

The War of the West

One company shows the world that stem cell research isn't going away
— and revives a worldwide controversy in the process

On 25 November, Michael West, President and CEO of Massachusetts-based Advanced Cell Technology (ACT, www.advancedcell.com), announced that his company had become the first to successfully clone human stem cells, a feat that has caused a mixture of applause and criticism. On one hand, ACT and its stem cell-focused ilk are praised for opening the door to radical new therapies with enormous life-saving potential. On the other hand, some feel that cloning of any kind is wrong and that even the therapeutic cloning that ACT is researching will lead down a “slippery slope” to inevitable human cloning. These critics predict a culture in which children are designed and widespread, genetic-based discrimination exists, much like the culture depicted in the movie worlds of *Gattaca* and *Brave New World*.

Who is right remains a subject for debate. But it seems certain that issues of stem cell research and therapeutic and human cloning are here to stay — a fact that could mean big opportunities for private investors.



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Since the biotech boom following the completion of the Human Genome Project, much of biotechnology has focused on genomics and postgenomics. Genomics companies like Maxygen, Inc., (www.maxygen.com) and Operon (www.operon.com) gained popularity as did cutting-edge proteomics entities like Diversa Corporation (www.diversa.com) and Applied Molecular Evolution (www.amevolution.com). But during the past year, investors, the media, and the general public have started to take a more wide-angle approach to biotechnology. Many people are looking at the industry's subsectors, especially those involving stem cells. President Bush heightened the fever with his controversial decision to limit stem cell research to the 64 existing stem cell lines. The president was vague in his speech — very few specific policy decisions were set. Stem cell stocks rose slightly, mainly because the decision, though somewhat liberating to scientists, was not as far reaching as originally anticipated.

Bush vs. Frist

What could have happened? Investors and scientists alike were hoping for a more empowering decision from the president, such as the proposal set forth by Senator Bill Frist (Rep-TN), the only medical doctor in the U.S. Senate. Frist proposed that stem cell research be allowed not only on existing stem cell lines, but also on stem cells derived from aborted embryos given to science by informed and consenting parents. Frist's strict but less cumbersome guidelines

would have allowed stem cell companies and researchers to operate more freely — thus accelerating discovery, products and therapies derived from those innovations, and subsequent financial returns. Bush's decision resulted in a tighter federal grip on stem cell companies, so researchers, doctors, patients, and investors all will have to wait longer for new and groundbreaking discoveries.

Wild, Wild West

West and ACT have boldly defied the President's decision. Now, the federal government is in a frenzy over what to do with them and with the entire stem cell industry. One of two scenarios could result from ACT's innovation.

Worst-case scenario. The government, spurred on by a clone-wary public, could further tighten its grip on stem cell and other biotechnology companies, forcing them to proceed even more slowly and under much stricter guidelines. Under this scenario, investment and venture capital dollars would most likely dry up as the prospect of serious returns creeps farther and farther down the time line.

Best-case scenario. On the other hand, West and ACT could convince the world that biotechnology (specifically stem cell research to treat modern day terrors like Parkinson's disease, Alzheimer's disease, juvenile diabetes, and others) is here to stay and must be allowed to progress because it will save millions of lives and alleviate the suffering of millions more people. Although in the current climate this course of action

seems the less likely of the two, it would create a situation that would revive the biotech industry and help to pull it from the nation's economic slump far faster than other high-tech fields (such as telecom, "dot coms," and information technology).

Biotech is once again surrounded by controversy and uncertainty. Ideally, the public will come to terms with its fears and accept and embrace the new technologies (much like it did in the 1960s and 1970s with the computer industry). Then the

government would respond accordingly by loosening restrictive measures on research. Not only would that rapidly increase the pace of drug discovery, but it would reduce to just a few years the time it takes to see revenues and investment returns on genomic and stem cell research.

Table 1. Index tracking

Index	Start	12/04/01	Gain/Loss
BioPharm Index	940	763	-218.8%
S&P 500	1,510	1,145	-224.1%
NASDAQ Composite	4,252	1,963	-253.8%

The Frist Proposal

Had President Bush chosen to accept the Frist bill rather than his own more limiting decision, biotechnology stocks might be more highly valued today. Senator Frist's proposal suggested three bans: on the creation of embryos for research purposes;

Table 2. Company tracking

Company	Ticker Symbol	Closing Price as of 12/04/01	52-Week High	52-Week Low	Market Capitalization (billions)	R&D Spending (millions)	Market Capitalization R&D Ratio
Abgenix, Inc.	ABGX	35.79	94.88	15.31	3.09	21.2	145
Affymetrix, Inc.	AFFX	36.03	103.75	24.63	2.09	40.5	51
Amgen Inc.	AMGN	66.66	80.44	45.44	69.99	822.8	85
Applied Molecular Evolution, Inc.	AMEV	10.00	40.25	5.75	0.24	4.2	56
Aviron	AVIR	45.15	70.56	21.00	1.41	68.2	20
Biogen, Inc.	BGEN	59.41	82.50	47.13	8.79	221.2	39
Celera Genomics	CRA	29.06	151.00	24.00	1.96	48.4	40
Celgene Corporation	CELG	33.04	76.00	16.94	2.49	19.6	127
Cephalon, Inc.	CEPH	69.62	83.63	32.50	3.52	46.4	75
Cubist Pharmaceuticals	CBST	31.45	64.13	12.00	0.89	19.4	45
Diversa Corporation	DVSA	12.41	55.00	9.50	0.44	12.1	36
Genentech, Inc.	DNA	56.91	97.25	38.50	30.00	367.3	81
Genzyme General	GENZ	56.17	103.75	40.38	11.92	97.7	121
Genzyme Transgenics Corporation	GZTC	4.72	40.38	3.88	0.14	15.1	9
Human Genome Sciences, Inc.	HGSI	38.51	106.81	25.00	4.92	60.6	81
IDEC Pharmaceuticals Corporation	IDPH	69.43	77.63	18.50	10.59	42.8	247
Immunex Corporation	IMNX	25.44	69.88	10.75	13.85	126.7	109
Incyte Genomics, Inc.	INCY	19.77	144.50	14.56	1.31	146.8	8
Ligand Pharmaceuticals Inc.	LGND	16.85	19.18	7.81	1.01	59.4	16
Maxygen, Inc.	MAXY	18.88	96.38	9.94	0.64	19.2	33
Medarex, Inc.	MEDX	22.28	75.00	12.06	1.62	19.9	81
MedImmune, Inc.	MEDI	42.32	89.81	21.06	9.06	59.2	152
Millennium Pharmaceuticals, Inc.	MLNM	33.51	81.00	23.75	7.42	159.9	46
Organogenesis Inc.	ORG	5.50	16.88	6.76	0.20	18.2	11
Protein Design Labs, Inc.	PDLI	37.04	146.25	25.88	3.26	36.1	90

Source: Yahoo! Finance. Information and dates herein, although believed to be accurate, are not guaranteed. Yahoo!, Inc. and BioPharm magazine will not be held liable for any inaccuracies.

SENATOR *Frist*

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on human cloning; and a continued funding ban on “derivation,” meaning federal dollars could be spent to research embryos and stem cells obtained only through private funding. The bill suggested an increase in government funding for adult stem cell research and a restriction on funding for embryonic stem cell research to embryos in the earliest stage. Frist called for a rigorous “informed consent” rule modeled on those now in place for organ donation giving donors the right to decide whether and how

to dispose of the embryo. Donors choosing to discard an embryo must approve the embryo’s use for research.

The senator also proposed a limit on the number of stem cell “lines” taken from each embryo to minimize bioethical problems. He envisioned a new public research oversight mechanism that would establish public research guidelines, including a national research registry.

Frist proposed an ongoing scientific and ethical review by The Institute of Medicine (www.iom.edu) and the creation of an independent presidential advisory panel to review the bioethical implications of stem-cell research. That review would also have required the secretary of Health and Human Services to report to Congress annually on the status of federal grants for stem cell research.

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