PIPRA

THE PUBLIC INTELLECTUAL PROPERTY RESOURCE FOR AGRICULTURE

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Supporting innovative agriculture worldwide.

PIPRA supports agricultural innovation for both humanitarian and small-scale commercial purposes. We bring together intellectual property from over 40 universities, public agencies, and non-profit institutes and help make their technologies available to innovators around the world.

Quick links

- IP handbook
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PIPRA is a non-profit alliance of public institutions

POLICY FORUM

INTELLECTUAL PROPERTY RIGHTS

Public Sector Collaboration for Agricultural IP Management

Richard C. Atkinson, Roger N. Beachy, Gordon Conway, France A. Cordova, Marye Anne Fox, Karen A. Holbrook, Daniel F. Klessig, Richard L. McCormick, Peter H. McPherson, Hunter R. Rawlings III, Rip Rapson, Larry N. Vanderhoef, John D. Wiley, Charles E. Young

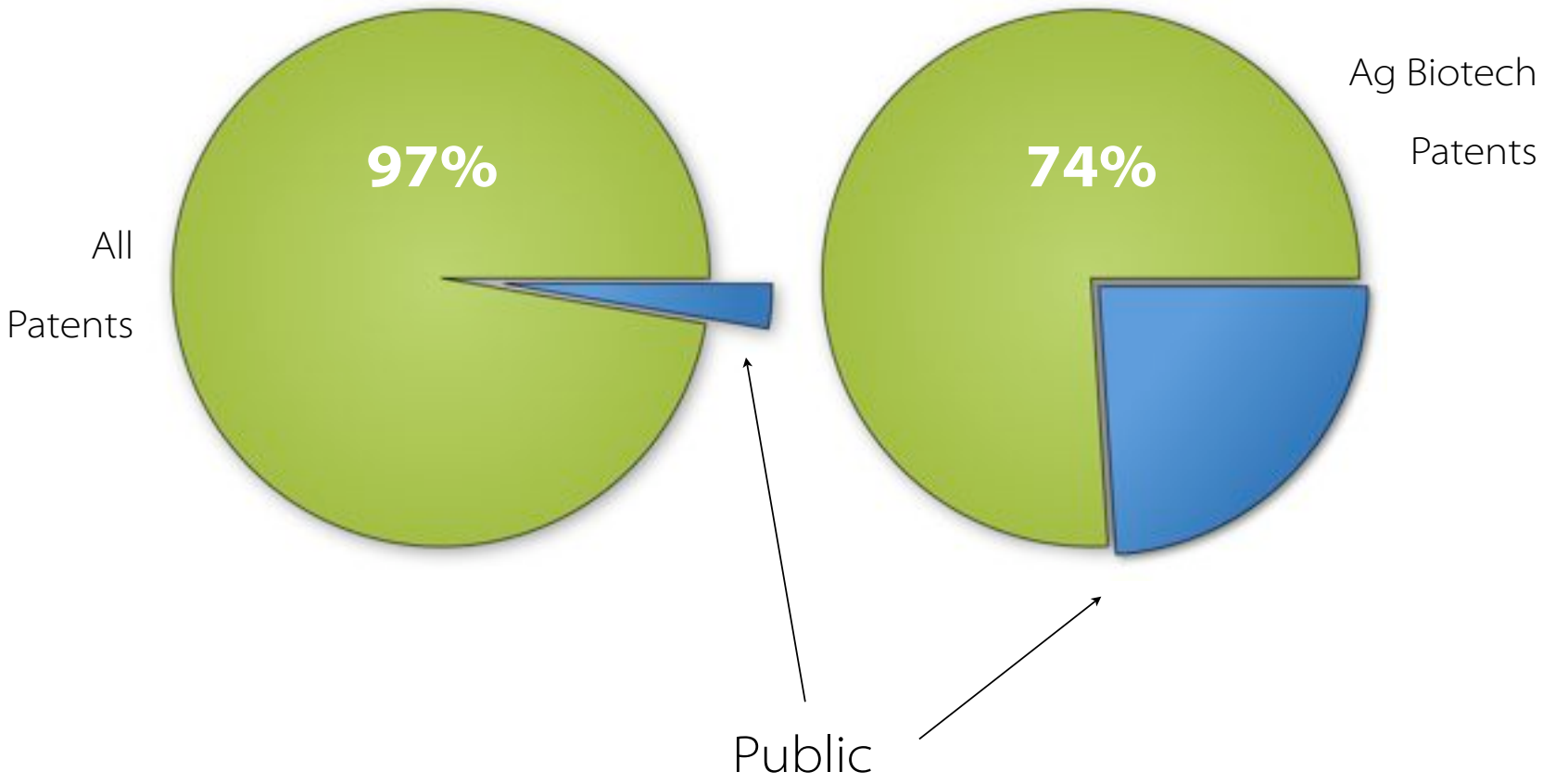
The impact of public-sector research is evident in many technology sectors, and this is particularly true in agriculture. Dating back to the establishment of the Land Grant College system in 1862, universities and other public-sector institutions have been the leaders in developing improved crop varieties that were transferred to farms and to the agricultural industry through cooperative extension services in the United States or equivalent organizations internationally. However, this model is changing rapidly because of increased intellectual property (IP) protec-

Annual grants of U.S. utility patents in the area of plant biotechnologies.

(3). However, these practices are not universally applied across institutions, with the net result that, although many significant discoveries and technologies have been generated with public funding, these discoveries are no longer accessible as "public goods."

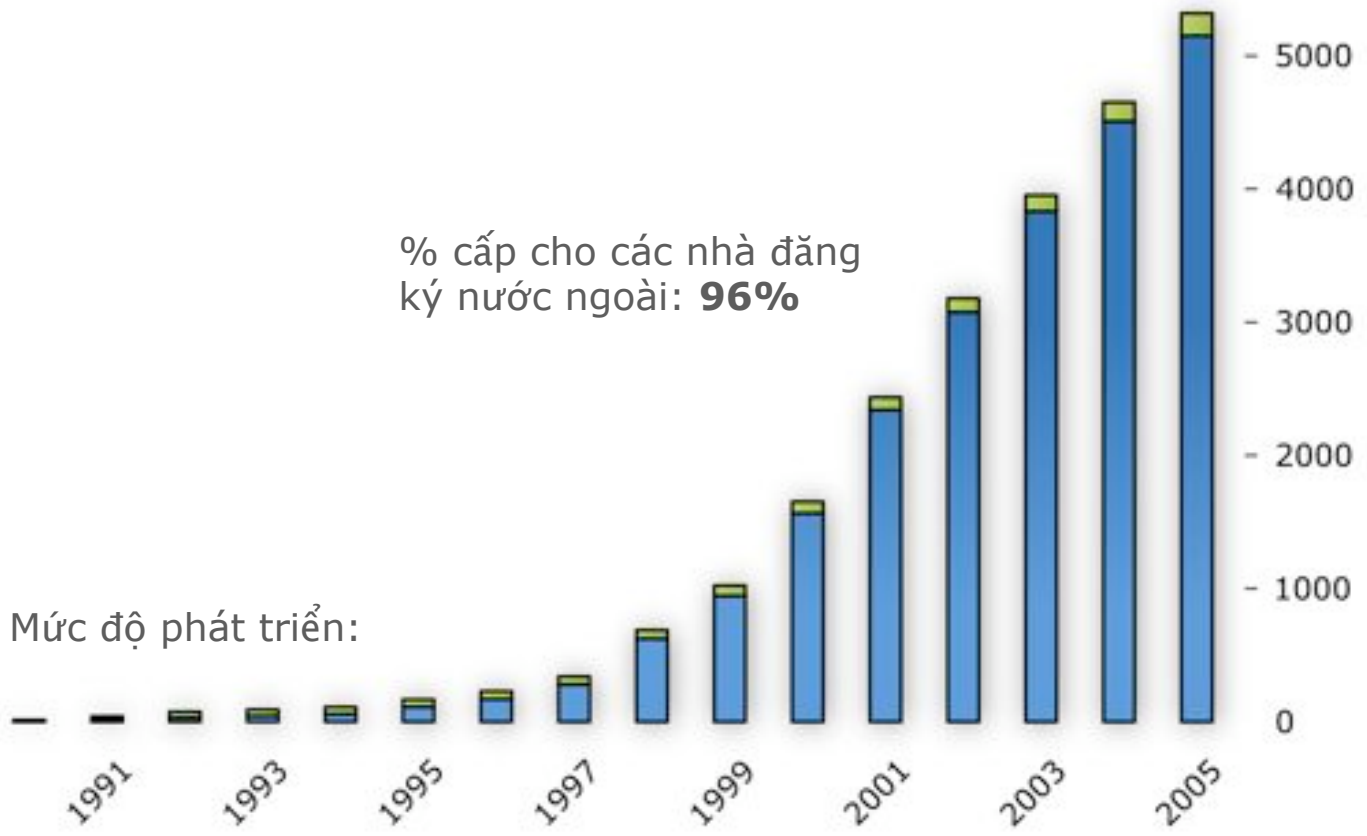
Our institutions have found that the public research sector finds itself increasingly restricted when wishing to develop new crops with the technologies it has itself invented, including so-called "enabling technologies"—the research tools necessary for further experimentation and innovation. In agricultural research, applied research and genetic improvement of crops are derivative processes based on pre-existing plant material, and each incremental improvement now brings with it a number of IP and germplasm constraints that have accumulated in the plant material. When IP rights for agricultural materials and technologies are held by multiple public- and private-

Public institutions are particularly strong in ag-biotech



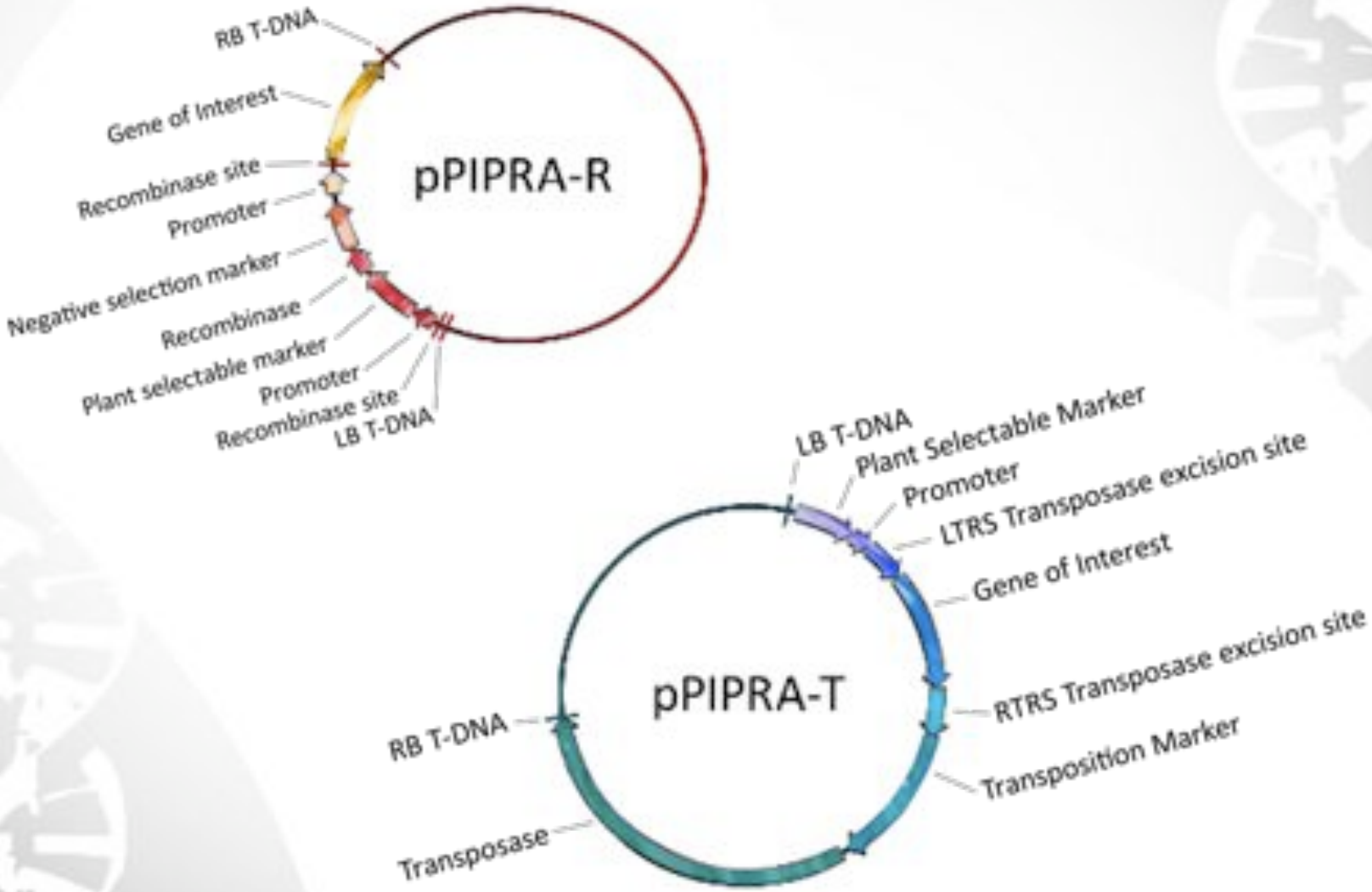
Sở hữu trí tuệ ở Việt Nam ngày càng phát triển

Intellectual property in Vietnam is growing rapidly



Hầu hết IP ở Việt Nam thuộc sở hữu của các công ty tư nhân nước ngoài.

We make "open source" biotech tools



We teach about IP in developing economies

> This Handbook... is a valuable guide in helping to navigate the complex—but rewarding—world of an increasingly global innovation system.
>
> — Norman Borlaug
> Nobel Peace Prize Laureate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And, we do IP research

POLICY FORUM

INTELLECTUAL PROPERTY

Intellectual Property Landscape of the Human Genome

Kyle Jensen and Fiona Murray*

Gene patents are the subject of considerable debate and yet, like the term "gene" itself, the definition of what constitutes a gene patent is fuzzy (*1*). Nonetheless, gene patents that seem to cause the most controversy are those claiming human protein-encoding nucleotide sequences. This category is the subject of our analysis of the patent landscape of the human genome (*2*).

Enhanced online at www.sciencemag.org/cgi/content/full/310/5746/239

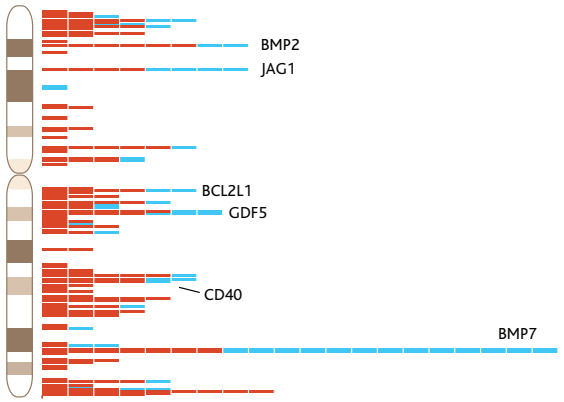
Critics describe the growth in gene sequence patents as an intellectual property (IP) "land grab" over a finite number of human genes (*3*, *4*). They suggest that overly broad patents might block follow-on research (*5*). Alternatively, gene IP rights may become highly fragmented and cause an anticommons effect, imposing high costs on future innovators and underuse of genomic resources (*6*). Both situations, critics argue, would increase the costs of genetic diagnostics, slow the development of new medicines, stifle academic research, and discourage investment in downstream R&D (*7*–*11*).

In contrast, the classic argument in support of gene patenting is that strong IP protection provides incentives crucial to downstream investment (*12*, *13*) and the disclosure of inventions. Patents are also regarded tinguishing patents on the human genome from those on other species (*23*).

Our detailed map was developed using bioinformatics methods to compare nucleotide sequences claimed in U.S. patents to the human genome. Specifically, this map is based on a BLAST (*24*) homology search linking nucleotide sequences disclosed and claimed in granted U.S. utility patents to the set of protein-encoding messenger RNA transcripts contained in the National Center for Biotechnology Information (NCBI) RefSeq (*25*) and Gene (*26*) databases. This method allows us to map gene-oriented IP rights to specific physical loci on the human genome (*27*) (see figure, right). Our approach is highly specific in its identification of patents that actually claim human nucleotide sequences. However, by limiting the search to patents using the canonical "SEQ ID NO" claim language we do not consider claims on genes defined through amino acid sequences. (See table S1 for a sensitivity analysis.)

California, Isis Pharmaceuticals, the former SmithKline Beecham, and Human Genome Sciences. The top patent assignee is Incyte Pharmaceuticals/Incyte Genomics, whose IP rights cover 2000 human genes, mainly for use as probes on DNA microarrays.

Although large expanses of the genome are unpatented, some genes have up to 20 patents asserting rights to various gene uses and manifestations including diagnostic uses, single nucleotide polymorphisms (SNPs), cell lines, and constructs containing the gene. The distribution of gene patents was nonuniform (see figure, page 240, top right): Specific regions of the genome are "hot spots" of heavy patent activity, usually with a one-gene-many-patents scenario (see figure, below). Although less common, there were cases in which a single patent claims many genes, typically as complementary DNA probes used on a microarray (see figure, p. 240, bottom).



Physical mapping of patent activity on chromosome 20, divided into 300-kb segments. Each horizontal bar represents a unique

The global stem cell patent landscape: implications for efficient technology transfer and commercial development

Karl Bergman & Gregory D Graff

Characteristics of the complex and growing stem cell patent landscape indicate strategies by which public sector research institutions could improve the efficiency of intellectual property agreements and technology transfers in stem cells.

The debate over access to research tools essential for stem cell research and development has been waged most strongly over patents granted in the United States to the Wisconsin Alumni Research Foundation (WARF) for work done at the University of Wisconsin on embryonic stem cells[1,2]. Although those WARF patents are now being widely licensed, the concerns that they raised[3–7] may soon be overshadowed by a more subtle but more chronic problem. Patent filing activity in stem cells has been growing steadily since the late 1990s. Given the particular characteristics of stem cells as a broadly enabling technology, many expect the field to be particularly susceptible to the emergence of a patent thicket[8–13], also known in property rights theory as an 'anti-commons'[14]. In a patent thicket, the existence of many overlapping patent claims can cause uncertainty about freedom to operate, impose multiple layers of transaction costs and stack royalty payments beyond levels that can be supported by the value of single innovations. By blocking pathways to market and dampening investor interest in commercialization, a patent thicket has the potential to slow and skew the overall development of new technical applications.

Proposals that seek to solve the patent thicket problem by altering, reducing or eliminating the granting of problematic property rights beforehand are important to consider for the long-term efficiency of the patent system[15,16]. This approach is fundamentally policy-oriented, seeking changes in patent law, particularly in scope and subject matter, or changes in patent administration and enforcement. In the short to medium term, however, this approach has at least two major drawbacks. First, changes in law tend to require a critical mass of political support. Second, the die has already been cast: the existing patent estates in the field of stem cells have already been created under current law and practice. Academia and industry must continue to operate under this legacy for the next two decades.

A second approach seeks more efficient exchange, transaction or redistribution of granted property rights after the fact[17–21]. This approach is market- or institutionally oriented, seeking ways that existing assets can be put to use more efficiently, regardless of the initial grant or scope of rights. This may be a more feasible approach in the short to medium term and, under the right conditions, a more efficient solution in the long term. Examples include mechanisms ranging from compulsory licensing, to open source licensing, to the formation of patent pools and other forms of collective action. Such approaches do not the existing environment to facilitate transactions in a more efficient manner than would be achieved under multiple rounds of one-on-one negotiations.

Issues in stem cell patenting and licensing

Until now, stem cell research within many academic settings has proceeded without paying heed to the patent environment. However, university research administrators and technology transfer offices are becoming more concerned, particularly when universities engage in commercially sponsored research projects or look for opportunities to license out university inventions. Specific issues that have arisen with the broad WARF patents may be indicative of future developments in the field. In industry, access to intellectual property has been a concern for some time, but at the same time has often been overshadowed by even greater concerns about ethical and regulatory constraints on the commercial viability of stem cell technologies and products based on them[22]. The emerging shape of the complexity of the field holds important implications about where bottlenecks are most likely to affect the rate and direction of stem cell research, development and commercial application.

The WARF patents, claiming all primate and human embryonic stem cell lines, embody one of the strongest possible property claims in the field of stem cells, establishing control at the very root of all possible lineages of cellular dif-

Karl Bergman is at the Göteborg International Bioscience Business School and Center for Intellectual Property Studies, Chalmers University of Technology and Göteborg University, Göteborg, Sweden and Gregory D. Graff is at the Public Intellectual Property

Bayh-Dole: if we knew then what we know now

Sara Boettiger & Alan B Bennett

More than 25 years after the US Bayh-Dole Act was passed to encourage technology transfer from universities, is it time to reexamine and revamp this key legislation?

The controversies surrounding the US Bayh-Dole Act[1], enacted 25 years ago, are a frequent topic of scholarly articles and conferences, as well as the topic of regular legislative forays designed to modify the Act's terms to achieve a variety of social or economic goals[2]. In addition to its importance as a component of the US innovation system, Bayh-Dole-like legislation is being adopted in other countries[3], providing an impetus to ask the question: If we were to write similar legislation today, what issues would be addressed differently, given our experience with the Bayh-Dole Act over the past quarter century?

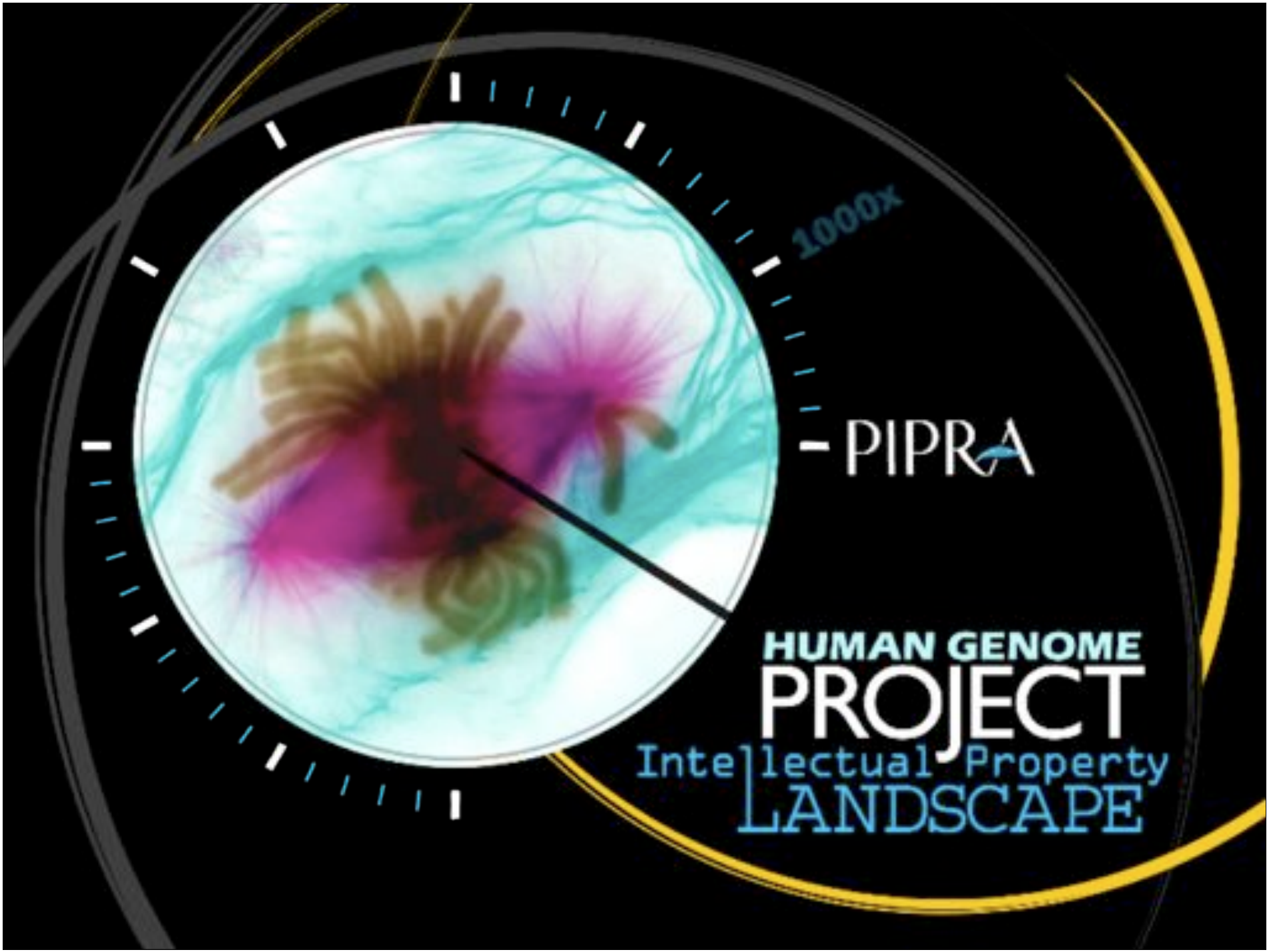
The track record

The range of immediate answers to the above question would likely reflect the now entrenched camps of opposing opinions. Supporters believe Bayh-Dole's nationally uniform framework is critical for the successful transfer of technology from university to industry, and that it serves as a catalyst for economic growth[4]. Critics argue that the Act has brought about deleterious consequences for the US innovation system and altered the nature of the public research enterprise[5]. A third camp in the debate believes that Bayh-Dole has had little impact, viewing the upswing in university technology transfer as the result of other, concurrent events, such as US Supreme Court decisions permitting the patenting of novel organisms, increased government investment in biomedical research and the emergence of research-intensive companies in information technology and life sciences that could exploit university inventions[6].

Fundamentally, Bayh-Dole shifted the incentive structure that governed the research and development path of federally funded inventions by allowing institutions to own inventions resulting from federally sponsored research and to exclusively license those inventions. The Act also requires the institution to establish patent policies for its employees, to actively seek patent protection and to encourage the development of their inventions. Beyond these basic requirements, the legislation leaves a great deal of discretion to the institutions. This flexibility has been both a source of strength for Bayh-Dole and a weakness. Many of the issues that are identified today as negative consequences of Bayh-Dole can be traced to the institutional policies structured to optimize institutional benefits and income, rather than to the Act itself.

Over time, universities have come to a more subtle understanding of the benefits and the limitations of technology transfer. Collectively, university technology transfer offices (TTOs) have learned that patent portfolios are difficult and expensive to manage, they take a long time to mature to the point where they will deliver revenue, results are widely variable and the investment required represents a long-term commitment. As a result, expectations have changed with the primary focus of technology transfer shifting from one that is narrowly based on institutional revenue to one encompassing impacts on the broader local economy, industry-university relations, the formation of new companies and the development of industry clusters. However, changing the metrics by which a TTO is evaluated, and thus indirectly changing the incentive system affecting those making patenting and licensing decisions, has been a slow and evolving process.

Sara Boettiger and Alan B. Bennett are at the Public Intellectual Property Resource for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Our analysis show that 4,382 of the 23,688 genes in the human genome are claimed in granted U.S. patents

NCBI Map Viewer. Build 35.1 http://www.ncbi.nlm.nih.gov/mapview/ (2005).

D. Maglott, J. Ostell, K. D. Pruitt, T. Tatusova, *Nucleic Acids Res* **33 Database Issue**, 54 (2005).

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October 14, 2005

Human Gene Patents 'Surprisingly High,' A New Study Shows

By SYLVIA PAGAN WESTPHAL
Staff Reporter of THE WALL STREET JOURNAL
October 14, 2005; Page B1

At least 18.5% of human genes are covered by U.S. patents, say researc who have produced the first comprehensive map of the patent landscap the genome.

The researchers called the figure "surprisingly high" and their findings journal Science, are likely to add fuel to an already heated debate over human gene sequences commercially.

U.S. and European patent law preclude anyone from patenting a gene for several decades, inventors and institutions have been filing for pate of isolating the genes or developing a specific therapeutic use for them

They have also been making similar claims over the specific proteins t produce. A well-known example is erythropoietin, a blood protein ma Epogen to stimulate the production of red blood cells and whose paten

Winning Rights

Top five patent assignees, by number of patents issued:

University of California	667
Incyte Pharmaceuticals	511
SmithKline Beecham	509
Genentech	398
Human Genome Sciences	391

Note: Analysis doesn't take into account adjustments for mergers and acquisitions, subsidiaries or spelling variations; some patents cover multiple genes.
Source: Kyle Jensen, Massachusetts Institute of Technology

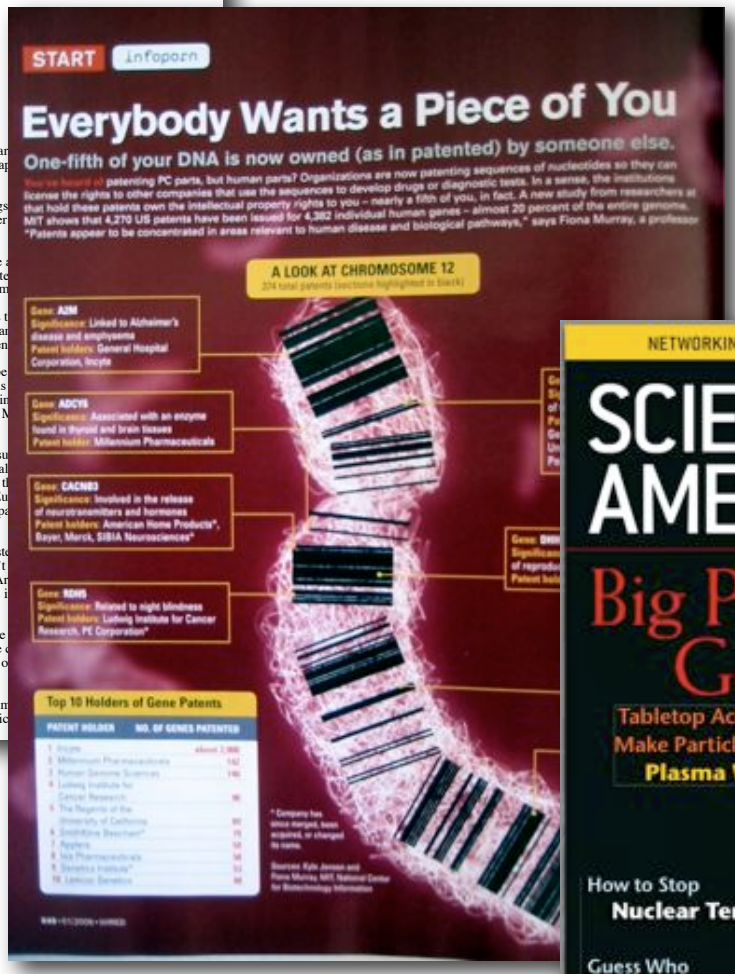
But gene patents can still be involved in breast cancer, is genes, with 14 patents issuin study by researchers at the M Technology.

The BRCA1 has been the su where several countries chal Genetics' patent claims on th diagnostic purposes. The Eu one of the company's key pa diagnostic use last year.

The opposition in Europe st that one company shouldn't and the test, according to Ar University who specializes i property.

As the number of gene patents increased in the late 1990s, mainly due genomics-based companies, concern grew that too many parties were sequences, says Ms. Rai. Some companies were patenting sequences o knowledge of what those genes did, she says.

Based on looking at a handful of genes, some groups had offered estim patenting, but nobody really knew for sure how widespread the practic



Patents on DNA have not caused the severe disruption of biomedical research

OWNING

By Gary Stix

There is a gene in your body's cells that plays a key role in early spinal cord development. It belongs to Harvard University. Another gene makes the protein that the hepatitis A virus uses to attach to cells; the U.S. Department of Health and Human Services holds the patent on that. Incyte Corporation, based in Wilmington, Del., has patented the gene of a receptor for histamine, the compound released by cells during the hay fever season. About half of all the genes known to be involved in cancer are patented.

Human cells carry nearly 24,000 genes that constitute the blueprint for the 100 trillion cells of our body. As of the middle of last year, the U.S. Patent and Trademark Office had issued patents to corporations, universities, government agencies and nonprofit groups for nearly 20 percent of the human genome. To be more precise, 4,382 of the 23,688 genes stored in the National Center for Biotechnology Information's database are tagged with at least one patent, according to a study published in the October 14, 2005, *Science* by Fiona Murray and Kyle L. Jensen of the Massachusetts Institute of Technology. Incyte alone owns nearly 10 percent of all human genes.

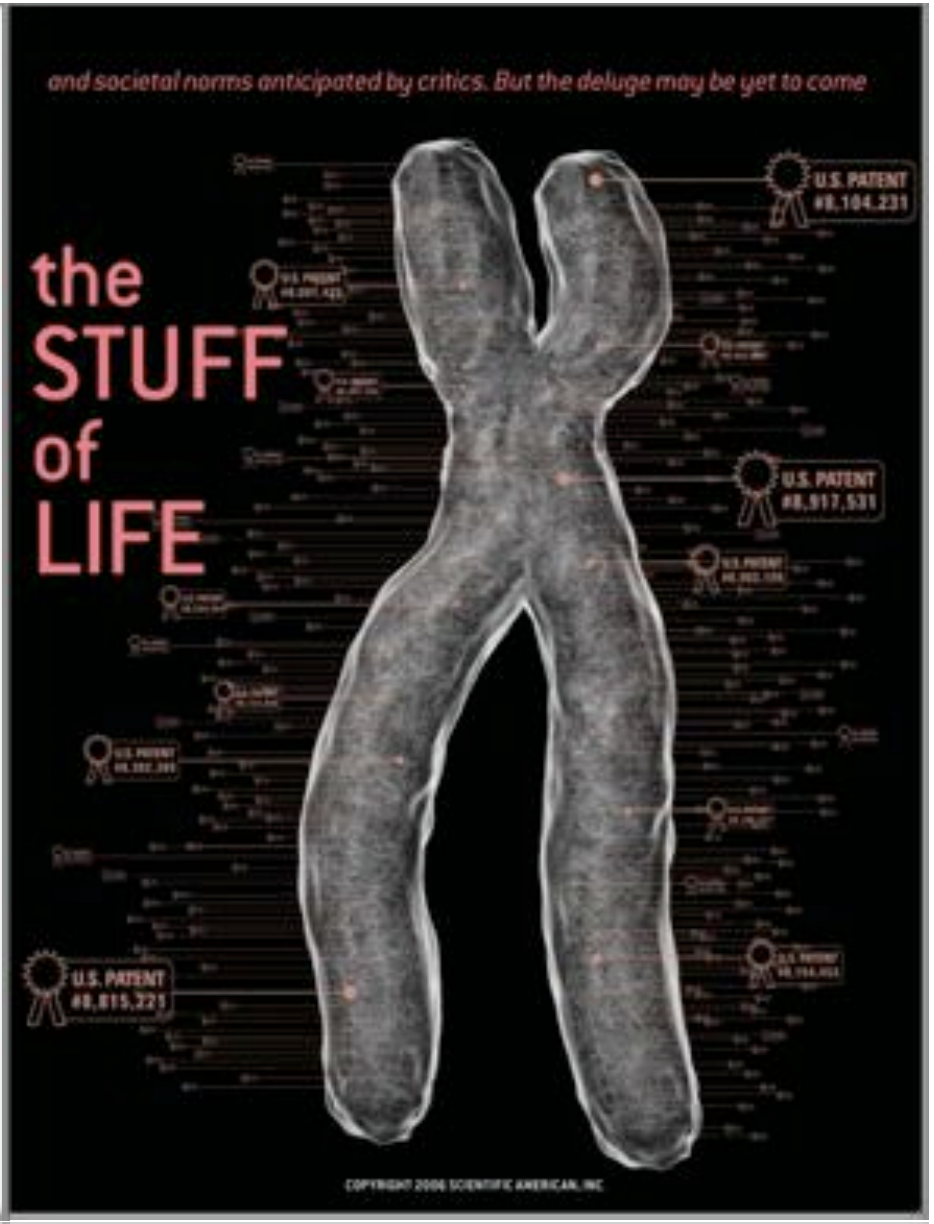
The survey of the gene database confirmed that the patenting of life is today well established. Yet it still strikes a lot of people as bizarre, unnatural and worrisome. "How can you patent my genes?" is often the first question that comes up. How can someone own property rights on a type of mouse or fish when nature, not humans, "invented" its genes? What happens to the openness of scientific research if half of all known cancer genes are patented? Does that mean that researchers must spend more time fighting in the courts than looking for a cure?

Ethicists, judges, scientists and patent examiners continue to immerse themselves in these debates, which will only grow more acute in a new era of personalized medicine and of genomics and proteomics research that examines the activities of many different genes or proteins at the same time. Doctors will rely increasingly on patented tests that let clinicians match genetically profiled patients with the best drugs. Investigators are already assessing the functioning of whole genomes. Potentially, many of the biological molecules deployed in these complex studies could come burdened with licensing stipulations that would prevent research leading to new therapies or that would fuel the nation's already robust health care inflation.

Anything under the Sun

THE QUESTION of "who owns life" has been asked before. But the M.I.T. researchers' taking stock of the intersection of intellectual property and molecular biology came fittingly at the 25th anniversary of a landmark decision by the U.S. Supreme Court that

and societal norms anticipated by critics. But the deluge may be yet to come



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OP-ED CONTRIBUTOR

Patenting Life

By MICHAEL CRICHTON
Published: February 13, 2007

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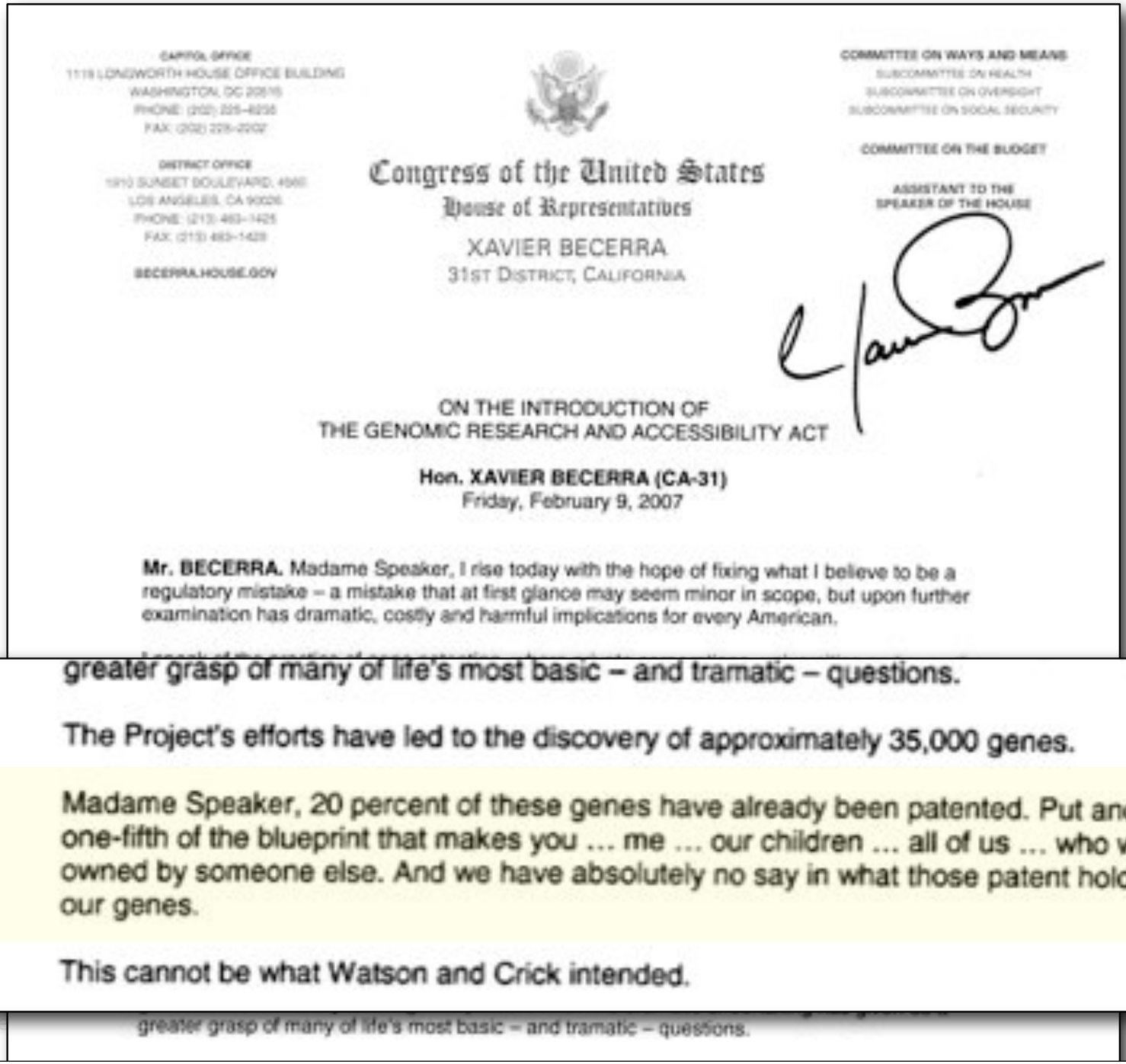
YOU, or someone you love, may die because of a gene patent that should never have been granted in the first place. Sound far-fetched? Unfortunately, it's only too real.

Gene patents are now used to halt research, prevent medical testing and keep vital information from you and your doctor. Gene patents slow the



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ON THE INTRODUCTION OF
THE GENOMIC RESEARCH AND ACCESSIBILITY ACT

Hon. XAVIER BECERRA (CA-31)
Friday, February 9, 2007

Mr. BECERRA. Madame Speaker, I rise today with the hope of fixing what I believe to be a regulatory mistake – a mistake that at first glance may seem minor in scope, but upon further examination has dramatic, costly and harmful implications for every American.

greater grasp of many of life's most basic – and tramatic – questions.

The Project's efforts have led to the discovery of approximately 35,000 genes.

Madame Speaker, 20 percent of these genes have already been patented. Put another way, one-fifth of the blueprint that makes you … me … our children … all of us … who we are is owned by someone else. And we have absolutely no say in what those patent holders do with our genes.

This cannot be what Watson and Crick intended.

greater grasp of many of life's most basic – and tramatic – questions.

110TH CONGRESS
1ST SESSION

H. R. 977

To amend title 35, United States Code, to prohibit the patenting of human genetic material.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 9, 2007

Mr. BECERRA (for himself and Mr. WELDON of Florida) introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To amend title 35, United States Code, to prohibit the patenting of human genetic material.

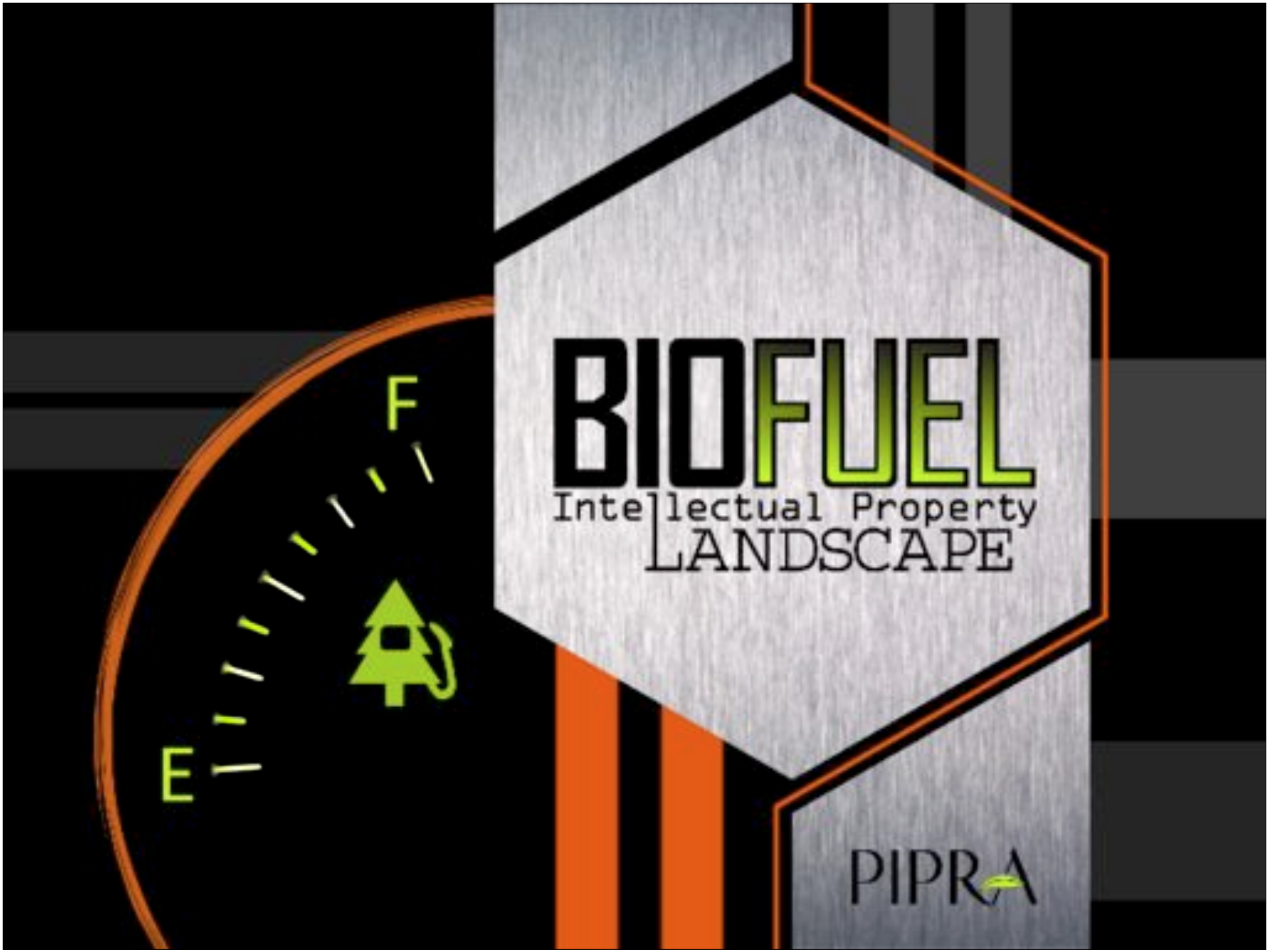
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Genomic Research and Accessibility Act''.

SEC. 2. PROHIBITION ON PATENT OF HUMAN GENETIC MATERIAL.

(a) IN GENERAL.—Chapter 10 of title 35, United States Code, is amended by adding at the end the fol-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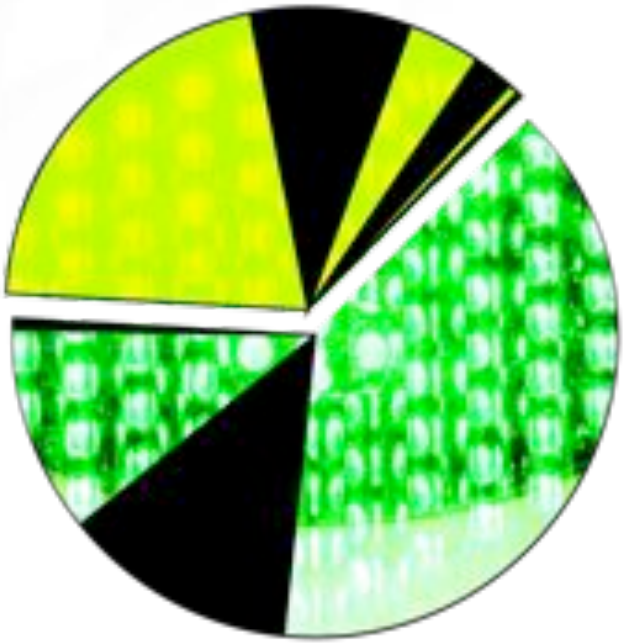
Public vs. Private IP Sector Distribution 2002 - 2008

— Private	~80%
— Public	~20%

Patent Activity per Enzyme Class

245 Hemicellulases

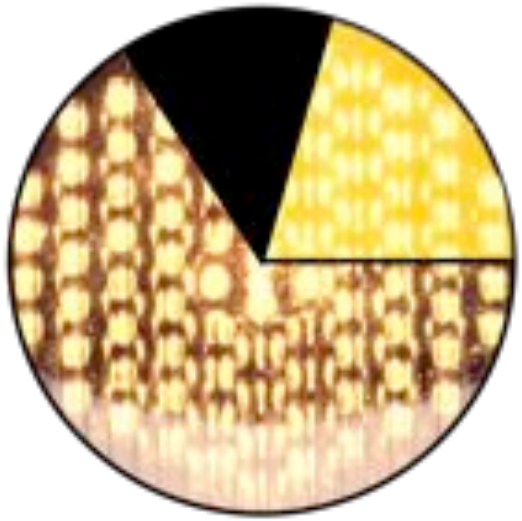
Xylanase	22%
Mannanase	8%
Arabanofuransidase	4%
Esterases	2%
Xylosidase	1%
Glucuronidase	~0%



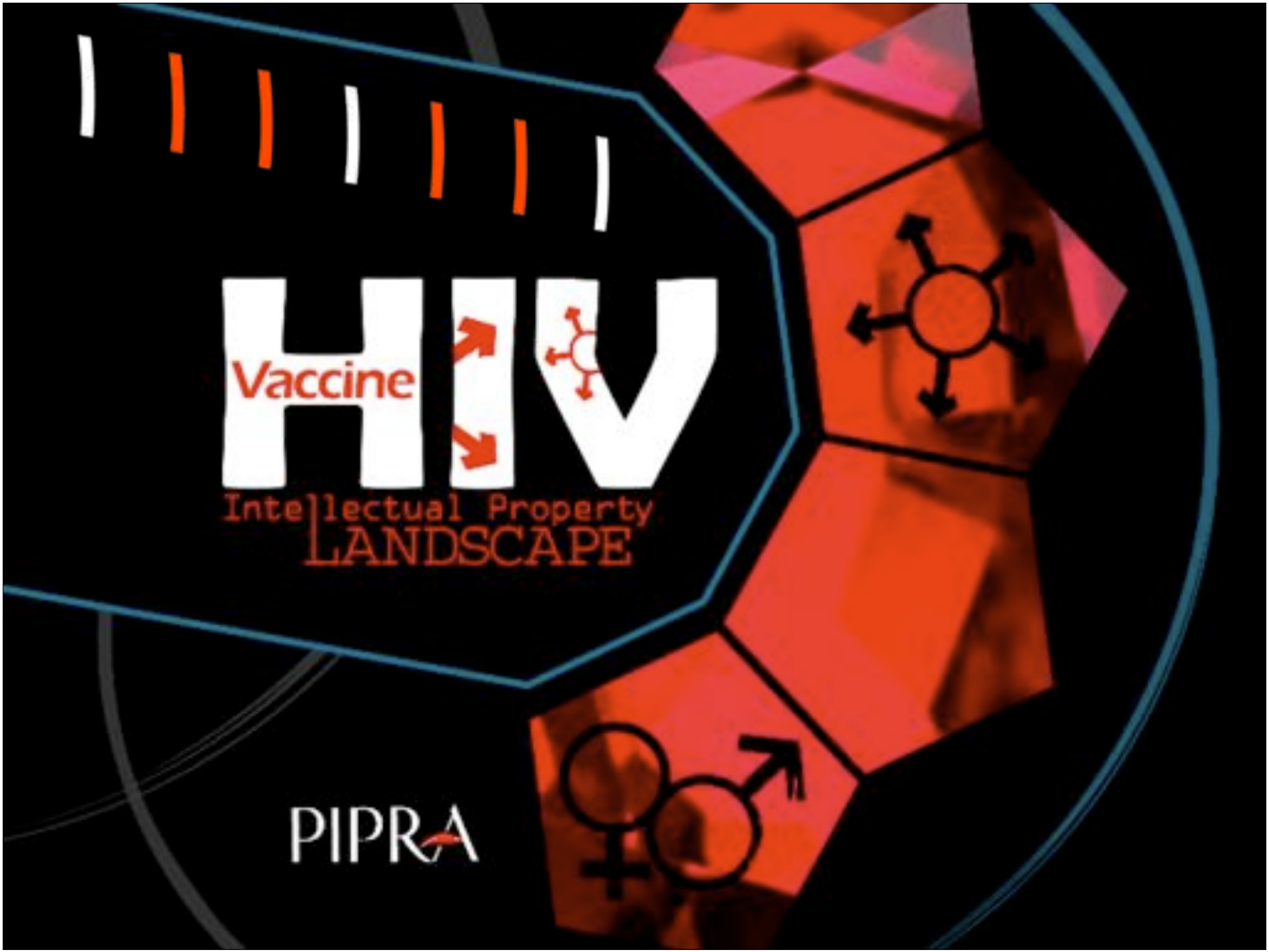
421 Cellulases

Phosphorylase	~0%
Exoglucanase	11%
ß-glucosidase	12%
Endoglucanase	40%

Focus of Patents/Applications Total IP: 1,000



Enzymes	66%
Production	21%
Compositions	13%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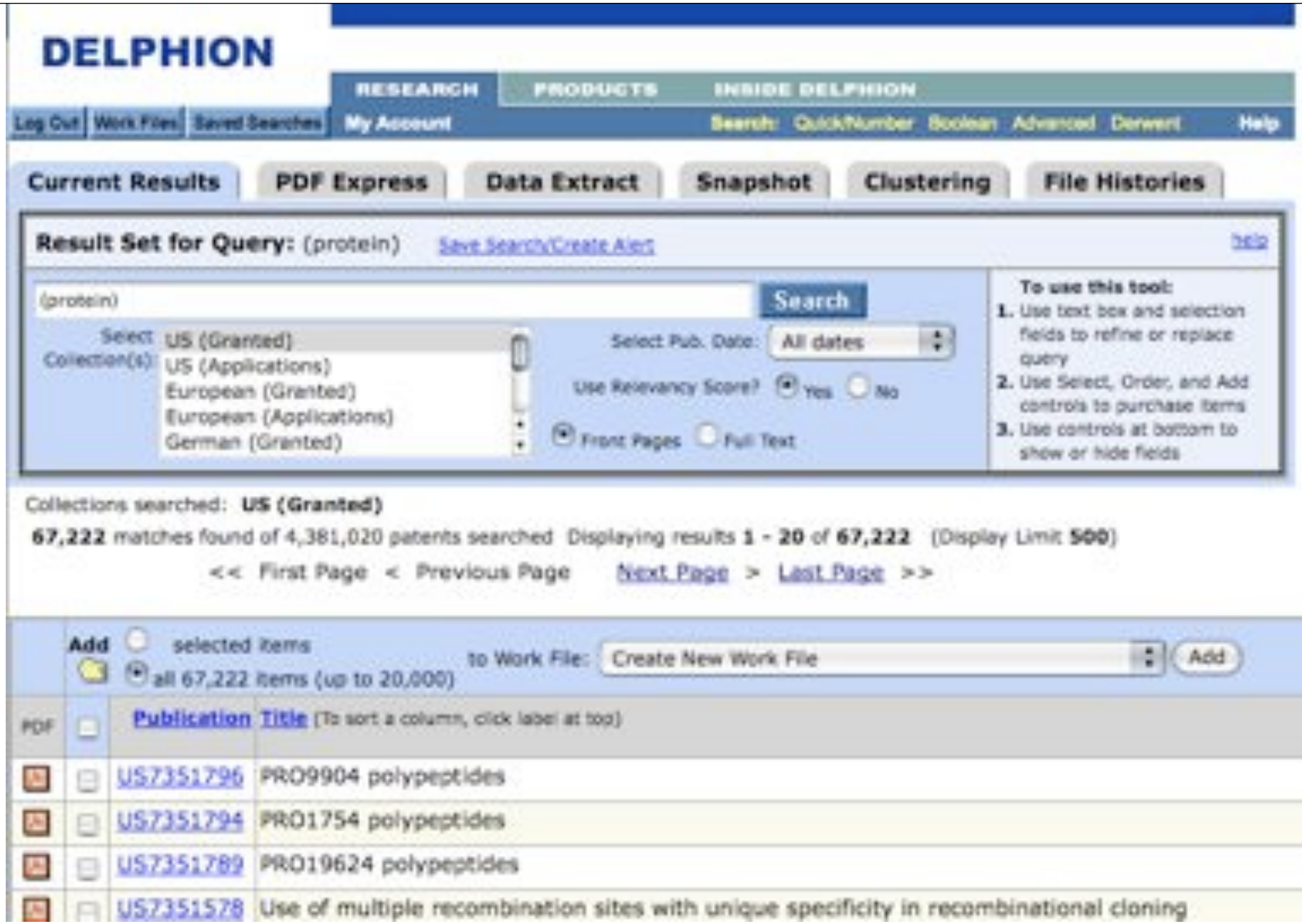
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US7351789 PRO19624 polypeptides
US7351578 Use of multiple recombination sites with unique specificity in recombinational cloning

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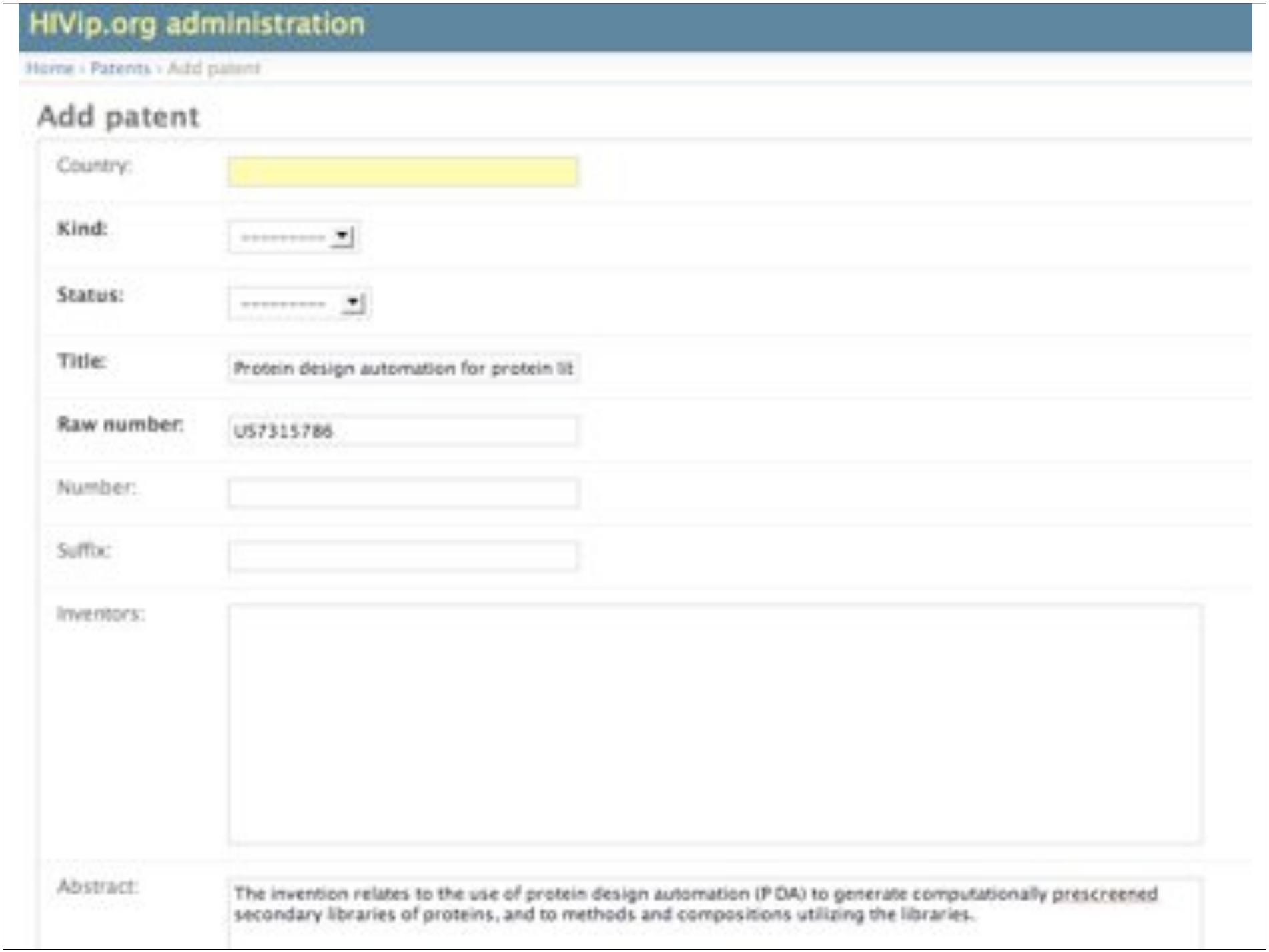
Title:	**US7315786: Protein design automation for protein libraries**
Derwent Title:	Generating secondary library of scaffold protein variants by generating primary variant positions in primary library comprising rank-ordered list of protein primary variant sequences, and combining the positions [Derwent Record]
Country:	**US** United States of America
Inventor:	**Dahiyat, Bassil I.**; Los Angeles, CA, United States of America **Bentzien, Jörg**; Pasadena, CA, United States of America **Fiebig, Klaus M.**; Frankfurt, Germany **Hayes, Robert J.**; Pasadena, CA, United States of America
Assignee:	**Xencor**, Monrovia, CA, United States of America other patents from XENCOR, INC. (R13275) (approx. 3) Corporate Tree data: Xencor Inc. (XENCOR); News, Profiles, Stocks and More about this company
Published / Filed:	**2008-01-01** / 2001-08-10
Application Number:	**US2001000927790**
IPC Code:	Advanced: C07K 1/04; C07K 1/06; C12N 9/42; C12N 9/86; C12N 15/10; C40B 30/04; G01N 31/00; G01N 33/68; G06F 17/00; G06F 19/00; Core: C07K 1/00; C12N 9/78; more
ECLA Code:	**G06F19/00C2**; C07K1/04C; C07K1/06A2; C12N9/42; C12N9/86; C12N15/10B; C12N15/10B2; C12N15/10C3; C12N15/10C16; C40B30/04; G01N33/68A10; L01J219/00C6N; S06F19/00C7;
U.S. Class:	**702/019**; 702/027; 706/045; 706/046;
Field of Search:	435/7.1,5,4 530/350 702/019,27 706/045,46
Priority Number:	2001-08-10 **US2001000927790**

High Resolution

Low Resolution

40 pages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Country:
Kind:
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Title:
Protein design automation for protein lit
Raw number:
US7315786
Number:
Suffix:
Inventors:
Abstract:
The invention relates to the use of protein design automation (PDA) to generate computationally prescreened secondary libraries of proteins, and to methods and compositions utilizing the libraries.

Patent citations:

US4939666

US5241470

US5265030

Nonpatent citations:

Shakhnovich. E. Folding and Design, 1998, 3. R45-R58.

Brenner and Berry, A., et al., "A quantitative methodology for the de novo design of proteins, Protein Sci. 3:1871-1882 (Oct. 1994).

Borman. "Proteins to Order, Chemical and Engineering Newsletter (C&EN) Oct. 6, 1997, 9-10 (1997).

Designated states:

Licensing status:

Filing date: 2001-08-10 Today |

August 2001

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			1	2	3	4
5	6	7	8	9	10	11
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Kerri rules the world

Published on March 27, 2008

Drought-tolerance in maize to increase food security in Africa is the subject of much ongoing global research. The Water-Efficient Maize for Africa (WEMA) project represents a key public-private partnership in this area, combining Monsanto's expertise in molecular marker assisted breeding and transgenics with CIMMYT's advanced breeding programs for tropical maize, and AATF's experience in the stewardship of genetically modified (GM) projects.
CIMMYT chose PIPRA and technology transactions attorney Jonathan Dickstein from the San Francisco offices of law firm Morrison & Foerster to integrate public sector issues and interests on behalf of CIMMYT into the WEMA public-private partnership (PPP) research agreement. PPPs can be difficult to negotiate, given the deep cultural differences between the public and private sectors related to confidentiality, publication rights, public goods, and intellectual property rights. PIPRA offers a unique resource with its experience in articulating public sector goals and its mission to provide services to support the strategic management of intellectual property rights among public agricultural research organizations worldwide.
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Published on March 7, 2008

This is a site where we will track the IP landscape of HIV vaccines and related technologies
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HIVip.org is a database of HIV-related intellectual property. Here you can find various "Collections" of patents, for example our Vaccine Collection. You can browse patents by their tags and stay informed about our effort by reading our posts. This database is a collaborative effort of PIPRA and Pierce Law Center.

Recently added patents

Protein design automation for protein libraries
Added Apr 7, 2008

Recombinational cloning using engineered recombination sites Added Apr 7, 2008

Patents by label

antibodies (1) , epitope (1) , protein (1) , vaccine (1)

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March, 2008

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US7304130: Recombinational cloning using engineered recombination sites

Date added: April 7, 2008

Abstract: Recombinational cloning is provided by the use of nucleic acids, vectors and methods, in vitro and in vivo, for moving or exchanging segments of DNA molecules using engineered recombination sites and recombination proteins to provide chimeric DNA molecules that have the desired characteristic(s) and/or DNA segment(s).

Claims:

1. A fusion polypeptide encoded by a coding region of a nucleic acid molecule, wherein said coding region comprises:

(a) a first nucleic acid comprising a full length sequence selected from the group consisting of SEQ ID NOs: 1-16, a loxP sequence, a DNA sequence complementary to any of the full length sequences of SEQ ID NOs: 1-16 or a loxP sequence, and an RNA sequence corresponding to any of the full length sequences of SEQ ID NOs: 1-16 or a loxP sequence; and

(b) a second nucleic acid sequence encoding a tag sequence, wherein said first nucleic acid sequence and said second nucleic acid

Patents by label

antibodies (1) , epitope (1) , protein (1) , vaccine

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