



# Standard Licenses, Open Access and Enhanced Publication

John Wilbanks

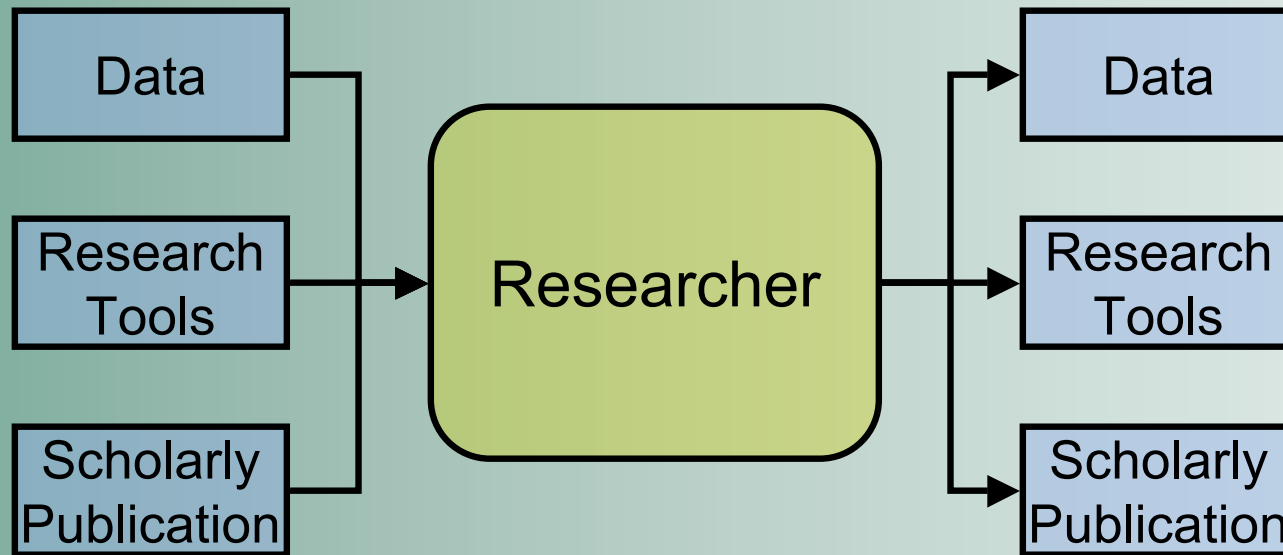
Executive Director, Science Commons

21 October 2005

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- Extend the Creative Commons approach into science
  - Standard legal code
  - Innovative technology application



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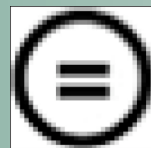
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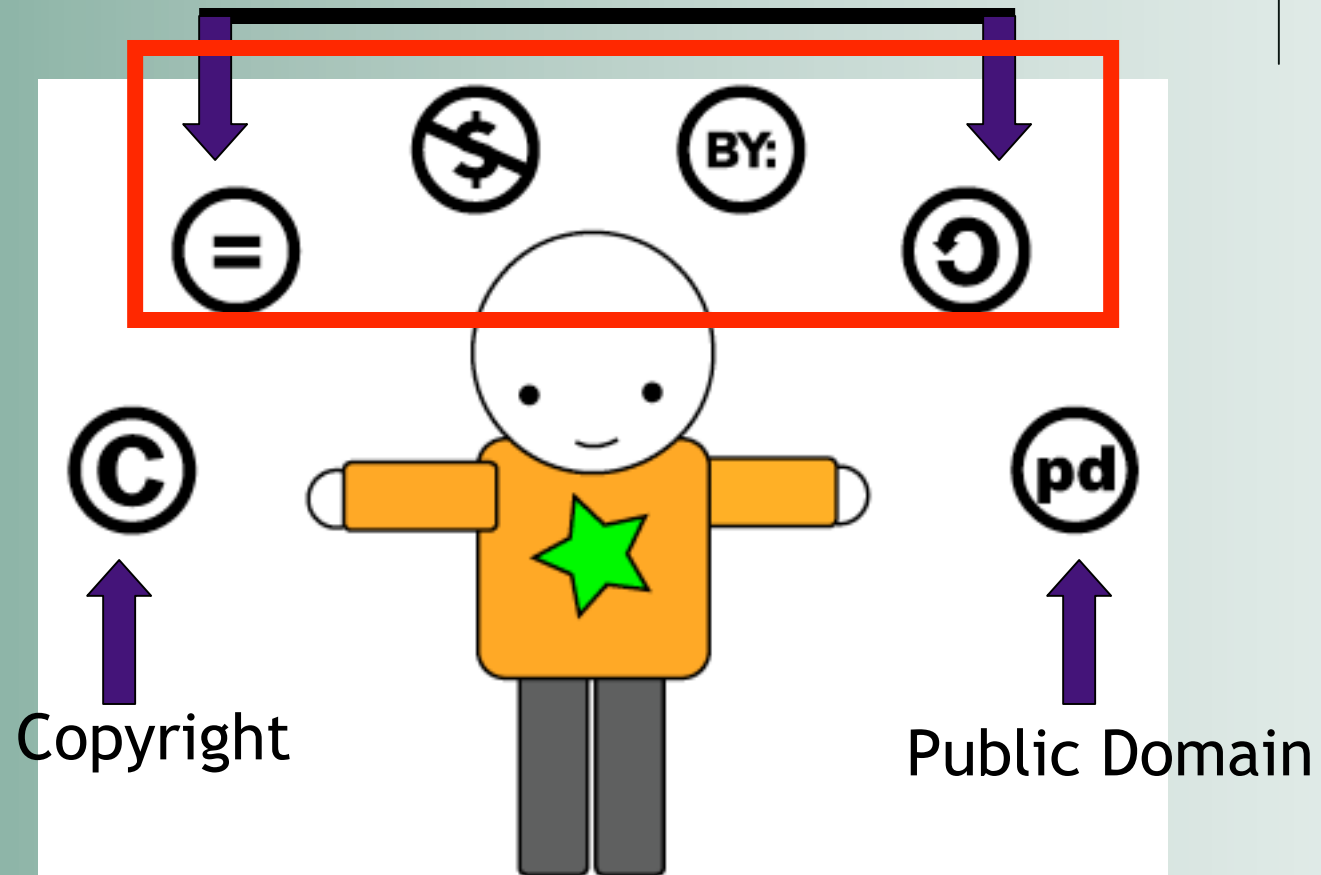


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49. Thompson MA, Ransom DG, Pratt SJ, MacLennan H, Kieran MW (1998) The cloche and spadetail genes differentially affect hematopoiesis and vasculogenesis. *Dev Biol* 197: 248–269. [Find this article online](#)
50. Kim HJ, Bar-Sagi D (2004) Modulation of signalling by *Sprouty* A developing story. *Nat Rev Mol Cell Biol* 5: 441–450. [Find this article online](#)
51. Brekken RA, Sage EH (2001) SPARC, a matricellular protein: At the crossroads of cell-matrix communication. *Matrix Biol* 19: 816–827. [Find this article online](#)
52. Marin F, Charnay P (2000) Hindbrain patterning: FGFs regulate *Krox20* and *mafB/kr* expression in the otic/preotic region. *Development* 127: 4925–4935. [Find this article online](#)



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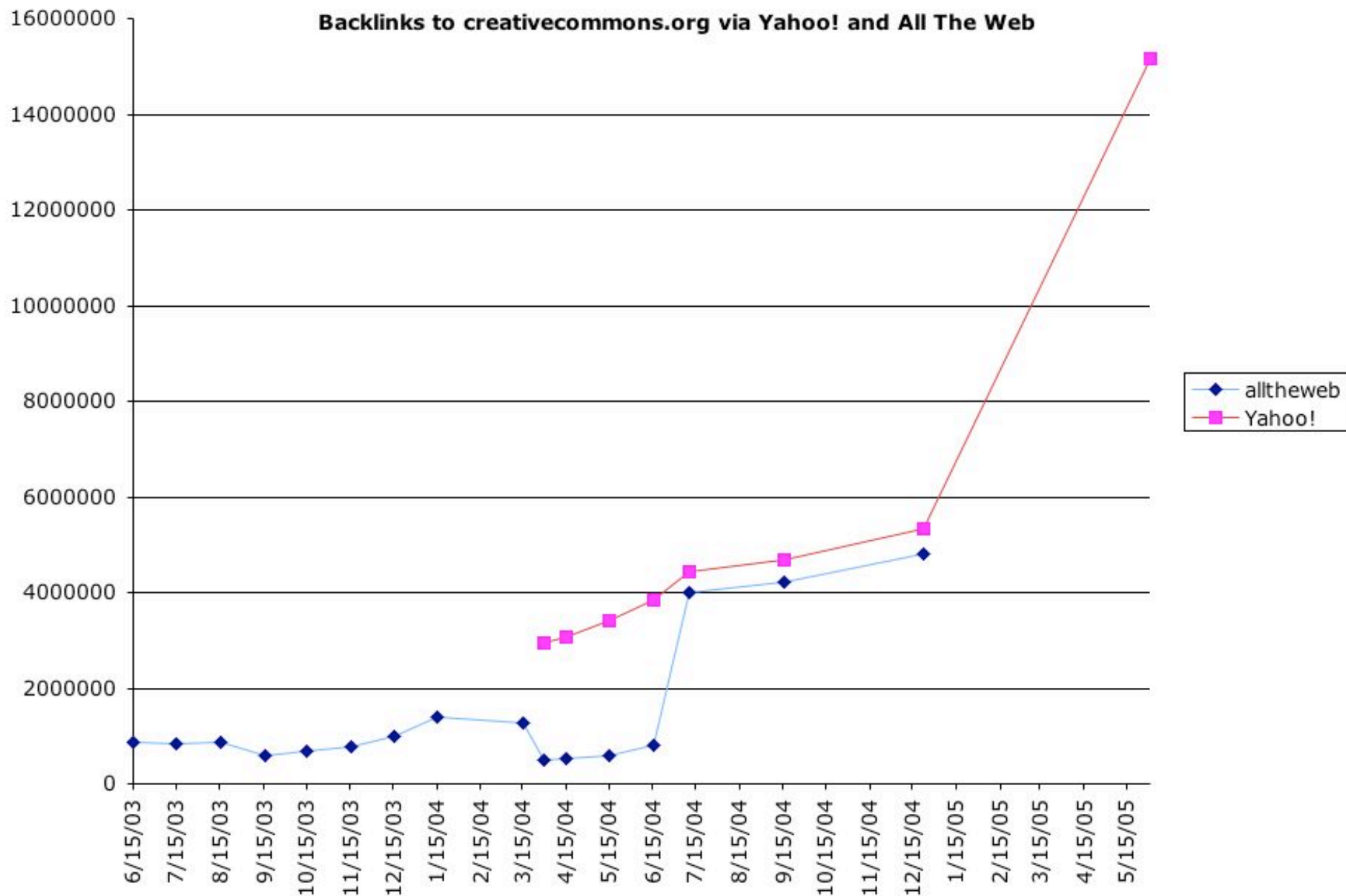
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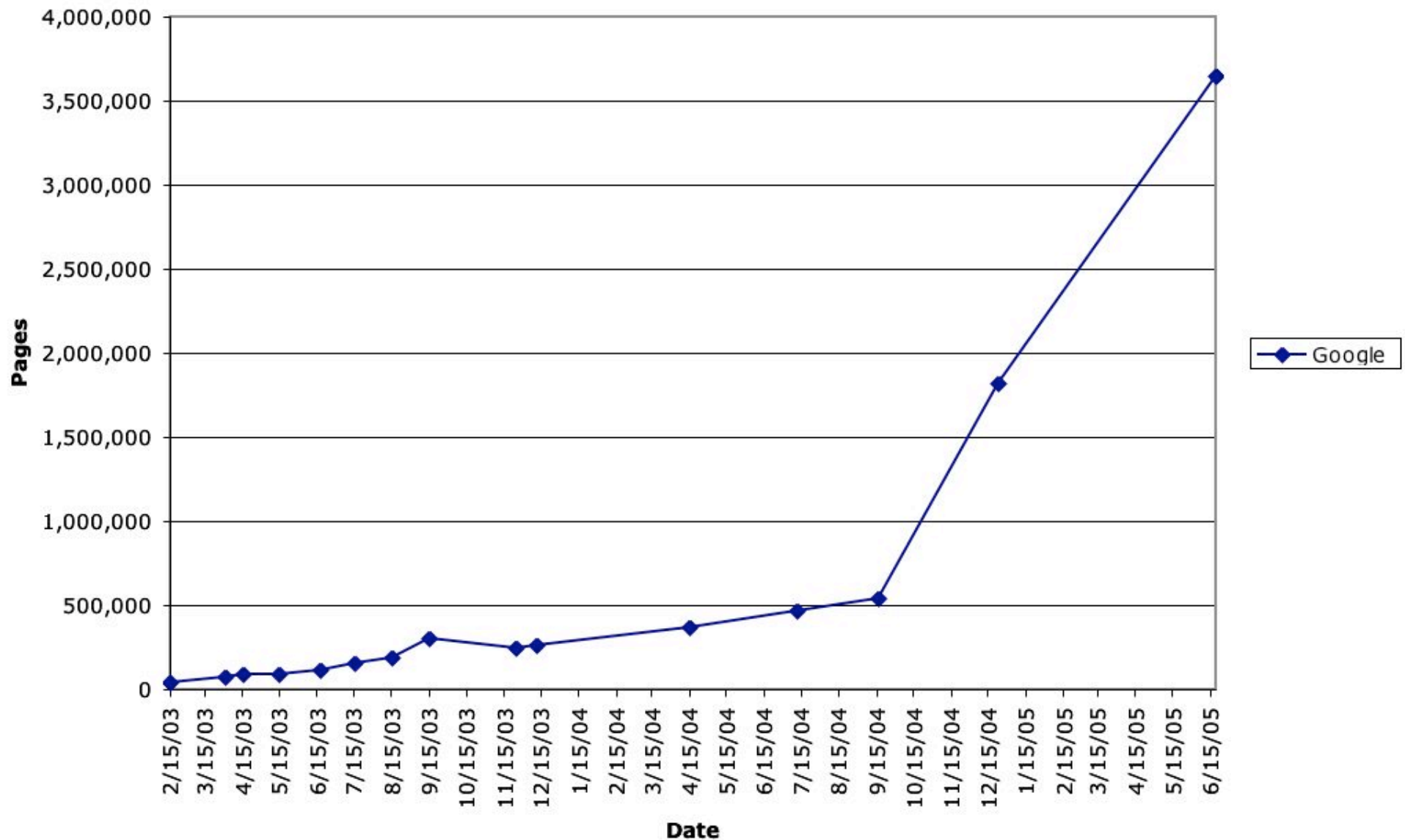
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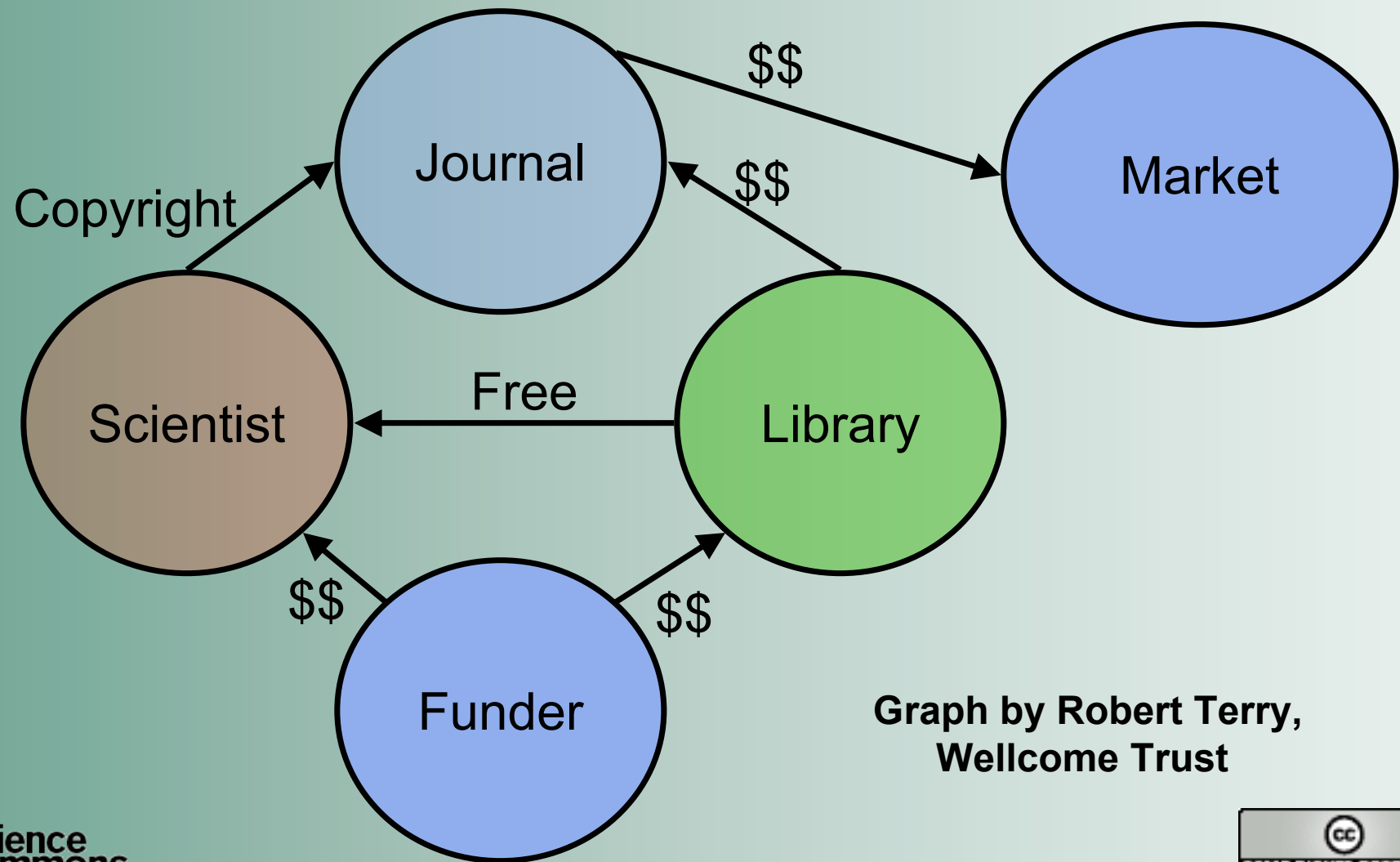
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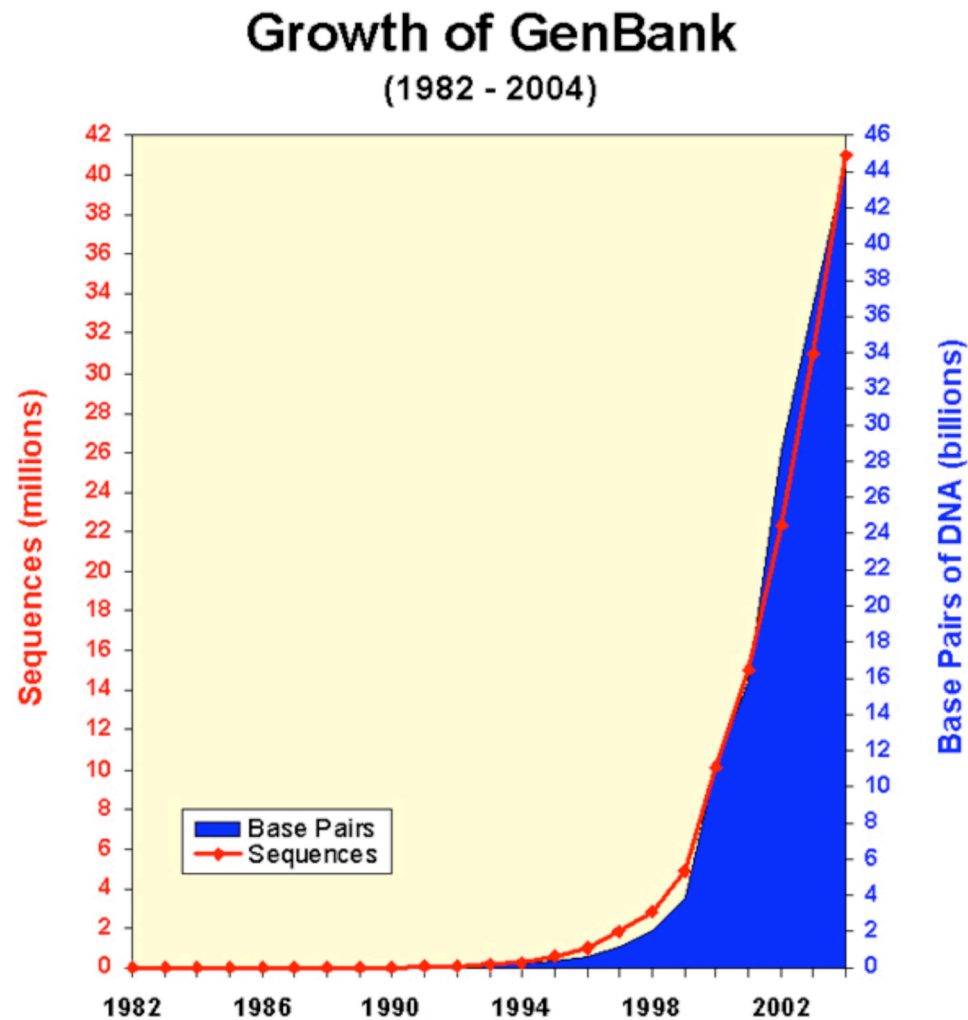


# And so we judge standing



- ...through citations in high impact journals
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# Norms under pressure



# Norms under pressure



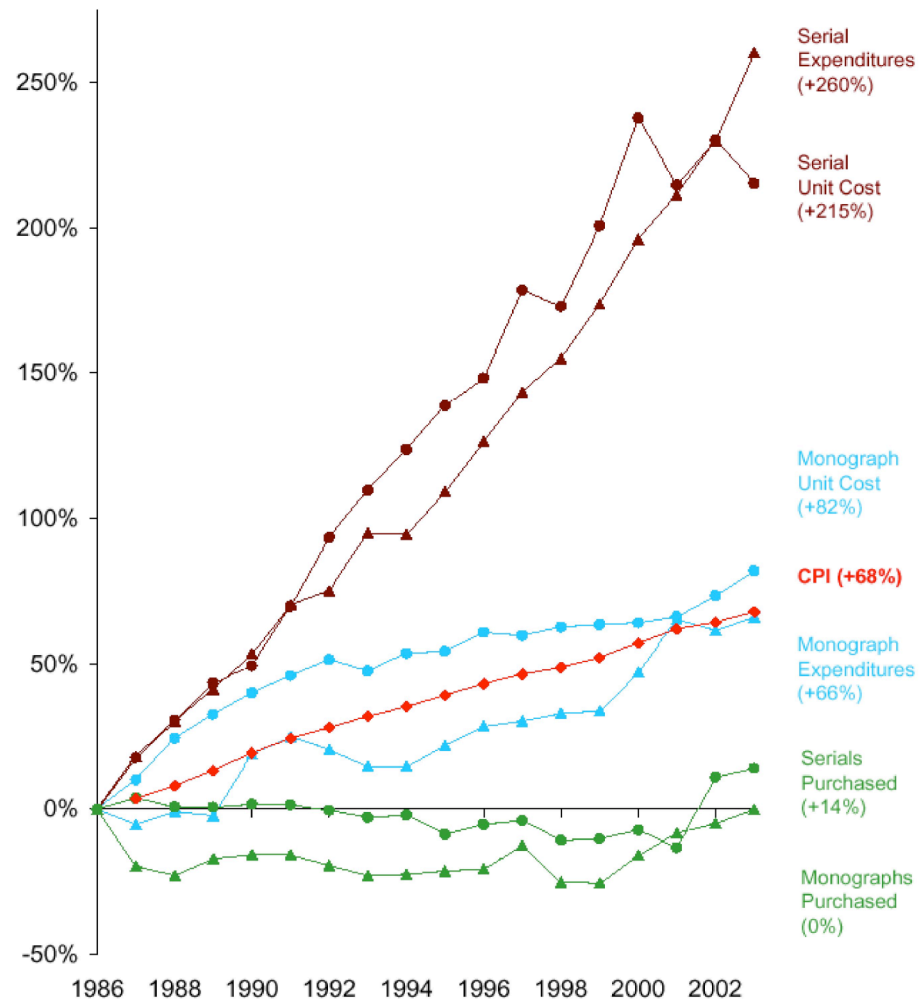
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# Norms Under Pressure



Monograph and Serial Costs  
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## Wanted: social entrepreneurs

Scientists-turned-entrepreneurs are resuscitating the research and development of drugs for neglected diseases. Researchers, administrators and funders should contribute their expertise to help these initiatives — or set up their own.

The all-embracing open-source encyclopedia Wikipedia doesn't have a dedicated page on kala-azar, or visceral leishmaniasis. But who cares? After all, the disease only transforms vast numbers of people in developing countries into walking skeletons carrying bellies bloated by an enlarging liver and spleen. With drugs costing up to US\$200 a course, it often goes untreated, causing some 200,000 deaths each year. In the research and development (R&D) chains that lead to drugs, more attention is devoted to silicone breast implants and pills for erectile dysfunction than to the roughly 8,000 orphan diseases. These neglected diseases each touch up to just 2,000 people, but together they affect millions.

The root cause is that the markets for these diseases are too small to seriously interest the large pharmaceutical companies, which are involved in partnerships to address them but must also answer to their shareholders. What can be done to redress this balance by the many stakeholders along the route from research to product?

A round table on neglected diseases, co-organized by *Nature* at the BioVision World Life Sciences Forum in Lyon, France, last week, left a depressing sense of how far we have all got to go to seriously address neglected diseases — but also provided some encouraging sparks of enlightenment, and pointers to possible ways forward.

The meeting was held to celebrate the 50th anniversary of the approval of a polio vaccine. Polio is on the brink of being eradicated, something that would have been impossible without the March of Dimes, which courageously supported key basic research into the disease, and the Rotary Foundation, which got the vaccine into the field by raising more than \$500 million and providing volunteers. They addressed critical bottlenecks, and won. As a result, most people reading this will be unaware that just a few decades ago, polio was a disease that every parent feared.

### New leaders

A new generation of 'social entrepreneurs' are testing imaginative ways to tackle neglected diseases. One small step for Victoria Hale, for example, may be a giant leap for mankind: the founding of a San Francisco-based not-for-profit drug company, the Institute for OneWorld Health. At the Lyon meeting she told of clinical-trial results that could lead to a safe and effective cure for kala-azar for just \$10 a course.

Instead of trying to develop a new drug from scratch, Hale started knocking on university and company doors, looking for drug leads

Neglected Diseases Initiative, instigated by Doctors without Borders, for a host of other neglected diseases. As well as testing and reformulating existing drugs, such initiatives are bridging the abyss between research and clinical development by focusing on leads that would otherwise have remained in the lab for lack of an industry sponsor.

Another key bottleneck in the pipeline is preclinical research in animal models or cell cultures. Genomics has revealed the molecular basis of some 1,200 orphan diseases, as well as major ones such as malaria and tuberculosis, revealing new drug targets. This is opening up many orphan diseases to possible cures for the first time. If the molecular basis involves the expression of interleukin A, for example, then existing interleukin A inhibitors might make potential drugs. But the many drug analogues needed by academic researchers to test this plethora of emerging targets are found only in industry.

So French gene therapist and social entrepreneur Alain Fischer is trying to persuade companies to give researchers access to the wealth of relevant drugs they hold but have not developed. The fledgling European Rare Disease Therapeutic Initiative gives the company the right of first refusal to market a promising molecule for a neglected disease. If it declines, the researchers can take it to another company or funder to take it to the clinic.

### Persistence for change

The catch is that all these initiatives are relatively small. Funding is a big issue, but Hale is bullish. The money is out there, she says, provided that scientists, doctors and social entrepreneurs build awareness and argue their case. Robert Scott, who spearheads the Rotary campaign against polio, agrees, pointing out that governments, companies and research institutes change: someone who says 'no' today may say 'yes' tomorrow. Dogged persistence pays off.

Ironically, getting rights and molecules from universities is often harder than obtaining them from companies. University technology offices tend to patent aggressively, look no further than generating income, and often fail to include provisions beneficial to tackling orphan diseases in their licensing deals with companies. More scientists and their institutions should sign up to organizations such as the Centre for the Management of Intellectual Property in Health Research and Development, Biological Innovation for Open Society, and the Science Commons, which help academics to exploit their research and intellectual property for social ends.

The scale of the market failure in neglected-disease R&D is





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# Result: Scientific Divide

- Access to the scientific canon more and more expensive
  - Innovation becomes harder without significant resources
- Applies beyond publications: materials, data expensive to produce, maintain and transfer
- Science should be globally shared, not restricted to the wealthy or the elite



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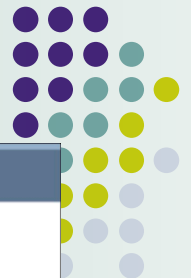
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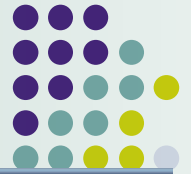
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# Data Withholding in Academic Genetics

## Evidence From a National Survey

Eric G. Campbell, PhD

Brian R. Clarridge, PhD

Manjusha Gokhale, MA

Lauren Birenbaum, BA

Stephen Hilgartner, PhD

Neil A. Holtzman, MD, MPH

David Blumenthal, MD, MPP

**W**ITHOUT THE FREE exchange of published scientific information and resources, researchers may unknowingly build on something less than the total accumulation of scientific knowledge or work on problems already solved.<sup>1</sup> However, a number of instances of data withholding (defining data to include the full range of research results, techniques, and materials useful in future investigations and withholding as the failure to share such published data) have been reported.<sup>2-7</sup> A 1994-1995 survey of academic life scientists found that 34% of respondents were denied research results requested from a fellow university scientist in the previous 3 years, and 8.9% said they had denied a request from another university scientist for access to research results.<sup>8</sup>

Weinberg<sup>9</sup> asserts that secrecy is more common in genetics and particularly human genetics than in other areas. Reasons may include the increased scientific competitiveness of the field and the opportunities for com-

**Context** The free and open sharing of information, data, and materials regarding published research is vital to the replication of published results, the efficient advancement of science, and the education of students. Yet in daily practice, the ideal of free sharing is often breached.

**Objective** To understand the nature, extent, and consequences of data withholding in academic genetics.

**Design, Setting, and Participants** Mailed survey (March-July 2000) of geneticists and other life scientists in the 100 US universities that received the most funding from the National Institutes of Health in 1998. Of a potential 3000 respondents, 2893 were eligible and 1849 responded, yielding an overall response rate of 64%. We analyzed a subsample of 1240 self-identified geneticists and made a limited number of comparisons with 600 self-identified nongeneticists.

**Main Outcome Measures** Percentage of faculty who made requests for data that were denied; percentage of respondents who denied requests; influences on and consequences of withholding data; and changes over time in perceived willingness to share data.

**Results** Forty-seven percent of geneticists who asked other faculty for additional information, data, or materials regarding published research reported that at least 1 of their requests had been denied in the preceding 3 years. Ten percent of all post-publication requests for additional information were denied. Because they were denied access to data, 28% of geneticists reported that they had been unable to confirm published research. Twelve percent said that in the previous 3 years, they had denied another academician's request for data concerning published results. Among geneticists who said they had intentionally withheld data regarding their published work, 80% reported that it required too much effort to produce the materials or information; 64%, that they were protecting the ability of a graduate student, post-doctoral fellow, or junior faculty member to publish; and 53%, that they were protecting their own ability to publish. Thirty-five percent of geneticists said that sharing had decreased during the last decade; 14%, that sharing had increased. Geneticists were as likely as other life scientists to deny others' requests (odds ratio [OR], 1.39; 95% confidence interval [CI], 0.81-2.40) and to have their own requests denied (OR, 0.97; 95% CI, 0.69-1.40). However, other life scientists were less likely to report that withholding had a negative impact on their own research as well as their field of research.

**Conclusions** Data withholding occurs in academic genetics and it affects essential scientific activities such as the ability to confirm published results. Lack of resources and issues of scientific priority may play an important role in scientists' decisions to withhold data, materials, and information from other academic geneticists.

JAMA 2002;287:473-480

www.jama.com



## The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries

Lita Nelsen\*

Universities that attempt to use patents arising from academic research to make medical treatments available in developing countries are caught in a paradox of the patent system. Simply put, if all the medicines and vaccines needed in developing countries existed today, one would wish the patent system to disappear. The absence of patents on medicines and vaccines would presumably allow maximum competition and drive prices down, thereby maximizing affordability and availability.

In reality, adequate treatments and preventatives do not exist for many diseases common to the developing world. If one wishes to encourage industry to use its skills and resources in the discovery, development, testing, quality control, and distribution of new drugs and vaccines, patent protection may be necessary to provide the incentive for industrial participation. Few, if any, companies will start on the long trail of new drug discovery and development unless they can depend on patent protection from competition should a drug prove successful. Thus, we come to the conclusion that patents are neither inherently bad nor inherently good for this purpose. Like all tools, they must be used wisely.

Research institutions such as universities, medical schools, and other non-profits engaged in biological and medical research (collectively referred to as "universities" in this piece) have a special role to play in the use of patents for the development and distribution of drugs and vaccines for developing countries. These institutions are often the main source for the core technologies and lead compounds that are developed into drugs and vaccines. The primary ways in which universities disseminate their discoveries are through publication and the training of students. But since the passage of the Bayh-Dole Act in 1980,<sup>1</sup> U.S. research institutions have

---

\* Lita Nelsen is the director of the Technology Licensing Office at the Massachusetts Institute of Technology.

1. Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015-3028 (codified as amended at





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(dated March 8, 1995)

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# Standard contracts for DNA?

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Use
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# “emergent structures”



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6101  <b>Nucleotide:</b> sequence database (GenBank) <a href="#">?</a>	186  <b>UniGene:</b> gene-oriented clusters of transcript sequences <a href="#">?</a>
3399  <b>Protein:</b> sequence database <a href="#">?</a>	12  <b>CDD:</b> conserved protein domain database <a href="#">?</a>
15  <b>Genome:</b> whole genome sequences <a href="#">?</a>	231  <b>3D Domains:</b> domains from Entrez Structure <a href="#">?</a>
60  <b>Structure:</b> three-dimensional macromolecular structures <a href="#">?</a>	144  <b>UniSTS:</b> markers and mapping data <a href="#">?</a>
none  <b>Taxonomy:</b> organisms in GenBank <a href="#">?</a>	10  <b>PopSet:</b> population study data sets <a href="#">?</a>
1463  <b>SNP:</b> single nucleotide polymorphism <a href="#">?</a>	123568  <b>GEO Profiles:</b> expression and molecular abundance profiles <a href="#">?</a>
925  <b>Gene:</b> gene-centered information <a href="#">?</a>	21  <b>GEO DataSets:</b> experimental sets of GEO data <a href="#">?</a>
693  <b>HomoloGene:</b> eukaryotic homology groups <a href="#">?</a>	292  <b>Cancer Chromosomes:</b> cytogenetic databases <a href="#">?</a>
none  <b>PubChem Compound:</b> small molecule chemical structures <a href="#">?</a>	none  <b>PubChem BioAssay:</b> bioactivity screens of chemical substances <a href="#">?</a>



# “emergent structures”



**p53 activates ICAM-1 (CD54) expression in an NF-kappaB-independent manner.**

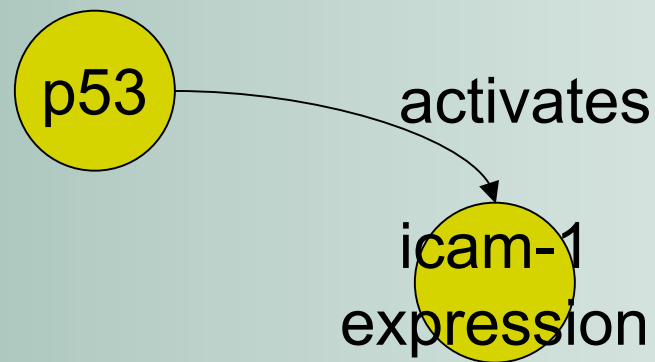
**Gorgoulis VG, Zacharatos P, Kotsinas A, Kletsas D, Mariatos G, Zoumpourlis V, Ryan KM, C, Papavassiliou AG.**

<p53><activates><icam-1 expression>

# “emergent structures”



<p53><activates><icam-1 expression>



# “emergent structures”



: Genes Dev. 1995 Sep 1;9(17):2143-56.

Rel:

**The WT1 gene product stabilizes p53 and inhibits p53-mediated apoptosis.**

**Maheswaran S, Englert C, Bennett P, Heinrich G, Haber DA.**

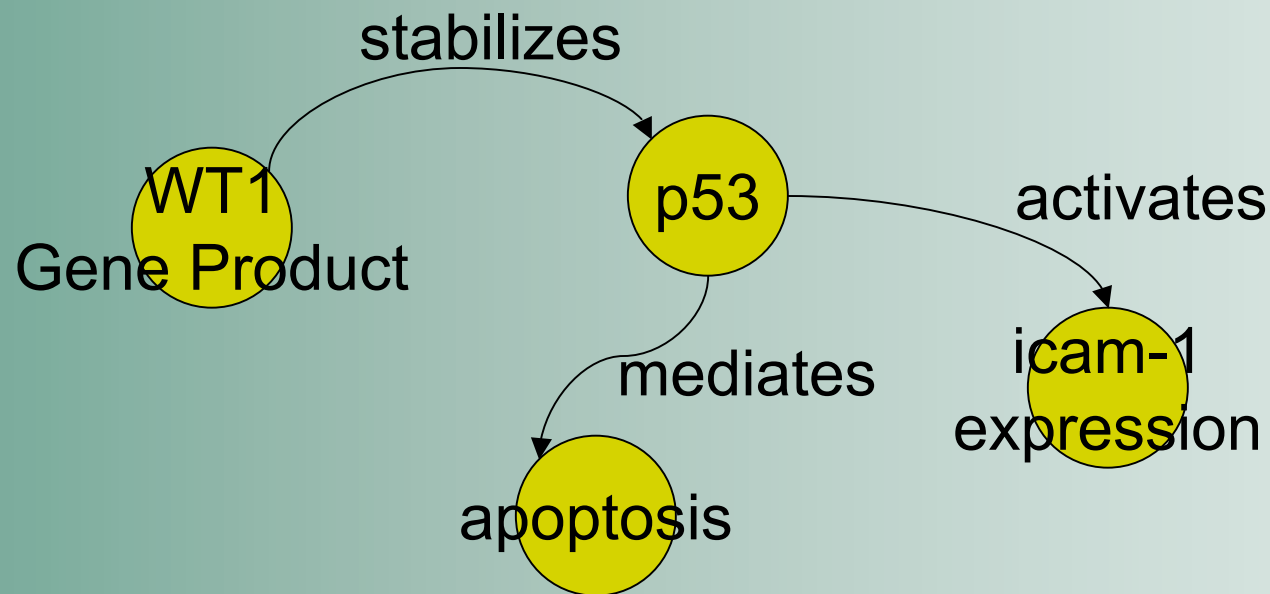
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<WT1 GP> <inhibits><p53-mediated apoptosis>



# “emergent structures”

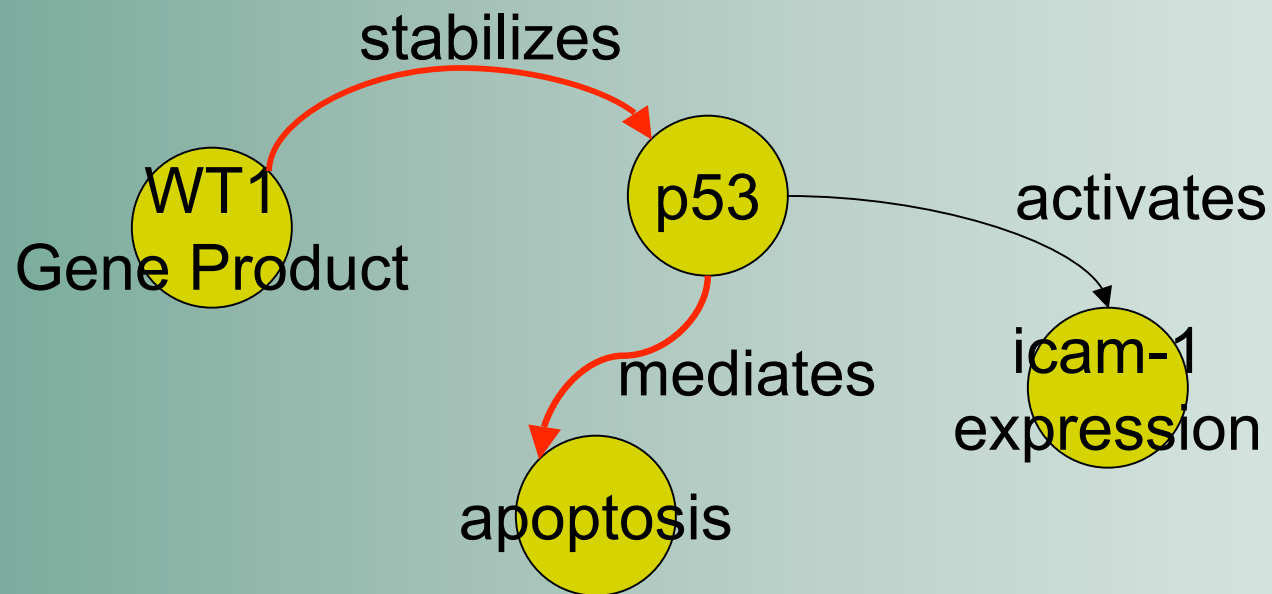
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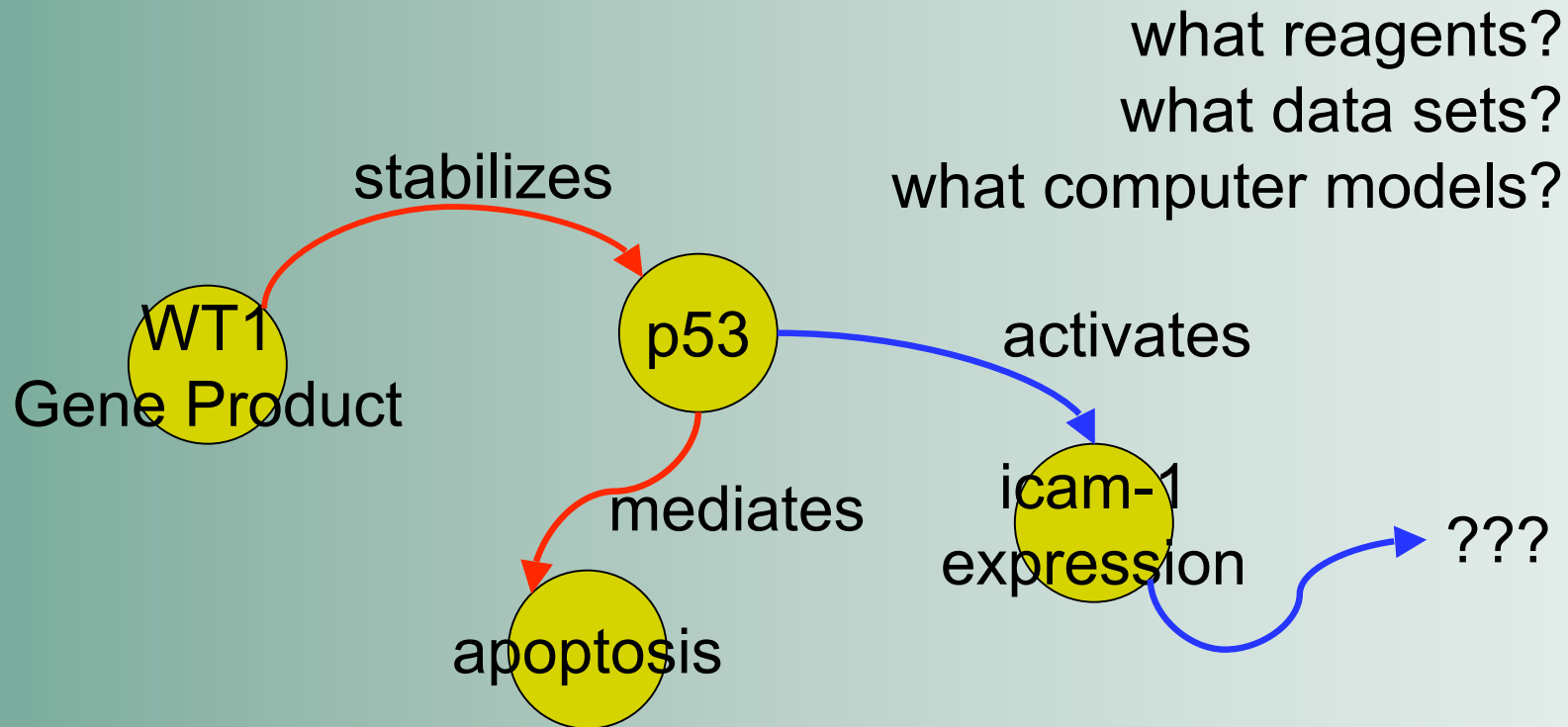


# “emergent structures”

<WT1 GP><stabilizes><p53>  
<p53><activates><icam-1 expression>



# “emergent structures”



# “emergent structures”



Connecting public data on ICAM-1  
from <http://ncbi.nlm.nih.gov>

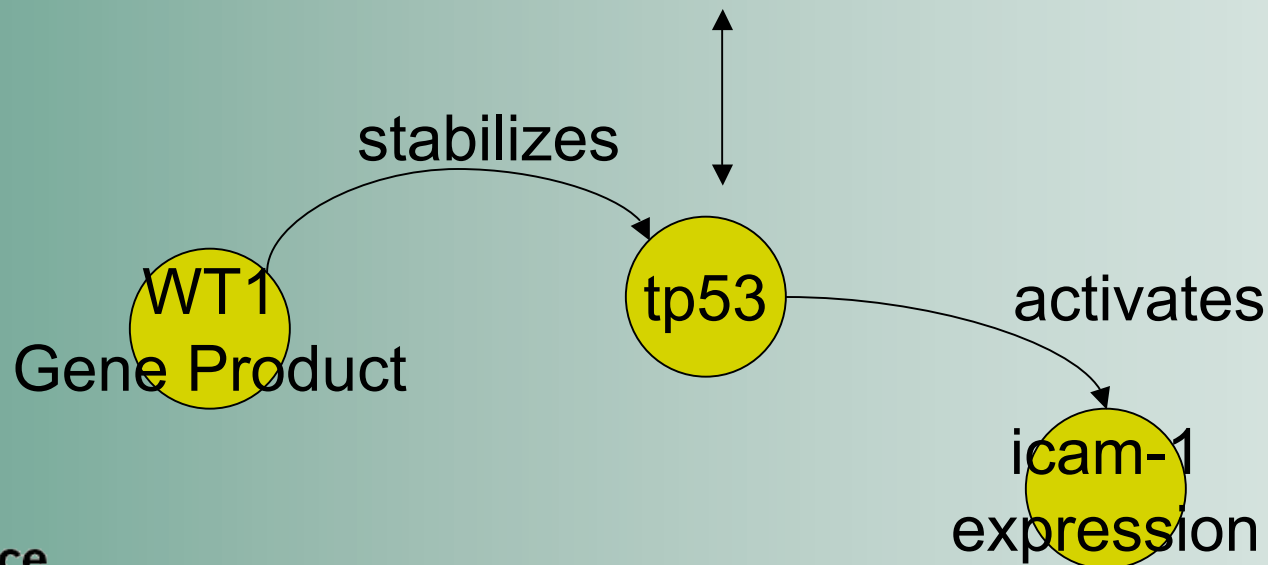
104. the expression of ICAM-1 might involve both p38 MAPK and NF-kappaB activities, whereas ICAM-3 expressions might be mediated through p38 MAPK but not NF-kappaB.
105. combined use of a vector driving the expression of OX40L with three other costimulatory molecules enhances initial activation and then further potentiates sustained activation of naive and effector T cells
106. serum levels elevated in asthmatic patients during acute attack
107. that genetic polymorphisms of ICAM-1 might be clinically important in the development and progression of the disease
108. AP-1 activation calcium-dependent, suggesting the central involvement of this transcription factor in the regulation of ICAM-1.
109. Chlamydomonas pneumoniae-induced ICAM-1 expression in HAECs requires NF-kappaB and PKC dependent
110. Circulating ICAM-1, IL-8, and MCP-1 in untreated obstructive sleep apnea were significantly reduced. OSAS-induced hypoxia and generation of inflammatory mediators.
111. the potential associations of ICAM-1 gene polymorphisms with endometriosis and its severity
112. activation of expression by p53



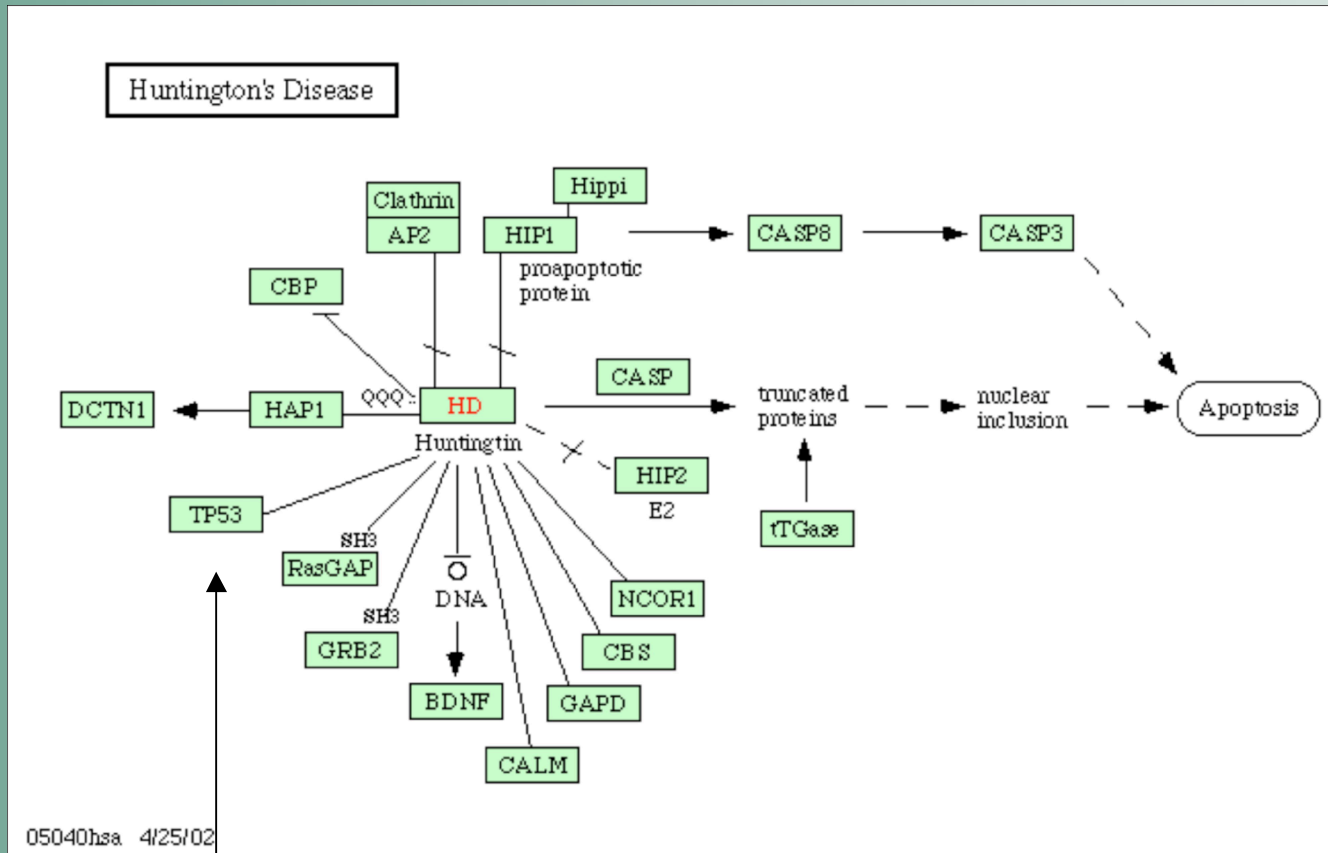
# “emergent structures”



Entry	7157	CDS	<a href="#">H.sapiens</a>
Gene name	TP53		
Definition	tumor protein p53 (Li-Fraumeni syndrome)		
KO	KO: <a href="#">K04451</a> tumor protein p53 <a href="#">OC search</a> <a href="#">OC viewer</a>		
Pathway	PATH: <a href="#">hsa04010</a> MAPK signaling pathway PATH: <a href="#">hsa04110</a> Cell cycle PATH: <a href="#">hsa04210</a> Apoptosis PATH: <a href="#">hsa04310</a> Wnt signaling pathway PATH: <a href="#">hsa05030</a> Amyotrophic lateral sclerosis (ALS) PATH: <a href="#">hsa05040</a> Huntington's disease		



# Papers + Data



stabilizes

WT1

tp53

activates

icam-1

expression

# Imagine how many graphs...



The screenshot shows the PubMed search interface. At the top, there are tabs for 'All Databases', 'PubMed', 'Nucleotide', 'Protein', and 'Gen'. The 'PubMed' tab is selected. Below the tabs is a search bar with the text 'Search PubMed' and a dropdown menu set to 'p53'. To the left of the search bar is a sidebar with links like 'About Entrez', 'Text Version', 'Entrez PubMed', 'Overview', 'Help | FAQ', 'Tutorial', 'New/Noteworthy', and 'E-Utilities'. Below the search bar are buttons for 'Limits', 'Preview/Index', 'History', and 'Clipboard'. The 'Display' dropdown is set to 'Summary', and the 'Show' dropdown is set to '20'. Below these are two boxes: 'All: 33558' and 'Review: 4021'. A red box highlights the text 'Items 1 - 20 of 33558'. Below this, the first search result is shown: '1: Kumaravel TS, Bristow RG. Detection of genetic instability at HER-2/r Breast Cancer Res Treat. 2005 May;91(1):89-94. PMID: 15868435 [PubMed - in process]'. The result is preceded by a checkbox and a document icon.

# Imagine all the data...



	10		PopSet: population study data sets	
	123568		GEO Profiles: expression and molecular abundance profiles	
	21		GEO DataSets: experimental sets of GEO data	

“GEO: 30,000 submissions representing approximately *half a billion individual molecular abundance measurements*, for over 100 organisms”

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