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GENEWATCH

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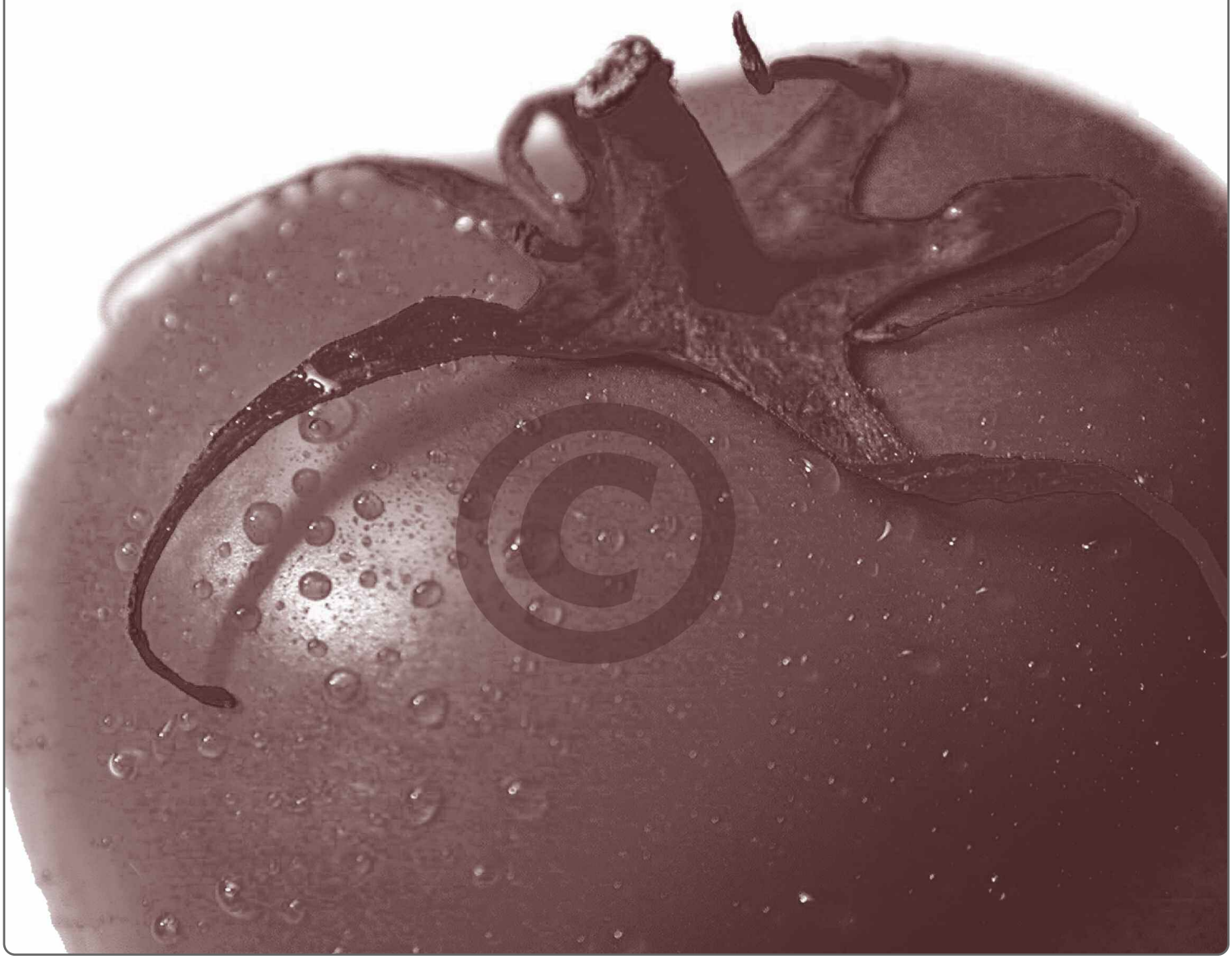

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EDITOR & DESIGNER
Evan Lerner

EDITORIAL ADVISOR
Sujatha Byravan

EDITORIAL COMMITTEE
Ruth Hubbard Rayna Rapp
Sheldon Krimsky

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Address 5 Upland Road, Suite 3 Cambridge, MA 02140 **Phone** 617.868.0870 **Fax** 617.491.5344
Net crg@gene-watch.org / www.gene-watch.org

Editorial

Evan Lerner

"He came dancing across the water, with his galleons and guns, looking for the new world and a palace in the sun." These are the opening words to one of pop music's most powerful indictments of colonialism, Neil Young's "Cortez the Killer." Cortez, in addition to perhaps being considered the embodiment of Quetzalcoatl by the Aztec people he was about to conquer, is a self-styled savior. Regardless of the mythic stature imparted to his arrival on the shores of Mexico, Cortez is god-like in his possession of the technology that would make Europe's conquest of the Americas possible.

"On the shore lay Montezuma, with his cocoa leaves and pearls; in his halls he often wondered with the secrets of the world." Young plays on the myth of the "Noble Savage," an idea wherein the victims of colonization were not victims at all, but rather people who lacked the wisdom and perspective, the science, of the modern world and thus could not capitalize on the riches they had all around them. Colonizers were indeed saviors; they saved the savages from their backwards selves and the misery of ignorance. Of course, one of the ancillary benefits of being the colonizer is that you can resell these riches to their previous owners; the search for marketable goods often spawns new markets.

Five hundred and four years later, there are few lands left to colonize, but the colonial urge remains. Like with all colonists, Cortez's motivation for seeking new lands and peoples was to acquire what his own land lacked. In this case it was gold, and Cortez planted Spain's flag in ground he believed contained it. Now information is the world's currency and the patent is the conquistador's flag. Modern explorers do not employ galleons and guns, but microscopes and pipettes. The new frontier is within humans and other organisms; colonialism has become biocolonialism. And like geographical colonialism, winners and losers will be determined by differences in their access to technology.

The novelist Iain M. Banks describes colonization as an "outside context problem." The colonized are unable to defend their way of life because they face a problem that is outside the context of other problems they have experience dealing with. The Aztec could not even conceive of the problems of guns, smallpox or mercantile capitalism until they faced them in a (relatively short) life-and-death struggle. A comparatively unskilled colonizer could turn the most heroic contestant in the indigenous struggles into an inert slab of meat from ten yards, and an undetectable microorganism could rapidly kill thousands of indigenous people while leaving the gift-bearing visitors unscathed.

As with the erstwhile form of colonialism, context remains king in the practice of biocolonialism as well, though instead of a battle between matchlocks and spears, it is through the competing socioeconomic and technologic models of a folk remedy and a blockbuster pharmaceutical. One is readily profitable, one is not. Take WR Grace's patenting of a fungicide based on the anti-fungal properties of the Neem tree. South Asians for centuries have used the products of the Neem tree for this purpose (among many others), but their application of this knowledge is not congruent with modern business models. The Neem example is an extreme one that merits its own sub classification: biopiracy.

Happily, WR Grace's patent was revoked in 2000, but this story has much in common with the root story of the Americas' colonial history: Columbus's "discovery" of the New World. The most significant of their similarities is that they are both semantic fabrications. Columbus may have been able to place those lands on an increasingly accurate map of the world, just as scientists were able to map the chemical pathways by which the proteins in the Neem tree act on fungi and insects. However, for the hundreds of thousands of people who lived in the

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The Politics of Patenting Race

BY JONATHAN KAHN

Difference as a Biotech Resource

A new phenomenon is emerging in biotechnology research and product development – the strategic use of race* as a genetic category to obtain patent protection and drug approval. The introduction of race into the field of patent law as an adjunct to biotechnological inventions may have profound implications for broader scientific and social understandings of race. When the federal government grants a patent to an invention that is based on an asserted or implied genetic basis for a particular racial group, it gives the imprimatur of the federal government to a potentially inappropriate characterization of race as genetic.[1] As a recent editorial in *Nature Biotechnology* put it, "Race is simply a poor proxy for the environmental and genetic causes of disease or drug response... Pooling people in race silos is akin to zoologists grouping raccoons, tigers and okapis on the basis that they are all stripey."[2] Beyond this, such patents are providing the basis for similarly race-based clinical trial designs, drug development, capital raising and marketing strategies that which imply that race is genetic to ever widening and powerful segments of society. As these new patents proliferate, commercial imperatives may be coming to eclipse scientific considerations of how or even whether to use racial categories in biotechnology.

A typical patent is divided into several sections. The "Claims" section presents a primary focus for investigation because it is the legal heart of a patent. The claims specify the legally operative scope of the patent, defining the formal legal boundaries of the territory covered by an invention. The "Abstract" is the basic summary presentation of the central purpose of the patent. Other sections typically include a "Background" or "Description of Invention," plus drawings or other technical support data.

A review of "Claims" and "Abstract" sections of gene-related patents and patent applications filed since 1976 indicates a significant trend toward using racial categories in gene-related patents,

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* This article does not attempt to present a definitive characterization of the meaning of race and/or ethnicity. It is concerned more with how these terms are being invoked in biotechnology patents. I am assuming both to be socially constructed categories that nonetheless have come to have biological implications as they play out in real world biomedical contexts. Thus, for example, being African American in the United States currently correlates with higher rates of such biological and partly-biological conditions as infant mortality, diabetes, hypertension and prostate cancer. These are significant biological differences, but they are not necessarily inherent or genetic. In the interests of economy and manageable syntax, in the remainder of the article I will often refer only to "race" when speaking generally of racial and ethnic categories.

with a marked increase in just the past few years. The table on the following page identifies patents that use categories of race and ethnicity* in a manner that implies or asserts a genetic component to, or basis for, race.+ The specific categories are chosen to reflect those employed in the Office of Management and Budget's Revised Directive 15 on "Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity," which governs the collection of data in federal and federally sponsored projects.[3]

The results indicate a remarkable trend toward the increasing use of racial and ethnic categories in relation to patenting gene-related biomedical innovations. The significance of this trend is not strictly statistical. Rather, it is indicative of an emerging phenomenon that deserves increased attention. This rise is clearly coincident both with an increase in genetic information being produced through such federally sponsored initiatives as the Human Genome and International Haplotype Map Projects, and also with rising federal emphases on requiring the use of racial and ethnic categories in the collection of data relating to clinical trials and drug applications.

The two columns of the table reflect the date classifications of patents and patent applications provided by the U.S. Patent and Trademark Office's (PTO) own web-based search engine. The table does not capture possible patent applications that may have been filed before 2001 and subsequently abandoned. Nonetheless, it remains highly suggestive of a recent and novel trend toward the increasing use of race in biotechnology patents. Thus, for example, of the twelve uses identified in granted patents, the earliest

* The results are from searches of the US PTO patent data base conducted between 8/25/05 and 9/15/05, using the web-based search engine available at www.uspto.gov. The search terms used included: "Race," "Racial," "Ethnic," "Ethnicity," "Caucasian," "Caucasoid," "African," "African-American," "Negro," "Negroid," "Asian," "Oriental," "Mongoloid," "Hispanic," "Latino," "Native American," "Alaska Native," and "Pacific Islander." The terms "black" and "white" alone were too broad to be useful and so were qualified with the additional terms of "biology" or "gene" or "genetic" or "DNA."

+ This is an admittedly subjective basis for sorting the patents. The categorization of patents that imply or assert a significant genetic component to race or ethnicity is meant to exclude those patents that use racial/ethnic categories as one or more of a longer list of general demographic characteristics, usually employed for information organization, rather than for identifying or treating a particular physiological state. Thus, for example, patents on cosmetic products and data base management were excluded. The categorization is meant to include those patents that use racial/ethnic categories as a basis for asserting a distinctive prevalence or etiology for a physiological condition, genetic variation, and/or drug response.

Racial Patents

The Changing Face of Patent Applications

Category	Issued Patents: 1976-1997	Issued Patents: 1998-2005	Patent Applications * filed since 2001
Race	0	2	15
Ethnic	0	0	2
African-American/Black	0	4	11
Alaska Native	0	0	0
Asian	0	0	13
Caucasian/White	0	6	18
Hispanic/Latino	0	0	3
Native American	0	0	2
Pacific Islander	0	0	1
Total	**0**	**12**	**65**

* Issued patents have been formally approved by the PTO. Patent applications are currently pending before the PTO for review. Under new policies they are made available to the public during the period.

relates to diagnostic testing for the BRCA1 genetic mutation for breast cancer and was granted only in 1998. There has been a more than five-fold increase in the use of racial and ethnic categories in gene-related patent applications over existing patents issued since 1976. This is not because race has not previously been used in biomedical research, but rather because it is taking on increasing significance in the commercial world of biotechnology patenting. While there are some overlapping uses (i.e. patents that use more than one OMB category) the trend remains powerful and clearly parallels the availability of vast new amounts of genetic information being produced and classified in federally sponsored data bases. The quantitative scope of the trend remains fully to be assessed, but its qualitative significance is already emerging.

How, exactly, is race being used in these patents? At the most pragmatic level, patent applicants appear to be invoking race in a strategically defensive manner to provide added protection against possible patent challenges. The structure of a typical Claims section of a patent begins with Claim #1 being as broad as possible. Successive claims generally provide a narrower and narrower focus to the territory covered by the patent. The idea here is that if the broadest claim is struck down by the patent examiner or a subsequent challenge, the narrower claims may still survive. Patent claims are thus structured something like a medieval castle, with an outer ring encompassing the most territory with successively smaller rings providing additional layers of protection back to the core area of the castle keep. Thus, a typical race-specific biotechnology patent may begin with a first claim that covers the use of a particular invention in a "mammal," the second claim may cover use in a "human," and the third claim may cover use in a "Caucasian" or "Asian" individual, etc.

There is not an inherent problem with looking at race in biomedical research. Many of the studies discussed in the "Background" sections of these patents, deal effectively with the nuances of variation in the relative frequencies of particular alleles (i.e. gene variants) across specified populations. In the legally operative Claims sections, however, all such nuance is lost as relative gene frequencies tend to be replaced by blanket assertions of efficacy or appropriateness for use in a specific race. The legal and commercial imperatives of patent law demand definitive and bounded categories of race to make the Claims appear stronger. Patent examiners in the PTO are unlikely to consider such slippage between claims of correlation and identity. Rather, they evaluate an application according to whether it meets the basic statutory criteria of novelty, non-obviousness, utility, and specification. The Claims thus supplant the more complex presentation of data in the underlying studies, in effect, distorting the science. The result is a patent that presents a simplistic conception of race as genetically constituted and bounded.

Racial categories can also be used more aggressively in patent law to expand or extend monopoly control over products and services. This is most evident in the case of the heart failure drug, BiDil. In June 2005, BiDil became the first drug ever approved by the FDA with a race specific

Editorial

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Americas before Columbus, or those who used the products of the Neem tree before it was patented, "right here" and "like this" were sufficient characterizations.

The contexts of locally traditional and technological problem-solving methods continue to clash most fiercely in the arena of genetically modified organisms. Crops genetically modified to produce more nutrients, or simply more food, are often touted as the solution to world hunger when the world in fact produces enough food to feed all its inhabitants, if only it were efficiently distributed to where it is needed. Similarly, crops engineered to produce medicines against diarrhea are touted as a solution for the developing world, though the more fundamental problem is a lack of clean water. On page 9, Robin Nixon provides us with "Wishing for What We Already Have," about the way in which Ventria's modified rice was sold to the U.S. Food and Drug Administration and how other pharmaceutical crops are likely to continue this trend.

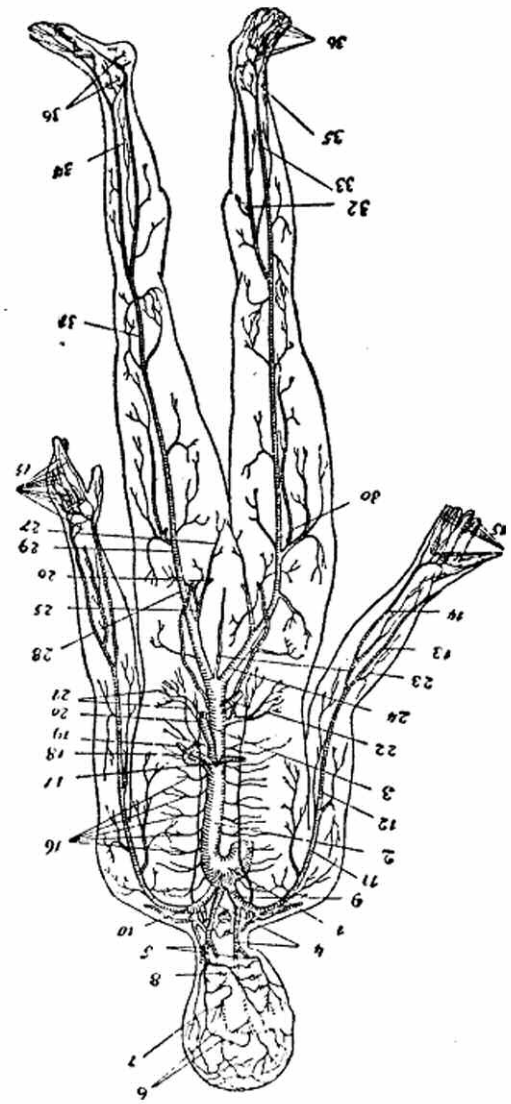
Ben Grosscup and Brian Tokar, long time activists in the field of genetically modified organisms, represent the perspective of the colonized in their articles, "Mass Movement" on page 12 and "Taking it to the Streets" on page 16. Grosscup takes a more local approach, describing how Massachusetts farmers are fighting to protect traditional agricultural production models against centralized, technological ones. Tokar takes a more global approach, exploring the local forms of the worldwide resistance to the biotechnology industry.

New technologies have allowed for new forms of biocolonialism. The modern emergence of race-based medicine points that way with new constructs of the Noble Savage and the outside context problem. Here, the "savageness" is itself the resource; whereas white populations were once considered sufficiently representative for the whole of humanity for purposes of drug testing, the exploration of possible genetic differences between races has generated new marketable products and new markets. The competing contexts in this case are the social construct of race that we generally deal with on a day-to-day basis and the specious biological construct necessary for patent protection. Jonathan Kahn deals with the troubling questions these competing contexts raise in "The Politics of Patenting Race" on page 3.

In fact, the problem of biocolonialism embodies one of CRG's core principles: that problems rooted in poverty, racism, and other forms of inequality cannot be remedied by technology alone. We must take account of the complex social frameworks in which these problems exist if we are to have any hope of applying technology to solve them. Though we might set sail with highest hopes and best intentions, we may be remembered as Neil Young remembers Cortez:

"What a killer."

indication: to treat heart failure in *African Americans*. Underlying the New Drug Application (NDA) submitted for this drug to the Food and Drug Administration (FDA) is a 2002 race-specific patent: to use the drug for treatment of heart failure *in an African American patient*.[4] NitroMed, the corporate sponsor of BiDil, also holds the rights to an earlier patent to use BiDil in the general population regardless of race.[5] This patent, however, expires in 2007, while the race-specific patent lasts until 2020, granting an additional thirteen years of monopoly control over the market for BiDil which NitroMed currently estimates as reaching $1-3 billion annually. Currently, BiDil is NitroMed's only product on the market.



NitroMed's second BiDil patent is premised on underlying assumptions regarding race and the genetic basis of heart disease. As NitroMed CEO, Michael Loberg put it, "Illnesses that seem identical in terms of symptoms...may actually be a group of diseases with distinct genetic pathways. This would help explain blacks' far higher mortality rates for a host of conditions, including diabetes, cancer and stroke."[6] By granting such a patent, the Patent and Trademark Office (PTO) is not only stifling useful innovation, it is also giving the imprimatur of the federal government to the use of race as a genetic category. The story of BiDil is one of how race and ethnicity were used in conjunction with patent law and the drug approval process to bring a new drug to market. NitroMed conducted a race-specific clinical trial, A-HeFT (African-American Heart Failure Trial), to support its NDA submission. All indications from the trial results seem to show that the drug is highly effective at treating heart failure, but the single race design of the trial does not support any claims as to whether the drug works differently or better in African Americans than in anyone else.[7] Indeed, designing a larger racially diverse clinical trial would have provided better information about BiDil's efficacy, most likely showing it worked in non-African Americans as well. Such a trial, however, would have threatened NitroMed's commercial interest in obtaining the extra thirteen years of patent protection ensured by a race-specific FDA approval.[8]

NitroMed's race-specific BiDil patent provided the underlying support that drove its subsequent development of a race-specific trial design, its campaign to raise money in capital markets, its approach to the FDA for race-specific approval, and its massive marketing campaign to third party payers, individual doctors, and the public at large.[9] As biotechnology patents become racialized, they are thus coming to drive broader scientific, political, and public understandings and uses (or, perhaps, misunderstandings and misuses) of racial categories.

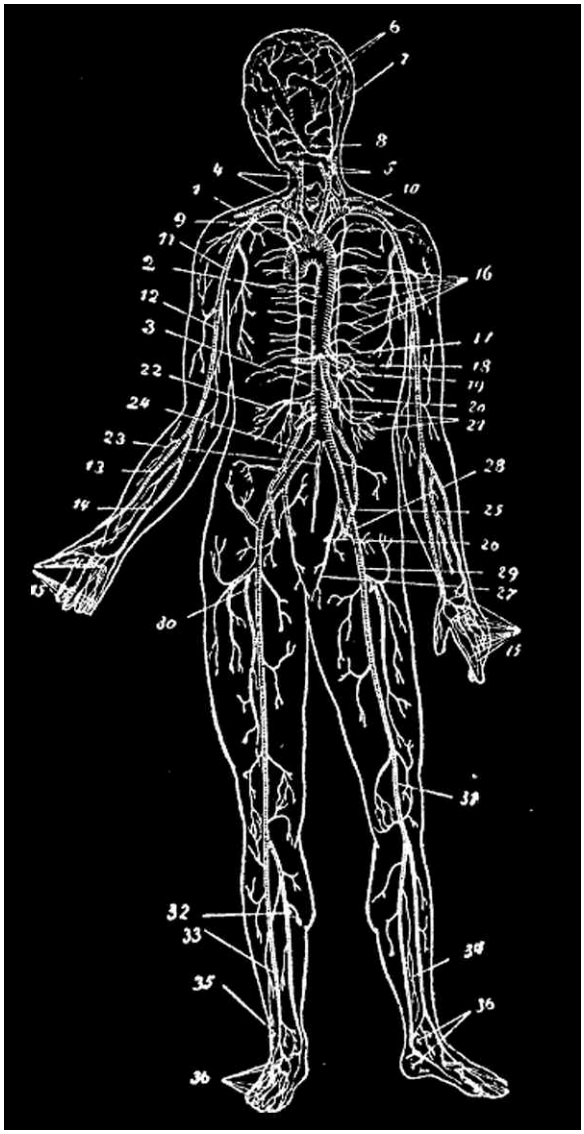
The dramatic rise of racial categories in biotechnology patents indicates that BiDil is not an anomaly. Recent reports of similar race-specific trials for the cancer drug Iressa and the statin Crestor, among others, would seem to indicate that BiDil is ushering in a new era of race-based medicine.[10] A 2005 report from the Royal Society in the United Kingdom asserted that the promise of truly individualized pharmacogenomic therapies remains decades away.[11] In the gap between present reality and future promises there may be various strategies for capitalizing on emerging genetic knowledge relating to drug response and efficacy. Targeting a racial audience presents a particularly attractive interim option because, at this point, the technology and resources do not exist to efficiently scan every individual's genetic profile. Instead, businesses may market the product to a particular social group that is hypothesized to have a higher prevalence of a relevant genetic variation. Patent protection provides an essential underpinning for such commercial ventures. As race is becoming more relevant to marketing drugs, it is becoming a salient component of underlying biotechnology patents.

Similar dynamics are at work in Europe. In June 2005, over the strenuous objections of the European Council of Human Genetics (ESGH), the European Patent Office upheld a patent owned by Myriad Genetics relating to testing for the BRCA2 genetic mutation "for diagnosing a predisposition to breast cancer in *Ashkenazi Jewish* women."[12] Opponents of the patent noted that the test is currently available for all women, regardless of ethnic or religious background. As a practical matter, this new patent means that women identified as Ashkenazi Jews will either have to pay a premium for the test or deny their identity. As with BiDil, here Myriad apparently is marking an ethnic group as genetically distinct primarily in order to extend patent protection – with potentially profound social and economic consequences.[13]

A "product of nature" cannot be patented. To be rendered patentable, it must be "purified and isolated" through human interventions to produce a substance that does not otherwise exists. Historically, this has involved complex chemicals such as adrenaline.[14] In the genomic era, however, it has come to encompass engineered complementary DNA (cDNA), synthesized in vitro by using an enzyme (reverse transcriptase), which produces a molecule containing only those nucleotide sequences from the original DNA that code for proteins (exons). While clearly scientific and technical in origin, isolation and purification are distinctively legal concepts when it comes to granting a patent. The PTO has asserted that, "the inventor's discovery of a gene can be the basis for a patent of the genetic composition *isolated from its natural state* and processed through *purifying* steps that *separate* the gene from other molecules *naturally associated* with it. [emphasis added]"[15]

The PTO constructs cDNA as isolated, not only in the sense of separating exons from introns, but more powerfully, in the sense of separating the genetic material itself from nature. This is not a scientific process but a legal one. The scientist may create cDNA but the PTO draws the line between nature and artifice. Similarly, purification involves stripping the genetic material of its identity as a part of nature – purifying it of its "natural associations."

In contrast, race enters the world of biotechnology as a social construct, often in the form of OMB 15 classifications. It serves as an admitted surrogate for presumed underlying genetic variations in particular populations. In the patent and drug approval process necessary to bring the drug to market, race is implicitly recoded as a genetic category. The patent process takes race as a social category and recodes it as "natural" by according it legal force as a component of a biotechnological invention. As corporations and markets come to attach commercial value to race as genetic there will be increased incentives to produce more examples of race as genetic in a commercial context. It is almost as if social categories of race are being used as seed money to produce genetic race as a commodity. Social race here becomes analogous to a sort of raw material that the patent process refines (i.e. purifies and strips of its "social associations") into a "novel" and "useful" manufactured product composed of genetic race. In patenting race, biotechnological inventions actually produce, (or reproduce) race as genetic.



Patent law is supposed to promote the invention of new and useful products. In recent biotechnology patents, race and ethnicity are being exploited in new ways that do not spur the invention of new products, but rather the reinvention of existing products as racial or ethnic. In so doing, patent law both racializes the space of intellectual property, transforming it into a terrain for the re-naturalization of race as some sort of "objective" biological category, and commodifies race and ethnicity as goods to be patented and subjected to the dictates of market forces.

Race has long been used in biomedical research. The new development of using race in patent law can fully be understood only when viewed in relation to broader federal initiatives that shape the production and use of racial categories in biomedical research. Prominent among these are a wide array of federal mandates that dictate the characterization and application of genetically-based biomedical interventions, such as pharmaceuticals and diagnostic tests, in relation to socially defined categories of race. Key federal mandates include: the NIH Revitalization Act of 1993, (PL 103-43), which directed the National Institutes of Health to establish guidelines for inclusion of women and minorities in clinical research; the Food and Drug Modernization Act of 1997 (111 Stat. 2296), which, in the context of drug development, directed that "the Secretary [of Health and Human Services] shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials...;" and two subsequent Food and Drug Administration "Guidances for Industry." The first, a 1999 guidance titled "Population Pharmacokinetics," makes recommendations on the use of population pharmacokinetics in the drug development process to help identify differences in drug safety and efficacy among population subgroups, including race and ethnicity.[16] The second, a 2005 guidance titled "Collection of Race and Ethnicity Data in Clinical Trials," recommends a standardized approach for collecting and reporting race and ethnicity information in clinical trials

that produce data for applications to the FDA for drug approval.[17] Underlying the standardization of data collection in all of these mandates are the racial and ethnic categories set forth in the Office of Management and Budget's Directive 15.

Collecting data on race for tracking such issues as health disparities, however, is fundamentally different from using racial categories in a genetic context. The former looks at race in relation to an array of social, environmental, and biological factors to understand disparities; the latter looks at race primarily as a molecular phenomenon. This is particularly so in drug trials that may not control for any of an array of social, economic or environmental factors that may bear on race in relation to health. The same federal directives that have produced valuable race-specific data to help understand the social phenomenon of health disparities are also producing data that are now being taken up for commercial purposes to use race as a crude genetic marker to exploit the gap between the present state of genetic technologies and the future promise of truly individualized genetic therapeutic interventions. Unlike biomedical research into possible correlations between genes and race, however, biotechnology patents tend to construct race as a clearly bounded, unproblematic genetic category. As racial patents proliferate, they may be coming to impose this conception of race-as-genetic onto the design of basic research, clinical trials, and product development.

It is almost as if social categories of race are being used as seed money to produce genetic race as a commodity.

As researchers derive new inventions based on mining existing genetic data bases, patent law provides powerful commercial incentives to conflate race and genetics. Scientific progress has always existed in a balance with commercial considerations. The rising strategic use of race to obtain extended patent protection for biotechnological inventions, however, portends a serious distortion of this relationship as commercial imperatives drive simplistic and scientifically weak conceptions of the complex relationships between social categories of race and genetics. ■■■

Jonathan Kahn is a professor at the Hamline University School of Law. He writes on issues in history, politics, and law and specializes in biotechnology implications for our ideas of identity and citizenship. Much of the material in this article is derived from Kahn's "Patenting Race" which appeared in Nature Biotechnology *24, 1349-1351 (2006).*

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Wishing for What We Already Have

BY ROBIN NIXON

Ventria's Pharmaceutical Rice Touches Down in Kansas

This spring, 450 acres of Kansas will be planted with rice that has been modified to contain human genes. It will look much like any normal field of rice, but the biotechnological innovation within each stalk is being sold as if it were magic from the Land of Oz.

Essentially, the Kansas field will be a factory. The machinery is the rice plant itself. The inputs are human genes. The outputs are human proteins – lactoferrin and lysozyme – normally found in breast milk and other secretions, such as tears. These proteins have antibiotic properties. Lactoferrin, with its ability to suppress inflammation and boost immune system activity, is being touted for its possible ability to treat everything from multiple sclerosis and arthritis to septic shock. Lysozyme is an adept and discriminating bacteria killer; it kills bad bacteria while leaving helpful strains, like acidophilus, alone.[1]

While both these proteins are found in foods already in many adults' diets (lactoferrin in cow's milk, lysozyme in egg white), the concentrations are not as high as in breast milk, and thus are not as potent for human consumers or drug developers.[2] Therefore, if these proteins could be manufactured cheaply and ethically, they would be highly desirable as medicinal and nutritional supplements.

Advances in biotechnology have made the manufacture of these proteins possible, and Ventria Bioscience is ready to start production. The California-based biotech firm has received FDA approval to begin "pharming" its genetically engineered rice – this type of mass production is more commercially viable than standard production methods, which harness the abilities of bacteria, yeast and cultured mammalian cells. Unlike most other genetically engineered crops, this rice is not for direct consumption by humans or livestock. It has not been modified to simply be heartier or more resistant to pests. Rather, it is the means to produce and store proteins for use in other product --- products in which the administration and dosage often need to be watched and controlled.[3,4]

For this and other reasons (primarily, the lack of knowledge about what the unintended consequences of introducing these transgenes may be), there is concern about this rice being planted in open fields. Ventria claims that its use of a self-pollinating plant, instead of a cross-pollinator like corn, creates a safe, "closed" system. However, self-pollinators actually cross-pollinate about 5% of the time. Rice does so via wind.[5,6] And, according to the National Weather Service, there were 92 tornadoes in Kansas in 2006; in 2005, there were 135.

Even if cross-pollination does not occur (currently no edible rice crops are grown in Kansas, although pollen could possibly reach surrounding states), the threat or fear of cross-pollination could do incredible damage to any economy in which pharmaceutical-producing plants are grown, due to global distrust of genetically modified organisms. This April, in comments submitted to the USDA's Animal

and Plant Health Inspection Service, the USA Rice Federation said that if foreign markets became spooked, "the financial devastation to the U.S. rice industry would likely be absolute."[7]

To prevent such a "spooking", the public would need to be adequately informed on the true risks and benefits of Ventria's pharma products. Unfortunately, nobody knows what these will be. Long-term studies and clinical trials were not necessary for Ventria's pharma rice to be granted FDA's Generally Recognized As Safe (GRAS) status.[8] This lack of knowledge needs to be addressed.

In the mean time, fields of pharma crops should be regulated like any factory producing drugs. Why not use greenhouses and other means, such as a color marker coupled to gene expression, to further lessen risks of possible cross-pollination and safeguard against human error?

DRUGS FOR THE DEVELOPING WORLD

Even if these precautions were put into place, a larger problem would remain in the current marketing of these supplements.

Ventria plans to use the extracted proteins to fortify granola, yogurt and oral rehydration salts. The latter is, at this time, their primary medicinal purpose. Fortified rehydration salts are being advertised as a way to decrease the nearly 2 million yearly childhood deaths caused by diarrhea.[9] On March 6, BBC television showed images of African children in a hospital to showcase potential beneficiaries of Ventria's new product.

Ventria's own study, conducted in Peru, showed that Ventria's fortified rehydration salts shortened the duration of childhood bouts of diarrhea by an average of one and a half days, with the implication that this would allow children to return to school a full day earlier than if they had taken a standard electrolyte solution.[10] Of course, that is only if they are affluent enough to be attending school in the first place. (In 2005, only 55% of Peruvian boys would make it through both primary and secondary school.[11])

Another study, conducted in Pakistan was able to divide the total number of sick days a child experienced, potentially over his or her entire lifetime, in half. The solution was not lysozyme or lactoferrin; it was being taught to wash one's hands with soap.[12]

Nnimmo Bassey, speaking for Friends of the Earth Africa, describes the Ventria pharma product as "unproven, unnecessary and a distraction" from other programs aimed at solving childhood diseases. "[We] do not need genetically modified solutions to diarrhea and condemn the use of African children as a tool to promote the new GM rice," she said.[13]

Diarrhea is not a mysterious illness. The causes have been long known and there are proven ways to prevent it. The World Health Organization lists effective solutions that have worked for many decades in scores of countries: access to clean water; sanitary living conditions; adequate and diverse nutritional sources; good hygiene habits.

While recurring illnesses like diarrhea exacerbate poverty, they are often a result of poverty as well. In affluent countries, a child rarely needs medical treatment to recover from a case of diarrhea. In the developing world, however, an attack of childhood diarrhea can easily prove fatal.

Should a family, with already limited resources, be encouraged to buy lysozyme supplements or to buy a hen? The hen's eggs contain lysozyme, protein, Vitamin A and can also be used to augment a family's income. Both battle diarrhea. The former has far-reaching positive side effects; the side effects of the latter are unknown.

Mis-educating parents, politicians and the general public about the true benefits of this product is dangerous. Will these touted solutions distract from the treatments of underlying causes? Will they divert funding from organizations trying to battle these conditions with more effective and sustainable initiatives, like education and water sanitation? Similar to advertising that once implied baby formula was better than breast milk, although it left babies malnourished and mothers in greater poverty, the ill effects of over-praising genetically engineered supplements can lead to future ill effects.[14]

At the end of *The Wizard of Oz*, the titular wizard shows those seeking magical solutions that their true desires have already been met by more conventional means. The Lion is courageous, the Scarecrow is smart and Dorothy is already home. And indeed, the Tin-men of the developed world do have hearts and care about those suffering from poverty and poverty-related illnesses. The ability to reduce this suffering, especially in regards to diarrhea, has exist-

ed for a long time. It does not require ruby slippers or new supplements flown to Africa, in a hot air balloon or otherwise. It requires raising public understanding of the situation by means of a vigorous application of the tools and knowledge already available. ■■■

Robin Nixon was a doctoral candidate in Neuroscience at New York University and earned a degree in Neurobiology from Columbia University. After years in the developing world, she is now involved in a journalism program at Harvard University.

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Mass Movement

Massachusetts Farmers Make Themselves Heard

BY BEN GROSSCUP

Since the year 2000, in many parts of New England – especially Vermont, Maine, and Massachusetts – there has been renewed interest in bringing resolutions to town meeting on a range of national and global issues. Measures concerning the USA PATRIOT Act, the military occupation of Iraq, impeachment of Bush Administration members, and global climate disruption have appeared on many town meeting warrants. One of the issues that has gained the most attention at New England town meetings in recent years is agricultural genetic engineering (GE). Since 2000, one hundred and twelve towns and cities in New England have passed resolutions opposing GE food and farming. Citizens in Massachusetts are currently expanding these efforts, taking lessons from similar efforts in neighboring states, and learning their own lessons.

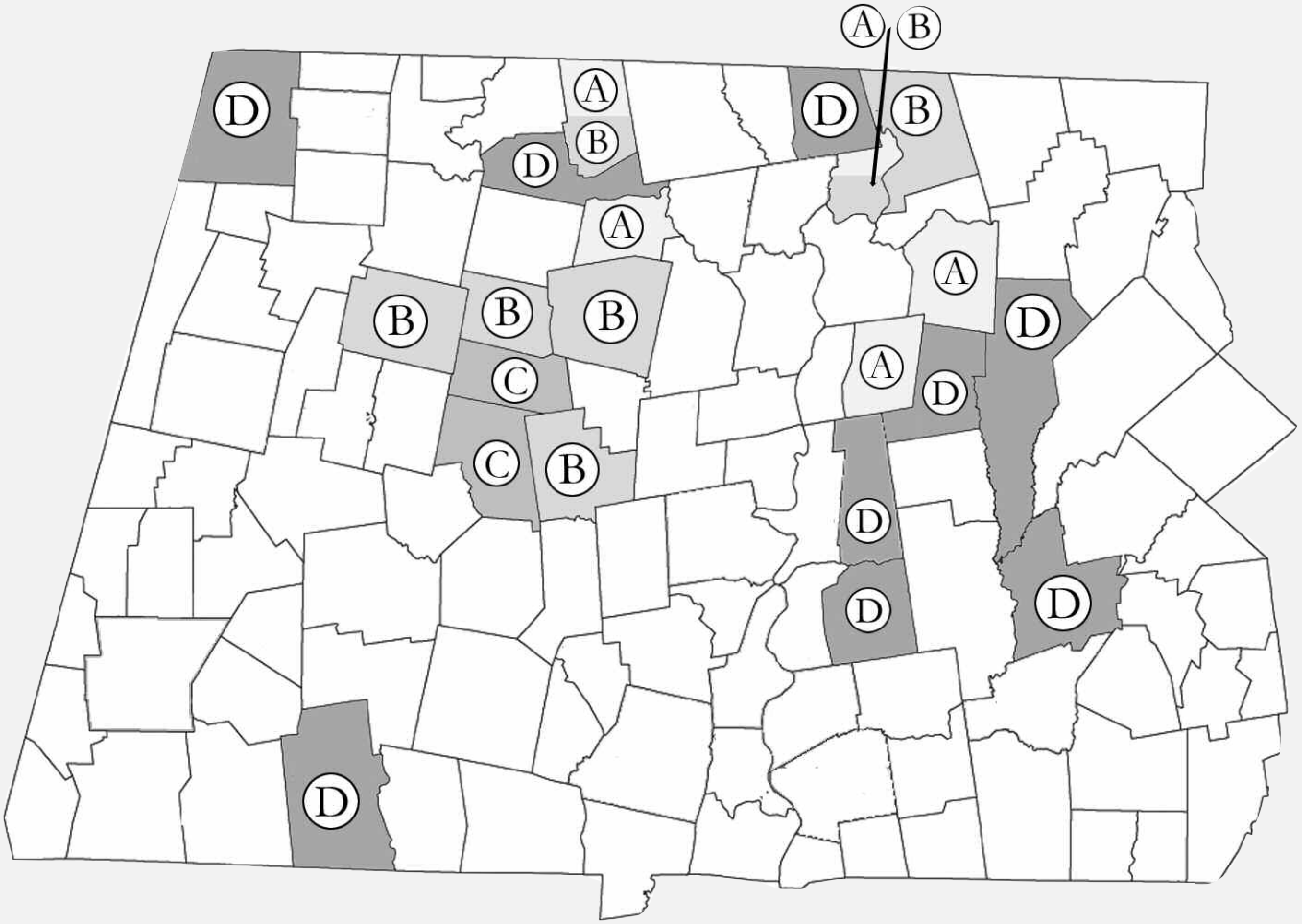
In Vermont, where town meeting advocacy against GE crops first took off on a large scale, 85 towns and cities have passed resolutions, exerting significant influence on state policy. In 2004, Vermont passed a first-in-the-nation law requiring clearer labeling of all GE seeds sold in the state. Then, in May 2006, the Vermont House and Senate passed landmark legislation that would have permitted farmers to sue GE crop manufacturers under private nuisance law in cases where damages from GE contamination that exceeded $3,500 could be demonstrated. On May 15, 2006, however, Governor Jim Douglas vetoed the bill, disappointing many farmers and local agriculture advocates.

In Maine, where two towns have passed measures on GE foods and crops, residents of Montville voted in 2006 to amend their town plan to prohibit the growing of GE crops. This may be the first such measure by a New England town to carry the force of law within its jurisdiction.

In Massachusetts, another major effort has been underway to get town meetings to take up genetic engineering. Led by the Northeast Organic Farming Association of Massachusetts (NOFA/Mass), 21 towns have passed resolutions since 2002 calling for a series of policy turnarounds. The resolutions in Massachusetts and other parts of New England have usually made three demands: 1) mandatory labeling of all GE foods by manufacturers; 2) strict liability protection to strengthen farmers' legal rights when dealing with biotechnology corporations; and 3) a moratorium on further growing of GE crops until independent scientific evidence proves them to be safe, and they can be demonstrated not to harm family farms.

The main activity of this resolution campaign has been educational. Local organizers collect signatures to put the resolution on the town warrant, distribute literature, reach out to the local agricultural community, organize film screenings and speak-

Massachusetts Towns that Have Passed Resolutions Opposing the Genetic Engineering of Crops



Passed in 2002	A	Buckland, Gill, Heath, Leverett, Wendell.
Passed in 2003	B	Northfield, Ashfield, Plainfield, Windsor, Chesterfield. (Resolutions passed again in Gill, Heath)
Passed in 2004	C	Cummington, Worthington
Passed in 2006	D	Charlemont, Shutesbury, Bernardston, Amherst, Granby, Ware Sandisfield, Williamstown, New Salem.

NOFA's Summer Conference

The Northeast Organic Farming Association (NOFA) is holding its 33rd annual Summer Conference from August 10-12, 2007 at Hampshire College in Amherst, MA. Coming out of the back to the land movement, the NOFA conference has provided a unique space for educating people on how to grow food organically. Over the years, workshop topics have become increasingly diverse and the conference has gained appeal to a wider audience of people concerned with ecological sustainability. This year there will be over 150 workshops on topics such as, nutrition, homesteading, herbology, animal husbandry, organic land care, natural building, alternative energies, growing locally, and food politics and activism.

The theme of this year's Summer Conference is a sustainable future based on the strength of local economies. Environmentalist and best-selling author, Bill McKibben will be the keynote speaker on Friday evening, August 10th. McKibben's first publication, "The End of Nature" has been translated into 20 languages and is a classic work addressing global warming. McKibben continues to raise alarm about the effects of climate change. He recently organized a huge national day of climate action on April 14, 2007 in which over 1,400 actions took place all over the United states demanding that Congress Cut Carbon emissions 80% by 2050.

Hazel Henderson will keynote the conference on Saturday evening. A first in NOFA Summer Conference history, she will be appearing via satellite transmission, due to her belief in not wasting fuel via airline transportation. Participants will have the unique opportunity to ask questions through this manner. Henderson is a world renowned futurist, evolutionary economist, a worldwide syndicated columnist, consultant on sustainable development, and author of *Beyond Globalization: Shaping a Sustainable Global Economy*, and eight other books.

NOFA is a non-profit organization of nearly 4,000 farmers, gardeners and consumers working to educate members and the general public about the benefits of a local organic food system based on complete cycles, natural materials and minimal waste for the health of individual beings, communities and the living planet. NOFA encompasses Connecticut, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island and Vermont.

For more information on the Summer conference, visit www.nofamass.org or call Julie Rawson at (978) 355-2853 or e-mail julie@nofamass.org.

ing events, and encourage their local media to run stories about their efforts.

That such a municipally-based campaign should emerge in New England is no accident. New England town meetings have roots that date back before the American Revolution and are unique governing institutions, whose openness and democratic character has made them lively sites of political action. To this day, in most town meetings, anyone who is registered to vote in the town can freely attend, speak on matters pertaining to the meeting's agenda, and propose articles for debate and decision. Town meeting is a face-to-face form of government in which the citizenry can participate directly, unlike federal and state representative bodies and even city councils. In Massachusetts, town meeting is the official system of government in the majority of municipalities – 302 towns throughout the state. In Vermont, there are 246 towns that are governed by town meeting.

These campaigns have helped politicize an issue that is often claimed by scientists as their exclusive domain. The town resolutions challenge the idea that the struggle over biotechnology is merely a matter of divergent scientific opinions, but establish that it is also a conflict about democracy, politics, and power. Many of the resolutions point out, for instance, that GE technology has been marketed without undergoing thorough, long-term, and independent scientific testing. The federal government's regulatory system fails to protect the public in part because it is thoroughly entwined with the biotechnology industry. Its profit interests distort scientific priorities in developing new agricultural technologies and assessing their safety. Scientific amateurs and experts alike have a stake in the issue, because the biotechnology industry threatens our local agricultural economies and our health.

One common argument that has been made against these resolutions is that towns do not really have the power to enact them, and that this is something that must be dealt

The Northeast Organic Farming Association continues legacy of promoting organic and local agriculture.

The 33rd Annual Summer Conference

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with on the federal level. As an organizer myself, I have pointed out that the federal government has shown itself to be consistently unresponsive to the threats these crops pose, and that local organizing is essential if we are going to ever change that.

Another pro-GE argument is that genetic engineering is "just another tool in the toolbox of farmers." This ignores the arguments against GE crops such as the dangers they pose to the environment and human health, and the way the technology has been developed to consolidate corporate control over the food supply through patents, terminator technology, and dependency on agrochemicals. It is driven by the economic argument that, if GE crops can save farmers money in the short term, they should not be banned.

This argument needs to be reframed, as farmers' economic concerns are not so far away from the ethical, political, health and ecological concerns of the activists, many of whom are farmers themselves. The same problems affect both groups. The biotechnology industry is using its legal authority, under corporate patent law, to strong-arm farmers into abandoning the practice of seed saving. Moreover, the industry is using its economic clout to make farmers more dependent on proprietary herbicide-tolerant GE seeds and the accompanying chemical inputs. But as fuel costs increase and food distribution conglomerates continue to pay farmers less money than it costs to produce food, these relations of dependency and servitude to corporate agribusiness are putting farmers in jeopardy.

In Massachusetts, dairy farmers – who grow the vast majority of GE crops in the state – are in dire straits financially. In the early 1990's, there were roughly 800 dairy farms in Massachusetts. Today, a mere 183 dairy farms remain. In 1996, GE crops were first commercialized on a massive scale in the United States, but they clearly did not help the survival of dairy farmers.

Despite the commonalities that different groups share within agricultural communities over the problems they face, agreement over GE crops within these communities won't be achieved until new solutions for the farm crisis become palpable. One dairy farmer who used to grow GE crops told me privately that he thought the only way for a dairy farm to survive economically in the Northeast is to go organic. I saw the same person publicly oppose efforts to put a resolution for a moratorium on GE crops. In our culture, the idea that short-term economic gain takes precedence over long-term ecological sustainability has tremendous power.

In the absence of substantial state aid for organic transition, NOFA/Mass, our sister chapter, NOFA/VT, and the Maine Organic Farmers and Gardeners Association all provide technical assistance to farmers who want to start using organic methods. These essential programs appeal primarily to a farmer's own self-interest to transition to organic milk, which gets a much fairer price than conventional milk. Meanwhile, our communities have a strong stake in this transition away from industrialized agriculture. With these elements in place, the movement must now ask itself what kinds of political changes are possible at the municipal level that not only oppose the encroachment of threats like biotechnology onto our food system, but support the political changes needed to preserve land for organic farming. ■■■

Ben Grosscup works with the NOFA/Mass Social Action program, organizing with farmers and advocates for sustainable agriculture throughout Massachusetts. In 2006 and 2007, he has been coordinating a major Massachusetts-wide campaign called The Town-to-Town Campaign on Genetic Engineering, as well as coordinating a campaign to stop the USDA's National Animal Identification System. To reach the author, contact ben.grosscup@nofamass.org. To reach NOFA/Mass, contact 978-355-2853 or nofa@nofamass.org.

To get more information about the campaign, its past successes, and its goals visit:
http://www.nofamass.org/programs/townmeeting.php

Taking it to the Streets

BY BRIAN TOKAR

BioJustice 2007 Comes to Boston

Since 1999, activists across North America have created comprehensive educational events, and determined oppositional media campaigns in response to the annual conventions of the Biotechnology Industry Organization (BIO). BIO is the world's largest biotech lobbying organization. Their annual conventions have grown in recent years to bring nearly 20,000 biotech executives to major cities across the continent, and have featured high profile speakers from Presidents Clinton and Bush, to Hollywood celebrities, such as the late Christopher Reeve and Michael J. Fox, who has Parkinson's disease. These conventions are a huge public relations extravaganza for the industry, and aim to saturate the host city's media with stories about the purported wonders of biotechnology.

This year, both the convention and the counter-events returned to Boston, which was previously the site of Biodevastation 2000, the largest gathering in this series. That response to BIO in March of 2000 included a 3-day teach-in featuring Vandana Shiva, Ralph Nader and Barry Commoner, among many others, as well as a colorful parade of more than 3000 people from Copley Square to the old Hynes Convention Center. Today, major Boston conventions are housed in a new fortress-sized facility on the edge of South Boston, and the activist climate just isn't what it was in early 2000, when the dramatic events surrounding the World Trade Organization's (WTO) Seattle ministerial meeting had just recently invigorated a worldwide movement for global justice. This year's plans have been considerably more modest, but the goal of significantly challenging the industry's PR image has remained a central focus.

The Biotechnology Industry Organization (BIO) is clearly the world's most powerful voice for the biotechnology industry, with an annual budget in the vicinity of $50 million. Its leading officials, including its president, former Pennsylvania congressman James Greenwood, spend millions every year trying to paint their conventioneers as an altruistic and scientifically-minded group, seeking cures to human disease and solutions to feed the world's hungry. But the BIO conventions are vastly different from typical scientific meetings. Less than ten percent of registrants have historically listed themselves as scientists, and the entrance fees range from $1,000 to over $2,000. Sessions on business development, intellectual property and finance far outweigh the conspicuously out-of-place presentations that are grouped together under the generic heading, "Science."

Companies pay up to $300,000 to become top-tier ("Double Helix") sponsors of the BIO convention. For 2007, these first-level sponsors include Johnson & Johnson, AstraZeneca and Novo Nordisk. Several Boston area companies such as Amgen (headquartered on both coasts), Biogen Idec and Genzyme (pioneer in the development of genetically engineered animals) are also in this first tier category. Other major sponsors (over $100,000) include well-known companies such as Bristol-Myers Squibb, Merck, Genentech, the investment firm Ernst & Young, and GE food giants Monsanto, Bayer, and Dow Agrosciences.

The annual counter-events trace their history to the first "Biodevastation" conference, organized by the Gateway Green Alliance in St. Louis in 1998. This event did not coincide with a BIO convention, but was perhaps the first large gathering on biotech issues in the US that focused mainly on popular education and grassroots mobilization.

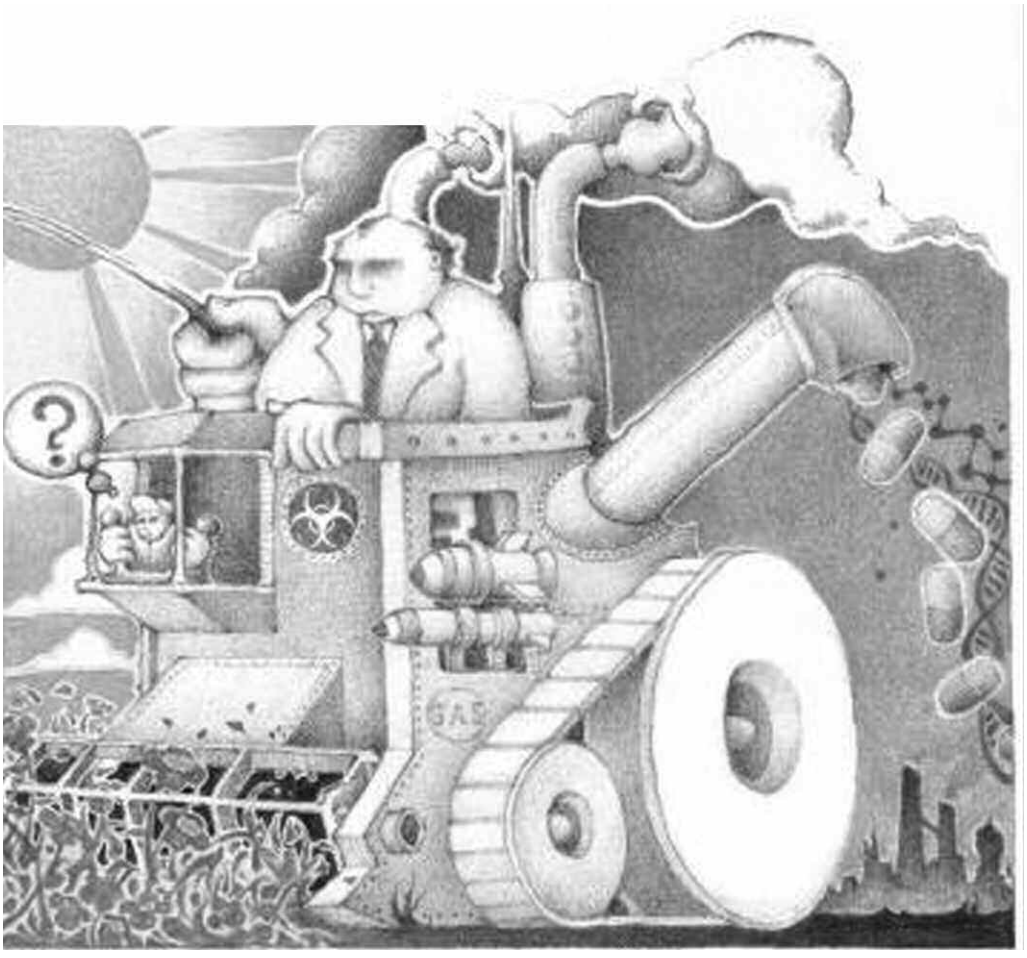
Participants from at least three continents assembled on the last day for a lively gathering just outside Monsanto's headquarters in the suburbs of St. Louis. Vandana Shiva, a keynote speaker in St. Louis, invited several organizers to a follow-up conference in India early the following year, and it was there that activists crystallized plans for an event to counter BIO's convention in Seattle in May of 1999. The Seattle event, hosted by Beth Burrows' Edmonds Institute, made national headlines when, on the last day of both "Biodevastation 3" and the BIO convention, scientists at Cornell University announced their dramatic finding that Bt corn pollen was lethal to monarch butterfly larvae. BIO announced that their next convention would take place in Boston and the activist community was quick to respond. At the Biodevestation event in Boston in May 2000, panelists and workshop leaders included scientists, farmers and activists from India, the Philippines, England, South Africa, Canada, Uruguay and all over the United States.

Subsequent years saw lively gatherings, under various names – Biojustice, Biodiversity, Biodemocracy, etc. – countering BIO's conventions in San Diego, Toronto, San Francisco, and Philadelphia. There was also a second event in St. Louis in 2003 that coincided with the first World Agricultural Forum, a creation of a former top Monsanto executive. Another very large event happened later that year in Sacramento, as the USDA hosted an international conference aimed at lobbying the world's agriculture ministries in the lead-up to the Cancún ministerial meeting of the WTO.

The 2004 gathering in San Francisco took up the theme of "Reclaim the Commons," with a focus on movements for ecological renewal in many Bay Area neighborhoods. The Philadelphia event in 2005 was the first to prominently feature a broad, three-part focus – implicit in several prior events – on GE agriculture; healthcare, human genetics and the pharmaceutical industry; and the growing US bioweapons establishment. Three marches, each highlighting one of these themes, converged in front of Philadelphia's historic City Hall.

The Boston "Biojustice" events in 2007 aimed to significantly replicate this triple focus. An opening session at Old South Church featured representatives of international farmers' movements from Bangladesh, Latin America and the US southwest, along with Berkeley professor Ignacio Chapela and author Anna Lappé. A panel on Biotechnology, Medicine, and Human Rights included Our Bodies Ourselves co-founder and director Judy Norsigian, Boston University bioethicist and CRG Board member George Annas, activist physicians and nurses, and Sonia Shah, author of a new book exposing drug company testing programs around the world. An entire day was devoted to events in support of local opposition to Boston University's planned Level 4 biolab, to be sited in one of Boston's most economically disadvantaged and densely populated neighborhoods and widely seen as a new center for US biowarfare research. Local activists in Boston planned a full week of parades, rallies, workshops, music, a free health care clinic and free daily non-GMO meals, aimed to dramatize popular resistance to the biotech agenda and highlight a broad scope of community-based alternatives.

Another important focus of recent events has been the biotech industry's largely empty promises of bringing economic development and new jobs to cities across the continent. Civic officials, hoping to court biotech companies, are always prominent among the convention's sponsors and featured speakers. But neither the Boston area nor San Francisco, acknowledged as the industry's two leading centers, can list a single biotech firm among the area's top 25 employers. "[I]t is unlikely," reported the Massachusetts Biotechnology Council several years ago, that the industry "will ever be a dominant contributor to the employment pool such as the computer industry has been over the past two decades." Biotech companies in the Boston area now each average around 100 employees. The biotech sector has



Looking Back

Biocolonialism

In GeneWatch *4-6, published in November 1987, Jack Kloppenburg, Jr. and Daniel Lee Kleinman paint a vivid picture of what biocolonialism looked like before widespread genetic engineering and the influence of digital rights management. The following is an excerpt from their article, "Plant Genetic Resources: Common Heritage or National Sovereignty?"*

Plant germplasm – the genetic information encoded within the seed – is a resource of tremendous value. Recently, questions of access to, control over, and preservation of plant genetic resources have emerged as a field of international concern and conflict.

In the capitalist world economy of today, extracted natural resources are treated as commodities. Plant germplasm is a notable exception. For over two centuries, scientists form the advanced industrial nations have freely appropriated the plant genetic resources from Third World nations for us in the plant breeding and improvement programs of the developed world. The unrecompensed extraction of these materials has been predicated on a widely accepted ideology that defines germplasm as the "common heritage of mankind." As "common heritage," germplasm is looked upon as a public good for which no payment is necessary or appropriate.

But as the private seed industries of the North have matured over the last decade, they have reached out for global markets. In order to facilitate this expansion, they have sought internal recognition of patent-like "plant breeders' rights" for the plant varieties they develop. With these developments, the developing nations began to see something of a contradiction in the status of their genetic resources as freely available "common heritage" and the status of seed companies' commercial varieties, many based on plant genetic resources originally obtained at no cost from the Third World, as "private property" available by purchase.

Mounting Third World dissatisfaction with this and other asymmetries found expression at the 1983 biennial conference of the Food and Agriculture Organization of the United Nations (FAO). At that time, an International Undertaking on Plant Genetic Resources was passed amid acrimonious debate and the vehement opposition of the capitalist nations of the industrial North. The Undertaking asserts the noble principle that "plant genetic resources are a heritage of mankind and consequently should be available without restriction." However, it goes on to specify that under the rubric of plant genetic resources are included "special genetic stocks (including elite and breeders lines)." That is, the Undertaking claims what are now proprietary materials as no less the common heritage – and therefore common property – of humanity than the peasant developed landraces of the Third World. (Landraces are genetically variable populations which exhibit different responses to pests, diseases, and fluctuations in environmental conditions.)

Such and arrangement is patently unacceptable to those advanced capitalist nations with powerful private seed industries....What the FAO Undertaking demands is literally the decommodification of commercial plant varieties.

At this juncture, we do not believe that the achievement of "common heritage" in plant genetic resources would result in more equitable relations or exchange between nations or benefit the mass of the world's people. We suggest that recognition of national sovereignty over plant genetic resources would between serve the nations and peoples of the Third World.

already lived through numerous boom and bust cycles and, according to a 2005 report by Ernst & Young, is responsible for an historic net loss to investors of more than $45 billion. Only a handful of biotech companies have ever been profitable, and most of those have relied on subcontracting research and development services to larger companies, mainly in the pharmaceutical industry.

In recent years, the combination of focused popular resistance and an industry awash in red ink has finally led to more skeptical media coverage of BIO's conventions. The mainstream press in various cities has begun to realize that biotechnology might not feed the world, instantly cure our most intractable diseases, or keep us safe from terrorism. Ironically, the biotech industry's latest move is to paint its products as the key to addressing global warming, through the creation of genetically engineered plants and microbes to facilitate the production of alternative fuels from crops, grasses and trees. In response, Biojustice 2007 featured a traveling road show from the climate justice group Rising Tide, and a showing of the recent film, *A Silent Forest*, which highlights the threat of genetically engineered trees.

This dialectic will surely become increasingly important in the coming years. As biotech advocates elaborate their message, activist critics are gaining adherent by elaborating and spreading theirs. ■■■

Brian Tokar is the editor of Redesigning Life? *and* Gene Traders*, among other books, and directs the Biotechnology Project at Vermont's Institute for Social Ecology (www.social-ecology.org).*

NEW STEM CELL BILL PASSES OUT OF SENATE, AWAITS VETO

The Senate has once again passed a bill that would allow federal funding for research conducted on stem cells created after August 9, 2001. President Bush first announced the availability of such funding in a speech on that date, but restricted it to preexisting stem cell lines, claiming that America "should not create life to destroy life." American scientists quickly derided this decision, arguing it would delay the development of potentially life-saving treatments and cause researchers to leave the country in pursuit of available funding. More recently, they complain that older stem cell lines are beginning to degrade and that some of them have become contaminated in storage.

The Senate bill has had bipartisan support for a number of years. Its predecessor, The Stem Cell Research Enhancement Act of 2005 was passed by Congress, but did not have the two-thirds majority to overturn President Bush's July 19, 2006 veto, the first of his presidency. Like the Act of 2005, The Stem Cell Research Enhancement Act of 2007 would allow for funding research on stem cells derived from embryos being stored in fertility clinics, which are routinely destroyed. However, like the 2005 Act, the 2007 Act does not have the needed support to overturn the expected veto from President Bush.

NEW CHIMERIC SHEEP IS 15% HUMAN

A University of Nevada scientist and professor, Esmail Zanjani, has created a human-animal chimera, which contains the greatest fraction of human cells of any human-animal chimera to date. The chimera is an apparently healthy sheep, 15% of the cells of whose are human. Zanjani implanted adult human cells a fetal sheep, with the goal of developing organs that would be transplantable to humans. If such organ transplants were to be successful, Zanjani hopes that human patients will one day be able to provide their own cells in the production of personalized chimeras.

GENETIC HEART DISEASE TESTS PROVE UNRELIABLE

A study, published in the April 11, 2007 edition of the *Journal of the American Medical Association* concluded that genetic tests for 85 gene variants, believed to be linked to greater susceptibility to atherosclerosis, had little to no predictive value. Atherosclerosis, or "hardening of the arteries," is a common condition that can lead to strokes, heart attacks and various other heart diseases.

Atherosclerosis is also an aspect of a group of conditions called the "metabolic syndrome," which includes insulin resistance and high blood pressure. Increased prevalence of the metabolic syndrome among black people, along with higher rates of mortality in this group, has been a factor in recent attempts to ascribe a genetic component to racial health disparities. However, while many of the conditions in this so-called syndrome have some genetic components, they are also highly correlated with lifestyle, economic and environmental factors, such as diet, exercise and stress.

For more on the way race is used in drug patenting, specifically in the case of BiDil (the hypertension medication that is the first drug with a race-specific label), please see Jonathan Kahn's "The Politics of Patenting Race" on page 3.

GENERIC BIOTECH DRUG BILL RAISES QUESTIONS OF FDA REGULATION

A new bill, introduced in April by the two Democratic Senators from New York – Hilary Clinton and Charles Schumer – aims to streamline the Food and Drug Administration's (FDA) approval process for generic biologic drugs. As opposed to synthetic pharmaceuticals, which have defined chemical structures, biologics are the products of living organisms, or in some cases, are the organisms themselves. The bill, which has wide, bipartisan support, would allow the FDA to approve generic biologics, on the basis of the trials of the original drug, without having to go through independent human trials. Critics of the bill, however, suggest that the complex nature of biologic drugs makes comparison between generics and originals insufficient for determining safety.

Biologics represent major revenue streams for pharmaceutical companies, since their yearly income from such products can reach hundreds of thousands of dollars per patient. The bill, which attempts to address this high cost, has resulted in role-reversals for both the politicians and the lobbyists who have worked on the issue in the past. Pharmaceutical industry lobbyists have historically fought legislation that would increase FDA regulation, because of its potentially chilling effect on the development of new drugs. Meanwhile, many of the current bill's sponsors, including Senators Clinton and Schumer, usually argue that the FDA's regulations should be stricter and more precautionary, so as to better guard patient safety.

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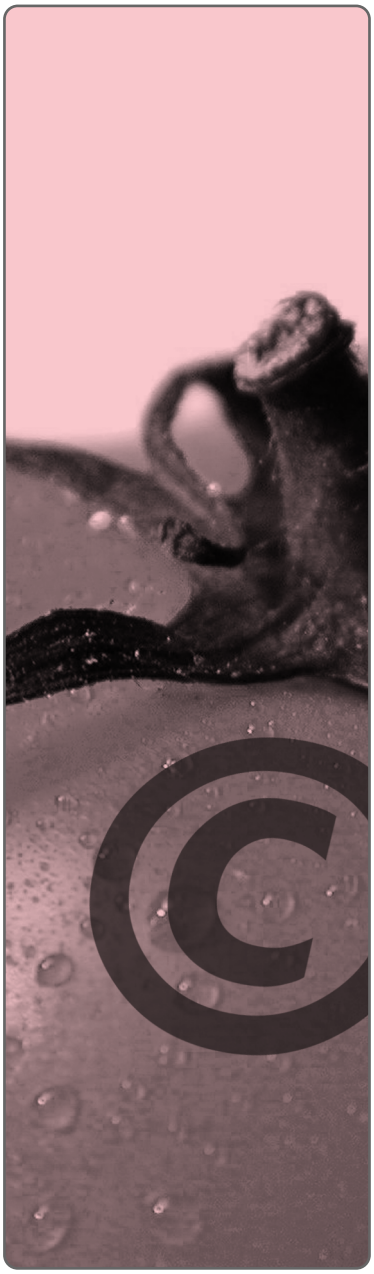
To learn more about helping CRG, please call us at 617.868.0870. You may also write the Council for Responsible Genetics at 5 Upland Road, Suite 3, Cambridge MA 02140, or send an email to crg@gene-watch.org.



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