments do not bode well for METI's biotech venture policies by any measure.

On the other hand, the totality of Japanese efforts outlined earlier have led some to characterize that the Japanese government, academia and private industry have been carrying out, in tandem, "an extremely well coordinated effort to excel in biotechnology"<sup>282</sup> with

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<sup>276</sup> Gov't Support for Innovation Vital, NIKKEI WEEKLY, Dec. 26, 2005.

<sup>277</sup> Takeuchi, *supra* note 266, at 41; *see also* David Kruger, *Japanese Port Looks to Medicine for a Makeover*, WALL ST. J., June 25, 2002, at A16.

<sup>278</sup> *See* KATHRYN IBATA-ARENS, INNOVATION AND ENTREPRENEURSHIP IN JAPAN 110-111 (2005) (concluding that METI was not very effective at developing sufficient conditions to foster a shared (national-local) vision among community stakeholders (and facilitating civic entrepreneurship) and most of METI's efforts was heavy on formal institution building and light on nurturing the informal social relations which were the important energizing drivers for the success of such clusters).

<sup>279</sup> *Id.* at 213.

<sup>280</sup> ECONOMIC RESEARCH INSTITUTE, JAPAN SOCIETY FOR THE PROMOTION OF MACHINE INDUSTRY, ENGINEERING INDUSTRIES OF JAPAN NO. 39: REVITALIZING THE JAPANESE MACHINE INDUSTRY AND CREATING NEW INDUSTRIES 3 (2005).

<sup>281</sup> Komberg, *supra* note 78, at 9.

<sup>282</sup> Kong Siu Kai, *The Competitiveness of Biotechnology in Japan*, 3 INT'L J. BIOTECHNOLOGY 184, 185 (2001).

“weak signals” of a bio-boom<sup>283</sup> as Japan's biotechnology sector was showing “signs of life.”<sup>284</sup> This was evident from the early excitement<sup>285</sup> in Japanese universities over venture companies,<sup>286</sup> and this was followed by some promising fledgling developments.<sup>287</sup>

University start-up ventures have currently gained wider acceptance in Japan<sup>288</sup> and several Japanese venture startups have even taken the U.S. model route of raising capital on the Japanese stock market<sup>289</sup> so much so that university/industry collaborations, especially in biotechnology, are “gaining momentum and are likely to

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<sup>283</sup> See Christian Muller & Takao Fujiwara, *The Commercialization of Biotechnology in Japan*, 7 DRUG DISCOVERY TODAY 699 (2003); Mariko Tamura, *Biotech Blastoff*, JAPAN JOURNAL, Mar. 2005, at 24.

<sup>284</sup> Keiko Kandachi, *Japan's Biotech Sector Shows Signs of Life*, 21 NATURE BIOTECHNOLOGY 1256 (2003).

<sup>285</sup> Dennis Normile, *Japanese Faculty Show Signs of Catching Start-up Fever*, 296 SCIENCE 397 (1999) (reporting that “Japanese government officials, business leaders, and editorial writers are trying to boost the sluggish economy by exhorting scientists to take the plunge in the business world”).

<sup>286</sup> See Aya Furuta, *Venture Companies Begin to Take Root*, NIHON KEIZAI SHIMBUN, June 14, 1999; *Universities Keen to Invest in Start-ups*, NIHON KEIZAI SHIMBUN, Nov. 8, 1999 (reporting that venture companies using Japanese university developed technology are “gradually but steadily increasing in Japan as more scientists and students are setting up businesses, more entrepreneurs are scouring Japan's campuses for good investments, and the government is offering more support for the emerging companies”).

<sup>287</sup> See Asako Saegusa, *Biotechnology Venture Capital Booms in Japan*, 18 NATURE BIOTECHNOLOGY 256 (2003); David Cyranoski, *Primed For A Biotech Boom - Osaka*, 437 NATURE 1060 (2005).

<sup>288</sup> Henry S. Rowen & A. Toyoda, *From Keiretsu to Startups: Japan's Push for High Tech Entrepreneurship* (Stanford Univ., Shorenstein Asia/Pacific Research Center (A/PARC), Working Papers, Oct. 2002), available at <http://aparc.stanford.edu/publications/workingpapers/>. Biotechnology ventures have been granted increased legitimacy as they secured the interest of one Japan's major trading houses which intends to “promote tieups of venture firms launched by Japanese universities and bio-companies in Europe and the U.S.” *Marubeni Buys Stake in Softbank Unit*, JAPAN TIMES, Jul. 29, 2003.

<sup>289</sup> ERNST & YOUNG, *supra* note 7, at 78 (noting that “most Japanese biotech IPOs have occurred in the past five years” with “the enthusiastic market for IPOs in 2003 pushed into 2004, but cooled during the latter part of the year” and concluding that “four of the five 2004 IPO companies were trading significantly below their debut price as of March 31, 2005 raising concerns about public offerings going forward”).

play a strong role in reducing the dependence of Japan's system of innovation on in-house R&D conducted within large corporations.”<sup>290</sup>

Judging from early results<sup>291</sup> the joint efforts of the government, universities and venture companies have contributed to the modest domestic development of a dynamic biotech environment where some biotechnologies - genetic-based customized therapies, molecular imaging and regenerative medicine - “developed in Japan features the highest level in the world.”<sup>292</sup>

Indeed such promising medical biotechnological science may, in the long run, enhance the overall competitiveness and innovation of Japanese biotech industry and play a role in the enrichment of the average salaried, white collared employees that will be employed in the new corps of knowledge-based companies that are expected to be generated by this anticipated biotechnology boom. This is the biggest difference from past attempts and why government’s current structural reforms have such Promethean potential for Japan's biotechnology. Japan's ability to reinvent itself is nothing new, as its postwar economic transformation has been amply demonstrated.<sup>293</sup>

## IX. THE CERTAIN COMMERCIAL UNCERTAINTY AHEAD

### A. Dolly - from Biotech Riches to Bankruptcy Auction

Although Japanese university venture companies carry the flag of hope and promise of future economic prosperity, like the many

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<sup>290</sup> See Kazuyuki Motohashi, *University–Industry Collaborations in Japan: The role of new Technology-based Firms in Transforming the National Innovation System*, 34 RESEARCH POL’Y 583, 584 (2005).

<sup>291</sup> See *Precision System To Be 1st Domestic Bio Venture To Turn Profit*, NIHON KEIZAI SHIMBUN, May 06, 2003; *College Ventures (1): Nearly 60% Of Start-Ups Profitable In FY04*, NIHON KEIZAI SHIMBUN, Aug. 10, 2005; *College Ventures (2): More Than Half Plan To Go Public*, NIHON KEIZAI SHIMBUN, Aug. 10, 2005.

<sup>292</sup> *Japan Biotech Plays to Strengths*, NIKKEI WEEKLY, Dec. 11, 2006.

<sup>293</sup> PORTER ET AL., *supra* note 68, at 189 (writing that in the post-war period, Japan “competed largely on low price and low wages, selling cheap imitations of Western goods. Understanding the limits of that approach, the nation underwent a stunning transformation to a new mode of competition. ... Japan began to compete not just on price but on quality.”).

American and European biotechnology clusters,<sup>294</sup> such venture start-ups carry well known problems and great risks, especially with the “depressing regularity of biotechnology failures.”<sup>295</sup> The American failure rate of biotechnology startups is “high”<sup>296</sup> and university spin-offs or startups have a higher failure rate than corporate spin-offs.<sup>297</sup> It is a sad but proven fact that even breath-taking landmark achievements from academic research do not always guarantee commercial success. The dismal demise of the animal cloning academic start-up venture company built around Dolly -- the world's first cloned mammal -- is the cautionary “classic tale of riches to rags.”<sup>298</sup>

PPL Therapeutics, the academic spin-off company from the Roslin Institute which created Dolly, once had an enviable stock market value of £500 million with 150 employees in Scotland and New Zealand. The Dolly cloning technology was supposed to revolutionize the biotechnology sector, where its modified cloned animal organs would be transplanted into humans and rescue the world from a donor crisis and also allow the manufacture of proteins by producing them in the milk of genetically-modified animals. As it turned out, PPL never even made, let alone sold, a single marketable healthcare product when it went into liquidation in 2003. The

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<sup>294</sup> See VITTORIO CHIESA & DAVIDE CHIARONI, *INDUSTRIAL CLUSTERS IN BIOTECHNOLOGY: DRIVING FORCES, DEVELOPMENT PROCESSES AND MANAGEMENT PRACTICES* (2005); see also Susannah Rodgers, *Swedish City Thrives on Biotechnology*, WALL ST. J., June 26, 2002, at B15.

<sup>295</sup> David Rasnik, *The Biotechnology Bubble Machine*, 21 NATURE BIOTECHNOLOGY 355, 355 (2003).

<sup>296</sup> Rhonda Rundle, *Biotech 'Jinx' Strikes the Hope of San Diego*, WALL ST. J., Oct. 18, 1994, at B1; David R. Olmos, *Drug Firm's Burst Bubble Stuns Investors Pharmaceuticals: The failure of SciClone's Trial of a Hepatitis Medicine Shows the Risks Inherent in Biotechnology*, L.A. TIMES, May 16, 1994, at 1.

<sup>297</sup> YALI FRIEDMAN, *BUILDING BIOTECHNOLOGY: STARTING, MANAGING, AND UNDERSTANDING BIOTECHNOLOGY COMPANIES* 70 (2004) (noting that a European study found that “university spin-offs showed a 45% failure rate, the failure rate for commercial spin-offs was only 15%”).

<sup>298</sup> John Bowker & William Lyons, *The Success That Could Not Be Cloned*, SCOTSMAN, Dec. 9, 2003; see also MARC ZIMMER, *GLOWING GENES: A REVOLUTION IN BIOTECHNOLOGY* 143 (2005) (reporting that Dolly died in 2003 and she was subsequently stuffed and put on display at the Royal Museum in Edinburgh, Scotland).



ignominious end came after its remaining physical assets, including laboratory equipment, centrifuges, industrial ovens, weighing scales, walk-in freezers and fancy ergonomic office chairs were unceremoniously auctioned off by the bailiff for a piddling £169,000, one freezing bleak December Scottish morning.

In the U.S. venture startup environment, business failure is an expected, forgivable, even celebrated, part of the entrepreneurial process as “failure provides experience with what does not work, what needs to be more refined, or what was simply bad timing. Nothing teaches like failure.”<sup>299</sup> In contrast, Japanese society is “cruelly unforgiving of failure”, as exemplified by the torment suffered by Yuichiro Itakura, a failed Japanese internet businessman, who was actually even named Entrepreneur of the Year by MITI in 1996. His company went bankrupt on Christmas Eve 1997; and in Itakura's second book, he described his feelings when handing a new business card bearing only his name and no credentials: "One man stared at my card for a minute and then said awkwardly, 'It's as if you were a politician.' My heart sank in shame.”<sup>300</sup>

The Japanese trends of “business recovery from bankruptcy is much lower and failure is not easily tolerated or forgiven”<sup>301</sup> have been identified in order to overcome them so that a new generation of Japanese entrepreneurship can bloom.<sup>302</sup> Indeed, just as METI had prepared the groundwork for biotechnology ventures to succeed, they had also taken measures in preparation for failure and rehabilitation of such ventures. This practice is prudent given biotechnology's less than stellar business record. METI has attempted to ameliorate the

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<sup>299</sup> Maryann Feldman, *Where Science comes to Life: University Bioscience, Commercial Spin-Offs, and Regional Economic Development*, 2 J. COMP. POL'Y ANALYSIS: RESEARCH & PRACTICE 352, 353 (2000).

<sup>300</sup> NATHAN, *supra* note 92, at 101. Even Japan reserves its worst scorn for politicians, a trait that is not uncommon elsewhere.

<sup>301</sup> ERIC A. MORSE & RONALD K. MITCHELL, *CASES IN ENTREPRENEURSHIP: THE VENTURE CREATION PROCESS* 17 (2005).

<sup>302</sup> See EDWARD A. FEIGENBAUM & DAVID J. BRUNNER, *THE JAPANESE ENTREPRENEUR: MAKING THE DESERT BLOOM - JAPAN'S FEAR OF FAILURE* (2002), available at [http://www.stanford-jc.or.jp/research/publication/books/cover&file/EAF\\_DJB.pdf](http://www.stanford-jc.or.jp/research/publication/books/cover&file/EAF_DJB.pdf).

social stigma<sup>303</sup> of such corporate venture failures<sup>304</sup> through its Early Business Revival strategy. This strategy involves the artful application and use of recently amended Japanese bankruptcy<sup>305</sup> and corporate restructuring laws<sup>306</sup> that were designed to promote and facilitate such venture-based entrepreneurship and provide a suitable safety net to fall down and recover in the long run.

*B. Biotech's Volatile on Both Sides of the Pacific*

Such contingency planning may actually be necessary, because notwithstanding the best laid plans or intentions as envisaged by the Japanese government for such biotechnology and industrial clusters,<sup>307</sup> recently, it appears that Japan's biotechnology university

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<sup>303</sup> RECOVERY FROM SUCCESS, *supra* note 235 at 95 (reporting that Japanese “scientists are not prepared to take the risk of joining a start-up firm when the chances of failure are high as they are for biotechnology.”).

<sup>304</sup> *METI Plans Small-Business Loans That Won't Require Guarantors*, NIHON KEIZAI SHIMBUN, Oct. 28, 2006 (reporting that “in order to encourage the launching of businesses by entrepreneurs”, METI plans to introduce a “new type of loan for small and midsize firms that does not require the business owner to become a personal guarantor.” Because currently, “the risk of starting a business in Japan is great because if the undertaking fails, the owner loses personal assets to the bank. Many experts believe that this is the reason why so few businesses are launched in Japan.”).

<sup>305</sup> VOGEL, *supra* note 24, at 86.

<sup>306</sup> A thorough examination of the new corporate bankruptcy provisions is beyond the scope of this article but the new provisions focus on corporate restructuring in contrast to liquidation. See EARLY BUSINESS REHABILITATION STUDY GROUP, MINISTRY OF ECONOMY, TRADE & INDUSTRY, TOWARD THE ESTABLISHMENT OF NEW BUSINESS REVIVAL MECHANISM FOCUSED ON EARLY IMPLEMENTATION AND PROMPT REVIVAL (2003); see also Shinjiro Takagi, *Restructuring in Japan*, in GLOBAL FORUM ON INSOLVENCY RISK MANAGEMENT STANDARDS AND STRATEGIES FOR THE NEXT DECADE CONFERENCE (World Bank 2003); Veronica Taylor, *Reregulating Japanese Transactions*, in JAPANESE GOVERNANCE: BEYOND JAPAN INC., *supra* note 272, at 138.

<sup>307</sup> See INDUSTRIAL CLUSTER STUDY GROUP, MINISTRY OF ECONOMY, TRADE & INDUSTRY, INDUSTRIAL CLUSTER STUDY REPORT 1, 30 (2005) [hereinafter CLUSTER STUDY] (reporting that the Japanese Government's main “support tools for the industrial cluster policy are categorized into six: network formation, R&D support, strengthening incubation function, support for market cultivation, collaboration with financing organizations, and fostering human resources” and after the formation of the industrial clusters, the next stage will be “networking promotion is continued and specific businesses are developed. At the same time, management innovation of companies and the creation of ventures are promoted. If necessary, projects are revised and new projects are prepared flexibly.”).

startup venture efforts are leading to a shakeout<sup>308</sup> thanks to an “overall downturn in Japan's biotechnology sector.”<sup>309</sup> Shortages of management personnel and expertise are also problematic for most of these academic biotech startups<sup>310</sup> so much so that many Japanese academic spin-offs are struggling for survival.<sup>311</sup> For most of 2006, Japan's fledgling publicly traded biotechnology start-up sector was struggling in the red.<sup>312</sup> Japan's “emerging biotechnology startups face potential financing challenges as public equity markets cool toward the sector” and past biotechnology investments “appear based on speculation rather than underlying fundamentals” where even though these Japanese biotechnology IPOs “achieved strong valuations, their share prices often fell in the months and years that followed.”<sup>313</sup>

However, this sinking feeling is not limited to biotech IPOs but widespread for most Japanese startup IPOs, across all sectors,<sup>314</sup> and it's also prevalent for many American biotech IPOs.<sup>315</sup> Japan also

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<sup>308</sup> One sure sign of Schumpeterian economic maturity model is the growth spurt followed by consolidation scenario that appears to be emerging in the Japanese market. See Sara Harris, *The Biotech Micro-Bubble*, J@PAN INC. MAGAZINE, Oct. 2001; *Bio-Venture Activity Suggests Industry Shakeout Ahead*, NIHON KEIZAI SHIMBUN, July 28, 2005; *8 Of 13 Biotech Start-Ups To Suffer Pretax Loss in FY05*, NIHON KEIZAI SHIMBUN, Dec. 27, 2005.

<sup>309</sup> Ichiko Fuyuno, *Stuck in the Middle*, 442 NATURE 237, 237 (2006).

<sup>310</sup> See Atsuki Maeyama, *Academic Start-ups Face Hurdles*, NIKKEI WEEKLY, Sep. 19, 2005 (reporting the hurdles of shortage of top caliber management personnel at university venture companies and an inability to expand through M&A operations).

<sup>311</sup> Ichiko Fuyuno, *Japanese Spin-offs Face Struggle for Survival*, 441 NATURE 280, 280 (2006).

<sup>312</sup> *Swelling R&D Costs Leave Biotech Start-ups in Red Ink*, NIKKEI WEEKLY, Apr. 24, 2006 (noting that 10 of 13 publicly traded biotechnology start-ups are expected to report pretax losses in their fiscal years ending in 2006).

<sup>313</sup> ERNST & YOUNG, *supra* note 7, at 81.

<sup>314</sup> *80% Of Newly Listed Firms See Stocks Sink Below Opening Levels*, NIKKEI FIN. DAILY, Dec. 28, 2006; *Investors Cool to IPOs Amid Stagnant Start-up Markets*, NIKKEI WEEKLY, Nov. 13, 2006.

<sup>315</sup> Lynn Cowan, *IPOs of Drug, Medical-Device Makers Drag the Overall Market*, WALL ST. J., Apr. 24, 2006, at C3 (reporting that all 3 biotech IPOs of April 2006 “ended their first day of trading either flat with or below their IPO prices.”); see also Tom Abate, *Tales of Scandalous IPOs and Corporate Hype Sound Too Familiar*, S.F. CHRON., Jan. 28, 2002, at E1 (reporting that 42 of the 51

witnessed a troublingly demoralizing absence of any Japanese biotechnology public offerings since March 2005,<sup>316</sup> and even in America, recent biotech IPOs have faced a timid reception<sup>317</sup> from American investors. This lack of receptiveness to IPO's is getting to the point where the IPO sentiment for the overall healthcare sector is "losing luster."<sup>318</sup> Some American biotech start-ups have even strayed from the IPO route.<sup>319</sup> Japan's biotech sector is a small scale version<sup>320</sup> of the intractably volatile American biotech sector, where such biotechnology stocks "are so often driven by speculation about the unknowable."<sup>321</sup> Biotechnology's speculative nature was vividly illustrated from the bursting bubble cycles<sup>322</sup> it has experienced. For

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newly listed biotech IPOs in between November 1999 to November 2000 are "trading well below their openings").

<sup>316</sup> *Enthusiasm for Listing Strong Despite Hurdles*, NIKKEI WEEKLY, Oct. 9, 2006 [hereinafter *Enthusiasm*] (reporting that since March 2005 "no biotech-related companies have been listed as a result of the TSE's toughening of listing requirements for them").

<sup>317</sup> Raymond Hennessey, *Biotech IPOs Get the Cold Shoulder*, WALL ST. J., May 28, 2004, at C4; Lynn Cowan, *Biotechnology IPOs May Face Tepid Reception From Market*, WALL ST. J., Feb. 3, 2005, at C4.

<sup>318</sup> Lynn Cowan, *Health-Care Sector Loses Luster*, WALL ST. J., Oct. 23, 2006, at C5.

<sup>319</sup> See David P. Hamilton, *Biotech Start-Ups Increasingly Opt For a Sale to Drug Firms Over an IPO*, WALL ST. J., Jul. 13, 2006, at C1.

<sup>320</sup> *Once Hot Mothers Market Losing Luster*, NIKKEI WEEKLY, Jul. 24, 2006 (reporting that there are only 14 biotech start-ups listed on Japan's stock exchanges). Japan's number is dwarfed by America's 330 publicly listed biotech companies. See Biotechnology Industry Organization, *Biotechnology Industry Facts - U.S. Biotech Industry Statistics: 1994-2004*, <http://www.bio.org/speeches/pubs/er/statistics.asp> (last visited January 26, 2007).

<sup>321</sup> David P. Hamilton, *Biotech's Dismal Bottom Line: More Than \$40 Billion in Losses*, WALL ST. J., May 20, 2004, at A1.

<sup>322</sup> Marius Meland, *Bubbles: From "Tronics" to "Dot com"*, FORBES, Jan. 14, 1999 (recounting the 1980s biotech bubble caused by Wall Street optimism on biotech companies' ability to find the cure to cancer and other insufferable diseases "quickly translated into soaring share prices" but "in the latter part of the 1980s, most biotech stocks lost three-quarters of their value amid questions about FDA approvals and a growing realization that sales had been overhyped"); see also Tom Abate, *Boom in Biotech Stocks Brings Back Memories of Bubbles Past*, S.F. CHRON., Feb. 28, 2000, at B1; David Ignatius, *Biotech Bubble*, WASH. POST., June 28, 2000, at A25; David P. Hamilton, *As Investors Flee Biotech Stocks, the Dreaded Burn Rate Returns*, WALL ST. J., July 30, 2002, at C1.

example, the one bubble that grew and burst over the completion of the human genome sequencing project<sup>323</sup> which feverishly raised the thrilling prospect of a great medical, and presumably financial payoff with cures to a panoply of diseases.<sup>324</sup> The impact of this scientific milestone has been likened to the landing on the moon.<sup>325</sup> Although from a business perspective, the moon landing analogy was not very comforting,<sup>326</sup> for investors soon realized that there was still much work to be done<sup>327</sup> and the remaining tasks were akin to scrambling for “medical needles in a genomic haystack.”<sup>328</sup> Upon realization that these genomic scientific advances were unlikely to translate into near-term financial return, the biotech bubble burst and many were burnt when biotech stocks plummeted.<sup>329</sup>

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<sup>323</sup> See KEVIN DAVIES, *CRACKING THE GENOME: INSIDE THE RACE TO UNLOCK HUMAN DNA* 236 (2001). It should be noted that only a working draft of the human genome that was announced with great fanfare in 2000 and the completed human genome sequencing was completed some three years later; see also Nicholas Wade, *Once Again, Scientists Say Human Genome Is Complete*, N.Y. TIMES, Apr. 15, 2003, at F1.

<sup>324</sup> See Scott Hensley, *New Race Heats Up to Turn Gene Information into Drug Discoveries*, WALL ST. J. June 26, 2000, at A1. See generally Scott Hensley & Sarah Lueck, *Genome Groups Complete Rough Drafts: Data Will Help Scientists Locate Specific Genes, Speed Cures for Disease*, WALL ST. J., June 27, 2000, at A1; NICHOLAS WADE, *LIFE SCRIPT: HOW THE HUMAN GENOME DISCOVERIES WILL TRANSFORM MEDICINE AND ENHANCE YOUR HEALTH* (2001).

<sup>325</sup> Svante Pääbo, *The Human Genome and Our View of Ourselves*, 291 SCIENCE 1219 (2001) (opining that the general public will greet the completion of the mapping of the human genome with “the same awestruck feeling that accompanied the landing of the first human on the moon and the detonation of the first atomic bomb”).

<sup>326</sup> Andrew Pollack, *Finding Gold in Scientific Paydirt*, N.Y. TIMES, Jan. 28, 2000, at C1. (noting that “three decades after Apollo 11, no one has yet made a profit going to the moon”).

<sup>327</sup> See Keay Davidson, *Sticking a Pin in Genome Mappers' Balloon*, S.F. CHRON., July 5, 2000, at A1; Tessa Richards, *Three Views of Genetics: The Enthusiast, the Visionary and the Sceptic*, 322 BRIT. MED. J. 1016–17 (2001) (arguing one of the major criticisms at the emerging field of genetic medicine is that it is surrounded by too much ‘hype’, speculation and unsubstantiated claims).

<sup>328</sup> Brian O'Reilly, *There's Gold in Them Thar Pills*, FORTUNE, July 23, 2001, at 5.

<sup>329</sup> See John Carey, *Biotechnology: "A Terrible Panic" among Private Biotechs*, BUS. WK., Nov. 20, 2002 (reporting the corporate casualties of

Currently, Japanese “biotechnology start-ups stocks as a whole were being shunned” and prudent Japanese investors have become “more selective” about Japanese biotech venture stocks and require these start-ups to show “sold achievements such as progress in developing new drugs and providing development rights to pharmaceutical companies.”<sup>330</sup> This “show me environment” parallels Wall Street's current circumspect attitude.<sup>331</sup> This is not surprising given that America's stock markets are littered with numerous biotechnology “headstones in the graveyard of investors' dreams”:<sup>332</sup> alluring biotech therapies failing,<sup>333</sup> politico-social issues,<sup>334</sup> global pandemic health scares,<sup>335</sup> and hundreds of millions of dollars spent by big pharmaceutical firms in the 1990s on “newfangled genomic databases and other exotic biotechnologies that didn't produce much.”<sup>336</sup> So the Japanese biotechnology sector's

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“2002's severe biotech downdraft” and one biotech venture capitalist warning that “lots and lots of companies are going to die”).

<sup>330</sup> Mitsutoshi Kouta, *Stocks of Drug Start-Ups Seen Bouncing Back*, NIKKEI FIN. DAILY, Dec. 25, 2006.

<sup>331</sup> Arlene Weintraub, *Why Biotech Stocks Are Sedated*, BUS. WK., June 13, 2005, at 48.

<sup>332</sup> Hamilton, *supra* note 319.

<sup>333</sup> Rick Wiess, *Dream Unmet 50 Years After DNA Milestone Gene Therapy Debacle Casts Pall on Field*, WASH. POST., Feb. 28, 2003, at A1.

<sup>334</sup> The political controversy surrounding the Bush administration's policy against stem cell research is exacerbated by scientific issues as well. See Michael Waldholz & Antonio Regalado, *Biggest Struggles in Stem-Cell Fight May Be in the Lab*, WALL ST. J., Aug. 12, 2004, at A1. Domestic and international acceptance of American agricultural biotechnology products have also been problematic. See Rick Weiss, *U.S. Uneasy About Biotech Food: Americans Lack Knowledge, Faith in FDA's Accuracy, Poll Finds*, WASH. POST, Dec. 7, 2006, at A16; Scott Miller, *Despite WTO, EU Plans No Shift on Genetically Modified Foods*, WALL ST. J., Feb. 9, 2006, at B5.

<sup>335</sup> Biotechnology companies have been impacted by the public reaction to current international health scares like SARS, bird flu, and West Nile virus. See Karen Talley, *'SARS Play' Get Hot Initially, Then Cool Off*, WALL ST. J., May 5, 2003, at C8; Jeff Clabaugh, *Cel-Sci Flies on Avian Flu Vaccine*, WASH. BUS. J., Apr. 4, 2006; Marilyn Chase & David P. Hamilton, *Tracking West Nile Virus -- Two Technologies Vie to Win New Market After Government Orders Blood Supply Screened*, WALL ST. J., Aug. 5, 2003, at B1.

<sup>336</sup> Robert Langreth & Matthew Harper, *Storm Warnings*, FORBES, Mar. 13, 2006, at 39. *Business Brief -- Bayer AG: Company Sells its 6.6% Stake in Millennium Pharmaceuticals*, WALL ST. J., Oct. 30, 2003, at B8 (reporting the

current doldrums is similar in some respect with America's, where profitability in America's thirty-year-old biotechnology sector has been the stubborn embarrassing exception<sup>337</sup> rather than the rule. Such losses, however, are at least "narrowing rapidly,"<sup>338</sup> even though losses continue for the American biotechnology industry as a whole. For example, the San Francisco Bay area's much emulated biotechnology cluster, America's largest and most diversified, sported a Janus-like visage in 2006 as the "top five and bottom four performers were all specializing in biotechnology and healthcare."<sup>339</sup> Across the Pacific in Japan, most university start-ups "also suffer from low profitability" or even losses, but "highly profitable companies have also emerged."<sup>340</sup> Indeed, Japan's biotech startup situation is also exhibiting this bipolar "feast or famine"<sup>341</sup> feature.

C. *Sitting on a Cold Stone for Three Years*

The Japanese have a suitable proverb to guide their biotechnology ventures for the days ahead: *ishi no ue ni mo san nen* 石の上にも三年 (sitting on a cold stone for three years, i.e. after sitting on a cold stone for three years, the stone becomes warm). The

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German giant's muted conclusion to its genomic adventure after making a headline grabbing USD 97 million investment in 1998).

<sup>337</sup> *Profitless Prosperity; Pharmaceuticals*, ECONOMIST, Apr. 22, 2006, at 63 (noting "thirty years after the biotechnology revolution began, the industry has yet to turn an aggregate profit" and that the secret to biotech's future finances lies in "need and greed" and "perhaps, one distant day, in profits too").

<sup>338</sup> Justin Gillis, *Biotech's Gains Again Outstrip Drug Giants'*, WASH. POST, Apr. 12, 2006, at D1.

<sup>339</sup> Pia Sarkar, *Biotech Stocks are Tops: Sector also Produced Bay Area's Worst Performers*, S.F. CHRON., Dec. 30, 2006, at C1; see also David P. Hamilton, *Gene Machines: As Others Sink, 2 Biotech Players Have Hit it Big*, WALL ST. J., Nov. 18, 2002, at A1 (reporting the poor profitability of America's biotech sector where Amgen and Genentech stand out as two of the few profitable, publicly traded biotech companies).

<sup>340</sup> *College-Based Start-Ups Trim R&D*, NIKKEI WEEKLY, Oct. 9, 2006. Okayama University start-up Testhe Corp., which developed an oral care antibody, reported a pretax profit-to-sales ratio of 71.4% and for fourteen of the top twenty profitable start-ups surveyed, the pre-tax profit-to-sales ratio was 10% or higher. *Id.* On the flip side, "[o]f the top 20 start-ups with pretax loss ranking, 17 were in the medical and biotechnology fields." *Id.*

<sup>341</sup> *Feast, Famine for TSE's Start-Up Mothers Market*, NIHON KEIZAI SHIMBUN, Jan. 20, 2006.

proverb means that with much patience you can achieve your goals. Certainly, it will take more than three years and efforts far more strenuous than sitting on a stone before Japan's biotech efforts see success.

It is worthwhile to note that even thirty years after the genesis of the biotechnology industry, only four out of sixteen biotechnology clusters in America, showed a net income in 2005.<sup>342</sup> Establishing university start-up/industry clusters does not always guarantee a pot of gold at the end of the biotechnology cluster rainbow,<sup>343</sup> and it requires a patient long-term effort and commitment as “[o]nly brothels and casinos [achieve] overnight success” and U.S. state governments “should expect 8-14 years to pass before seeing a return on an investment made in biotech.”<sup>344</sup>

The Japanese government's industrial cluster strategy, which is supposed to feed the biotechnology sector, appears to have this proverb at heart as it has recognized that “long-term views and strategies are indispensable because it takes several decades to form a cluster” and incorporated this lengthy timeframe into its plans.<sup>345</sup>

Treading the university biotech venture led path to recover Japan's biotechnology lost decade will require dollops of stone-sitting patience, perseverance, and endurance. The main reason for this is the lengthy time<sup>346</sup> it takes to develop new healthcare drugs, which

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<sup>342</sup> Selected 2005 U.S. Biotechnology Public Company Financial Highlights (by Geographic Region), in ERNST & YOUNG, *supra* note 7, at 28.

<sup>343</sup> Not all American research universities or clusters have been able to generate local economic effects. See Irwin Feller, *Universities as Engines of R&D-Based Economic Growth: They Think They Can*, 19 RESEARCH POL'Y 335-348 (1990).

<sup>344</sup> Ken Howard Wilan, *Chasing Biotech, State By State--Winners and Losers*, 23 NATURE BIOTECHNOLOGY 175, 177 (2005).

<sup>345</sup> CLUSTER STUDY, *supra* note 307, at i, 31 (envisioning three stages of development for industrial clusters: a start-up period of industrial sectors (2001-2005), a growth period of industrial clusters (2006-2010), and a self-sustaining developing period of industrial clusters (2011-2020)).

<sup>346</sup> Futoshi Kuwamoto, *Scandal Puts Univ Ventures Under Critical Spotlight*, NIKKEI BUS. DAILY, July 3, 2006 (reporting that most listed Japanese university ventures are in the bioengineering and medical fields and since “it usually takes more than a decade to bring a drug through basic research to commercial viability, growth can only come after a considerable amount of time”). The position is no different in America. See Michael S. Rosenwald, *Something to Show for 15 Years - Human Genome Sciences Puts 2 Drugs to Final Tests*, WASH. POST, Dec. 25, 2006, at D7. (reporting that it took HGS, a biotech company that was honored with



leads to persistent non-profitability and decreased investment funding, a fundamental requirement to developing new drugs in the first place.<sup>347</sup> Even if candidates for new drugs are found, it may still suffer “the cruelest of cruelties of the drug development business . . . the drugs still might fail.”<sup>348</sup> The failure rate in drug development is very high<sup>349</sup> and extremely expensive.<sup>350</sup>

Presumably the recent slumping fortunes of Japan's publicly traded biotech sector was not what Japan's industrial policy commissars had in mind when they indicated that they would be “working with the market.”<sup>351</sup> In the long run, such market downturns are to be expected, even welcomed in order to weed out the weaker from the strong, as it has been sagely observed, “You only

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a celebratory 1995 Business Week front cover story, fifteen years to finally enter “the last stage of testing for one of its drugs”).

<sup>347</sup> *Listed Biotechs Get Less Money, Limiting R&D*, NIKKEI WEEKLY, July 10, 2006 (bleakly reporting that “[v]enture capital companies are noticeably slowing their investment in the biotechnology sector, due partly to a delay in the development of new drugs by listed biotech ventures”); *Venture Capital Investment Rebounds in Fiscal 2005*, NIKKEI WEEKLY, July 10, 2006 (reporting that despite the enthusiastic investment pouring capital into Japanese start-ups, investment in biotech and medical start-ups declined for the first time in seven years).

<sup>348</sup> Rosenwald, *supra* note 346.

<sup>349</sup> Andy Kessler, *Business Bookshelf: Why Biotech's Promise Is So Great, but Not Its Profits (So Far)*, WALL ST. J., Jan. 3, 2007, at D9 (commenting that “only one drug out of 6,000 newly developed compounds actually goes on sale”); *see also* R.L. Woosley & J. Cossman, *Drug Development and the FDA's Critical Path Initiative*, 81 CLINICAL PHARMACOLOGY AND THERAPEUTICS 142 (2007) (noting that “only one in 10 drugs that enter clinical testing receives eventual FDA approval” and “for drugs in phase III that have shown evidence of effectiveness in phase II, the failure rate was 50%”).

<sup>350</sup> *See* Alex Berenson & Andrew Pollack, *Pfizer Shares Plummet on Loss of a Promising Heart Drug*, N.Y. TIMES, Dec. 6, 2006, at C1 (reporting that after announcing the failure of one of its most promising experimental drugs in clinical tests, Pfizer's stock dropped by “almost 11 percent” which “shaved more than \$21 billion off its market value”); Alex Halperin, *Biotech Bets for the Fearless*, BUS. WK., Dec. 13, 2005 (noting that “when a small company's drug candidate fails a clinical trial, it can devastate the stock”).

<sup>351</sup> STEVEN K. VOGEL, JAPAN REMODELED: HOW GOVERNMENT AND INDUSTRY ARE REFORMING JAPANESE CAPITALISM 88 (2006) (quoting a METI official that Japan's current industrial policy is different as it is “promoting promising technology rather than specific industrial sectors”).

learn who has been swimming naked when the tide goes out.”<sup>352</sup> In the long-term, Japan's biotechnology sector will grow stronger, as only the nimblest, best-managed and strongest biotechnology companies will survive on their own steam in a free market public stock exchange environment, and the minnows will either be acquired by stronger rivals or be “culled to improve quality.”<sup>353</sup> Notwithstanding these challenging business conditions and hurdles, in Japan many university biotech startups remain enthusiastic.<sup>354</sup>

Only time will tell whether government policy reforms on university education, venture capital, and technology transfer unleashes the Promethean potential of Japan's struggling biotechnology sector or whether this was just another case of policymakers' “inflated expectations” that industry-corporate-university relations “would somehow kick-start a new era of invention and entrepreneurship.”<sup>355</sup>

#### D. Long Wave of Incremental Japanese Reforms

Japan's current biotechnology efforts are but a microcosm of the larger sea change swirling in contemporary Japan and part of “a long wave of incremental reforms, which together have changed politics, the economy, and financial markets far more than most people realize, promising the country a bright long future.”<sup>356</sup> The motivation for the previously discussed reforms to Japan's S&T policy, university administration, patent laws, venture-friendly and corporate restructuring laws and provisions arose organically through “an interactive process of government reform and corporate adjustment”<sup>357</sup> in tune with the reality that something had to be done.

On a macro scale, the Japanese people's popular support for reform in general was translated by “[a]cademics, . . . administrators

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<sup>352</sup> WARREN BUFFET, 2004 CHAIRMAN'S LETTER 11 (2004), available at <http://www.berkshirehathaway.com/letters/2004ltr.pdf>.

<sup>353</sup> Kazuhiro Kida, *Start-Up Markets Face Crossroads In '07*, NIKKEI FIN. DAILY, Dec. 29, 2006.

<sup>354</sup> *Enthusiasm*, *supra* note 316.

<sup>355</sup> See MARIE ANCHORDOGUY, REPROGRAMMING JAPAN: THE HIGH TECH CRISIS UNDER COMMUNITARIAN CAPITALISM 62-63 (2005) (observing that Japan's elite had similar unrealistic expectations that the internet and dotcom boom was going to “spark economic revitalization” in the late 1990s).

<sup>356</sup> *The Sun Also Rises*, ECONOMIST, Oct. 8, 2005, at 11.

<sup>357</sup> VOGEL, *supra* note 351, at 220.

and politicians [which] provided intellectual backing for administrative reform, proselytized for the cause and served on many advisory councils.”<sup>358</sup> The reform effort was also actively supported by the “Keidanren, . . . [which was] a persistent and far-reaching advocate of reforms” and by the Japanese government bureaucracy itself through the Management and Coordination Agency (MCA), which implemented prime minister or Cabinet issued orders to carry out various reforms.<sup>359</sup> These reforms were not driven by pressure from some well-intentioned foreign government ally.<sup>360</sup> Over the past 130 years, domestic motivations, namely survival as a nation-state and economic survival, have been the primordial drivers of Japan's two periods of dramatic and radical reinvention.<sup>361</sup> There is no doubt that the stakes are equally high this time, as Japan's continued future prosperity depends on an innovation-based economy.

Japan's policy actors realized that in order for “things to stay as they are, things will have to change.”<sup>362</sup> Wearied from repeated recessions, bureaucratic scandals, and failed attempts at economic revival, the Japanese citizenry popularly supported reform in general. To paraphrase Lampedusa, it was fortunate that the misery of Japan's

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<sup>358</sup> See Gregory W. Noble, *Reforms and Continuity in Japan's Shingikai Deliberation Councils*, in JAPANESE GOVERNANCE, *supra* note 272, at 116.

<sup>359</sup> *Id.*; see also Atsushi Kusano, *Deregulation in Japan and the Role of Naiatsu (Domestic Pressure)*, 2 SOCIAL SCI. JAPAN J. 65, 65-84 (1999) (noting some Japanese reform measures were compelled by the presence of domestic factors, not outside pressure from foreign governments, which combined to produce domestic pressure (*naiatsu*) to step up efforts in Japan to eliminate or ease regulations and enact reforms); Bullock, *supra* note 215.

<sup>360</sup> Foreign pressure (*gaiatsu*) has been the dominant subtext underlying Japanese-American trade and economic dialog, but the consensus is that “American pressure will succeed only when it works with domestic politics in Japan.” See LEONARD J. SCHOPPA, BARGAINING WITH JAPAN 317 (1997).

<sup>361</sup> Gibney, *supra* note 43, at 77 (observing that “Japan has undergone historical transformations so radical as to be unbelievable even to those who lived through them” and that Japan's “third opening,” its transformation to restructure both its economy and society to compete in a global world, had already begun (Japan's first transformation being the 1868 Meiji Restoration and the second its miraculous economic rebirth after the rubble of defeat in World War II)).

<sup>362</sup> GIUSEPPE DI LAMPEDUSA, THE LEOPARD 40 (1991). Lampedusa's great novel of aristocratic decline in 19th-century Sicily is noted for this *bon mot* about institutional reform and change.

lost decade was stronger than her policymakers' vanity.<sup>363</sup> It was this public discontent that drove this incremental but certain transformation of the modalities (producing more life science graduates, greater internationalization of authorship of Japanese science and research papers, pro-patent IP laws, university startups, university/industry clusters, lower barriers to venture companies, biotech startups with IPOs) of the Japanese biotechnology sector.

These biotech-related reforms seek to inculcate the best practices that have been successfully preached and executed in the birthplace of the world's biotechnology business, America.<sup>364</sup> Ironically, the Japanese biotechnology sector appears to mirror the stock market travails of America's biotechnology sector *sans* the presence of a Japanese version of US biotech successes like Amgen and Genentech. And in view of the possible consolidation of the few Japanese listed biotechnology companies,<sup>365</sup> it is hoped that Japan's biotech sector does not grow old before it gets rich.

The administration of ex-Prime Minister Koizumi emphasized structural reforms as the necessary “creative destruction” to “move beyond Japanese modernization and build a twenty-first century system.”<sup>366</sup> The Japanese government, to its credit, has instituted a comprehensive root and branch approach. In order for Japan to “gain

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<sup>363</sup> *Id.* at 212 (observing that the Sicilians' decline was due to “the simple reason that they think themselves perfect; their vanity is stronger than their misery”).

<sup>364</sup> THUROW, *supra* note 2, at 232 (explaining that America's “[e]normous individual economic opportunities in biotechnology would not have opened up unless the community had been willing to invest enormous sums in research and development and in the Ph.D. training in biology and medicine that were necessary to build the foundations for this new industry”).

<sup>365</sup> *Many Biotech, Drug Firms See M&As as Means of Expanding Ops: Poll*, NIKKEI IND. DAILY, Nov. 9, 2006.

<sup>366</sup> SAKAKIBARA, *supra* note 41. For a more sobering view of Japan's current overall reform efforts see LEONARD J. SCHOPPA, RACE FOR THE EXITS: THE UNRAVELING OF JAPAN'S SYSTEM OF SOCIAL PROTECTION 210-211 (2006), which notes that while “Koizumi spoke eloquently of 'structural reforms with no sacred cows' and called for a long list of reforms . . . over the next several years Koizumi disappointed many of these hopes.” Even his stunning September 11, 2005 election victory over postal privatization reform against 'LDP' rebels was seen as a “victory of reform confined to a narrow group [like postmasters and postal workers].” *Id.* See generally AURELIA GEORGE MULGAN, JAPAN'S FAILED REVOLUTION: KOIZUMI AND THE POLITICS OF ECONOMIC REFORM (2003).

a place at the frontiers of biotechnology,”<sup>367</sup> it is using every policy instrument available to reform the relevant conditions of education, economy, industry, finance, science and technology policy, intellectual property laws, and the university and financial regulatory environment that impact the behavior of scientists, entrepreneurs, investors, and society.

Still, we should not entertain the illusion that that the work ahead is going to be easy.<sup>368</sup> It is perhaps overly optimistic to predict that the “structural reforms needed to create a new Japan will take a long time perhaps five to ten years,”<sup>369</sup> but it would be a far greater mistake to think that it would take anything shorter.<sup>370</sup>

Whether biotech can significantly contribute to Japan's transformation into a modern, knowledge-based economy depends on the relevant policy actors – scientists, entrepreneurs, investors, society, and regulators – operating successfully under these reformed conditions. Japanese science has a proven track record in the American pharmaceutical market<sup>371</sup> and so Japanese biotechnology has the potential to succeed given the right conditions.

As Japan has demonstrated in its historical periods of radical transformation “if it mind-sets change, Japan has the capacity to move rapidly.”<sup>372</sup> The best bet is that Japan “will be back as a vital economic force”<sup>373</sup> and recent macroeconomic indications happily

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<sup>367</sup> Komberg, *supra* note 78, at 9. (exhorting Japan to lower “cultural barriers, adopt a more global orientation and encourage the entrepreneurial zeal of academic scientists and venture capitalists,” which apparently Japan has done in the last several years).

<sup>368</sup> Nariai Osamu, *A Long-Term Vision for Fiscal & Economic Health*, JAPAN ECHO, Dec. 2005, at 44 (observing that the scale of Prime Minister Koizumi's landslide election victory of September 2005 was a vindication of Koizumi's reforms, but also concluding that the Koizumi “administration and those that will follow it face heavy load of homework”).

<sup>369</sup> SAKAKIBARA, *supra* note 43, at 157.

<sup>370</sup> *Id.* at 158.

<sup>371</sup> America's pharmaceutical industry has recognized Japanese pharmaceutical innovations as a resource to supplement its pipeline of new drugs. See Peter Landers & Jason Singer, *Pharmaceutical Makers See Feast in Japan*, WALL ST. J., Apr. 29, 2002, at C1.

<sup>372</sup> PORTER ET AL., *supra* note 68, at 190.

<sup>373</sup> PACIFIC COUNCIL ON INTERNATIONAL POLICY, CAN JAPAN COME BACK? 32 (2002).

point to that direction.<sup>374</sup> Given that Japanese science is becoming more internationalized in terms of authorship and collaboration, more and more scientists from the U.S., Europe, and other countries will conduct their research work in collaboration with Japanese scientists at Japanese universities. Foreign scientists and their respective university-employers should feel comforted to know that even if there has been a pre-filing disclosure of their research results, Japanese universities have a statutory grace period against novelty destroying disclosures that can salvage potentially lucrative inventions.

Using Japan's six-month novelty grace period to salvage a researcher's or fledgling biotech startup's patentable crown jewels from the public domain is merely the first step on the long and arduous quest to attain biotechnology's riches. Nevertheless, notwithstanding the short-term volatility and profitability problems of Japan's biotech sector, Japan's science-venture-patent driven biotechnology gambit<sup>375</sup> will likely play an integral part of Japan's goal to become a world-beating, knowledge-based economy.

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<sup>374</sup> Shinichi Okada et al., *The End of the Lost Decade*, JAPAN PLUS ASIA PACIFIC PERSPECTIVES, Feb. 2006 (reporting that the Japanese economy has successfully emerged from its long-term slump known as the Lost Decade), available at [http://www.jijigaho.or.jp/app/0602/eng/s\\_edition.html](http://www.jijigaho.or.jp/app/0602/eng/s_edition.html); see also Akira Kojima, *Tasks to Tackle After Japan's 10-Year Slump*, JAPAN ECON. CURRENTS, Jan.-Feb. 2006, at 1.

<sup>375</sup> Hamilton, *supra* note 321 (reporting that amongst Wall Street analysts, biotechnology stocks are the “ultimate roulette game” and are “high risk, high reward,” but that biotech's odds are “better than in Vegas”).