What's the Problem with Patents?

Overview

Patents are an integral part of American lives whether it is recognized or not. A brief history of patents via primary sources is related to public access to research findings and how this may affect ethics in the future.

Objectives

Students will be able to:

- Analyze 20th century primary sources to scrutinize patents over time.
- Identify sources of discussion with patent laws and how they can be subject to bioethics.
- Debate in a professional manner about bioethics and how it relates to government legislation.

Investigative Question

How have federally funded scientific innovations and patents enhanced the American public's access to new technologies?

Time Required

2-3 class periods of 50 minutes

- Day 1: Readings (Steps 1-7)
- Day 2: Video and debate (Steps 8-10)
- Day 3: Ongoing project and reflections (Steps 11-12)

Recommended Grade Range

9th-12th grade

Subject / Sub-Subject

This lesson pairs well with a biological science class. It also includes primary sources that link to history and social studies and utilizes the Library of Congress and Dole Archives materials.

Standards –Common Core ELA Standards for 9th and 10th grade

History/Social Studies Standards:

- CCSS.ELA-LITERACY.RH.9-10.1
  Cite specific textual evidence to support analysis of primary and secondary sources, attending to such features as the date and origin of the information.

- CCSS.ELA-LITERACY.RH.9-10.2
  Determine the central ideas or information of a primary or secondary source; provide an accurate summary of how key events or ideas develop over the course of the text.
- CCSS.ELA-LITERACY.RH.9-10.3
  Analyze in detail a series of events described in a text; determine whether earlier events caused later ones or simply preceded them.
- CCSS.ELA-LITERACY.RH.9-10.4
  Determine the meaning of words and phrases as they are used in a text, including vocabulary describing political, social, or economic aspects of history/social science.
- CCSS.ELA-LITERACY.RH.9-10.5
  Analyze how a text uses structure to emphasize key points or advance an explanation or analysis.
- CCSS.ELA-LITERACY.RH.9-10.6
  Compare the point of view of two or more authors for how they treat the same or similar topics, including which details they include and emphasize in their respective accounts.
- CCSS.ELA-LITERACY.RH.9-10.9
  Compare and contrast treatments of the same topic in several primary and secondary sources.

Science & Technical Subjects:

- CCSS.ELA-LITERACY.RST.9-10.1
  Cite specific textual evidence to support analysis of science and technical texts, attending to the precise details of explanations or descriptions.
- CCSS.ELA-LITERACY.RST.9-10.2
  Determine the central ideas or conclusions of a text; trace the text's explanation or depiction of a complex process, phenomenon, or concept; provide an accurate summary of the text.
- CCSS.ELA-LITERACY.RST.9-10.8
  Assess the extent to which the reasoning and evidence in a text support the author's claim or a recommendation for solving a scientific or technical problem.
- CCSS.ELA-LITERACY.RST.9-10.9
  Compare and contrast findings presented in a text to those from other sources (including their own experiments), noting when the findings support or contradict previous explanations or accounts.

Credits

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PREPARATION

Materials Used

Primary Source Analysis sheet created by the Dole Institute of Politics

Resources Used

*"*Millions are Saved*." Dakota farmers' leader.* (Canton, S.D.), 04 Oct. 1907. *Chronicling America: Historic American Newspapers*. Lib. of Congress.
http://chroniclingamerica.loc.gov/lccn/sn00065127/1907-10-04/ed-1/seq-3/
http://chroniclingamerica.loc.gov/lccn/sn00065127/

"Coloring Book of Patents 2016" The National Archives of the United States. Patented Feb. 28, 1911.
https://archivesaotus.files.wordpress.com/2016/02/patentscoloringbook.pdf?dom=prime&src=syn

Raloff, Janet. "Explainer: What is a patent?" Science News for Students. Society for Science & the Public, 20 Mar. 2013. Web. 03 May 2016.
https://student.societyforscience.org/article/explainer-what-patent

"'Public The Victim' for lack of limited patent right policy, Dole says" May 16, 1979. Digitized press releases. Box 22, Folder 18. Robert J. Dole Archive and Special Collections, University of Kansas. http://dolearchivecollections.ku.edu/collections/press_releases/s-press_022_018_023.pdf

Simoncelli, T. (2014, November). Should you be able to patent a human gene? [TED Video file.] Retrieved from
https://www.ted.com/talks/tania_simoncelli_should_you_be_able_to_patent_a_human_gene?language=en#t-1071062

Association for the Molecular Pathology et al. v. Myriad Genetics, Inc., et al. No 12-398. Supreme Court of the United State. 569 U.S. __ (2103).
http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf

Description of Procedure

This Inquiry Includes: Wonder, Investigate, Construct, Express, Reflect, Connect

Day 1 -

1. Bellwork: Introduce Library of Congress newspaper article from 1907. "Millions are Saved – Federal Scientists Do Not Patent their Inventions" http://chroniclingamerica.loc.gov/lccn/sn00065127/1907-10-04/ed-1/seq-3/
   Provide copies for every student.
   a. Students can work in groups or individually read article and take notes if need.
   b. Summarize, as a class, while referring to characteristics they notice (old newspaper, who, what, where, why, etc.).
2. Investigate what is a patent. Hear class background knowledge on patents – what do they already know?
   a. May show pictures of early patents: bicycle, automobile, toilet paper, etc. Also, the National Archives has produced a fun coloring book with some random patents from the past. https://archivesaotus.files.wordpress.com/2016/02/patentscoloringbook.pdf?dom=prime&src=syn
   b. Patent = protection of an invention
      i. New – nobody has made the same thing or something similar in the past.
      ii. Inventive step – created something, not easily made.
      iii. Application – useful in the real world.
3. If extra explanation into patents is needed, provide the article from *Science News* for students.
   a. https://student.societyforscience.org/article/explainer-what-patent
4. Summarize the 1907 article on the absence of patenting for the good of the government.
   a. http://chroniclingamerica.loc.gov/lccn/sn00065127/1907-10-04/ed-1/seq-3/
   b. Don't want them to become wealthy – for the greater good

Moving from patents from the beginning of the 20th century to near the end of the century…

5. Apply what the students learned from 1907 article to the 1979 press release from the Dole Archives detailing the Bayh-Dole Act (pronounced "Bye") (or 1996 fax). Read through in small groups with Dole Institute of Politics Primary Source Analysis worksheet. Instructor: please see end of this document for background information on the Bayh-Dole Act.
   a. Public is the victim because they are not receiving the end product of research in a timely manner. Millions of dollars in federal money is going towards research, but innovations are wrapped up in government red tape and not getting to the public for usage.

   b. The Bayh-Dole Act opens up this research. This amendment to the Patent and Trademark Act allows universities, non-profit research labs, and private companies to hold patents on federally funded research. This allows the technology transfer of medicines, biotechnology, and other crucial research to the public faster than having it bogged down in red tape as before. Therefore, the public can benefit from medicinal breakthroughs and vaccines quicker as research can move faster and freely. Bayh-Dole is credited with helping create the biotechnology industry.

6. Have students summarize the Dole reading in small groups and go over the Primary Source Analysis worksheet. Have the students pick out words they don't understand and define these terms in small group research.
7. Compare and contrast the 1907 vs. 1979 article to consider how government and patent views have changed.
   a. Does the government pre-1980 have too much reign over technology and research? Did that stifle the public's access to research?

Day 2 -
Investigating patents further to present day and complicated ethical issues…

8. Ask students what has changed in their society in the last 30 years? Medicinal breakthroughs, iPhones, technology, etc. Hopefully, they mention about diseases and medicines. Ask them what they think about patenting genes. Can we patent something that is in your body right now? Technically, more than 20% of the genes in your body right now are patented and cannot be used by someone other than the patent holder for research. Is that ethical? Introduce the subject of bioethics.
9. Show class the TED talk video of Tania Simoncelli on "Should you be able to patent a human gene?" https://www.ted.com/talks/tania_simoncelli_should_you_be_able_to_patent_a_human_gene?language=en#t-1071062
   a. She details the Supreme Court decision of 2013 of Association for Molecular Pathology vs. Myriad Genetics, Inc.
      i. If you would like to reference the formal ruling of the Court: http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf
      ii. Basically, the final decision was that isolated genomic DNA (gDNA) cannot be patented (the act of isolation is not inventive) but complementary DNA (cDNA) can because it is not naturally occurring.
      iii. Patents allow private companies to restrict growth of research if they sue anybody else for using their materials. This diminishes healthy competition and public choice for tests and examinations.
      iv. Is Ms. Simoncelli a primary source? Is the TED talk a primary source?
10. Proctor a debate on patents on medical research and patents. Let students work through the process and listen to all sides. Is this ethical?

a. Conclusions: Does the government now give too much freedom to researchers? Patenting our own body? Where will it end?
b. How have patents changed over time? Where do you think we, as a society, will go with patents? More or less patents? Has it gotten too ridiculous? Who owns your own body?

Day 3 -
Explore patent ideals for the different sources and times.

- 1907 source: The government doesn't want researchers to acquire wealth for their federally funded work
- 1980 source: It doesn't matter if researchers get wealthy as long as they further science
- 2013 source: Some research has been restricted because of "selfish" patents – not furthering important research and companies becoming very wealthy

11. Have students create a timeline of an innovation. This can be on paper or a digital presentation. How has patent frequencies changed over the decades? Are there more patents now this decade because of technology, smarter people, or just more to patent? Describe major patents of different eras.
    a. Patent numbers for a variety of class groups such as apparel, prosthesis, chairs, X-rays, etc. from pre-1995-2015. Patent counts by class by year: http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.htm
    b. U.S. patent activity from 1790-2015. http://www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.htm
    c. Great American patents as complied by Listverse.com http://listverse.com/2008/03/31/10-really-great-american-patents/
    d. Are recent inventions the same as patents? Does an invention have to be patented?
12. Class discussion or individual journal entry –
    a. Reflect on what life would be like if some of these items were never invented? What could we be without? Would this create a domino effect? Is it good to patent?
    b. How has bioethics affected legislation and government policies?
    c. How do you think inventors from the early 1900's would react to these laws and stipulations now?
    d. If you were to invent something, would you create it for the greater good or to get rich?
        i. Does this matter if it is a life-saving drug, a trinket, or a fun app?

Extensions

- Connect to the bioethics question of HeLa cells – Henrietta Lacks and her immortal cells that have many, many contributions to scientific research but were taken without her permission and hidden from her family.
- Research the extended reaches of the Bayh-Dole Act of 1980 or other congressional legislation that affects science.
    - See article on congressional process. The author was a staff member of the U.S. Senate Judiciary Committee with Sen. Bayh and was instrumental in the passage of the Act.
        - Allen, Joseph. "The Enactment of Bayh-Dole, An Inside Perspective." *IPWatchdog*. 28 November 2010. Web. 17 May 2016. http://www.ipwatchdog.com/2010/11/28/the-enactment-of-bayh-dole-an-inside-perspective/id=13442/

Evaluation

Informal evaluation will take place during debate time. Formal evaluation of primary source analysis will take place within groups, the individual final project on patent innovations through time, and through the individual journal entry.

Background for instructor:

(Below adapted from "Coalition to Promote Technology Transfer" Sept. 10, 1993. Legislative Relations. Box 433, Folder 28. Robert J. Dole Archive and Special Collections, University of Kansas.)

What is the Bayh-Dole Act of 1980?

It is a federal law passed by Congress in 1980 with sponsors Senator Birch Bayh (Indiana – D) (pronounced *"Bye"*) and Senator Robert Dole (Kansas – R) to facilitate the commercialization of technology developed with government support. Bayh-Dole forged a new partnership between the nation's universities, non-profit research laboratories and the private sector that has, among other things, spawned the biotechnology industry and revitalized American technological leadership in the world. Before 1980, the federal government retained title to all university and non-profit research inventions if any federal funding was involved.

Why shouldn't the government control the price if the invention was made with some federal assistance?

Because the cost of bringing a technology to market is vastly greater than

the cost of inventing it (a CRS report quotes a study which suggests that in general it costs more than 100 times as much to commercialize a new technology than to invent it), and once it is on the market there is no guarantee that those costs can be recouped let alone a profit made. Without exclusive licenses and market prices, the prospects of recouping an investment are minimal. Companies will not bear the financial risk of bringing a new technology to market without these reasonable incentives. Prior to the passage of the current incentive system, virtually no technology developed with federal assistance was brought to the market.

How do taxpayers benefit from the current system?
First, the research they support benefits them as new life-saving pharmaceuticals and other products. Second, prior to Bayh-Dole, much of taxpayers' money was wasted on the invention of new technologies that never saw the light of day because the government retained all patent rights. Third, royalties that universities and non-profit research laboratories receive from their commercialized inventions are (by law) poured back into research and education both expanding the scope of research and diminishing the need for federal assistance. Fourth, commercialized inventions like those that form the basis of the biotech industry create economic activity that results in new taxes and revenue to the government. Fifth, commercialized inventions mean new jobs---45,000 well paid, high technology jobs so far and growing by 25 to 30 percent each year, according to one estimate. Sixth, technology transfer has placed the United States in the forefront of world trade in areas like biotechnology and communications thus reducing the trade and balance of payment deficits.

Good summary of major Bayh-Dole Act implications, easy to read:
"Innovation's golden goose." Technology Quarterly: Q4 2002. *The Economist.* The Economist Newspaper Limited. 12 December 2002. Web. 24 May 2016.
http://www.economist.com/node/1476653

Primary Source Analysis

Type of source: (Check one)

☐ Newspaper ☐ Letter ☐ Memorandum ☐ Press Release

☐ Report ☐ Speech ☐ Photograph ☐ Congressional record

Other _____

Who created this?

Who was it made for?

When?

Where?

Why was it created?

What else do you observe? Any unique characteristics (letterhead, seals, handwritten)?

List three things the author said that you think are important.

1)

2)

3)

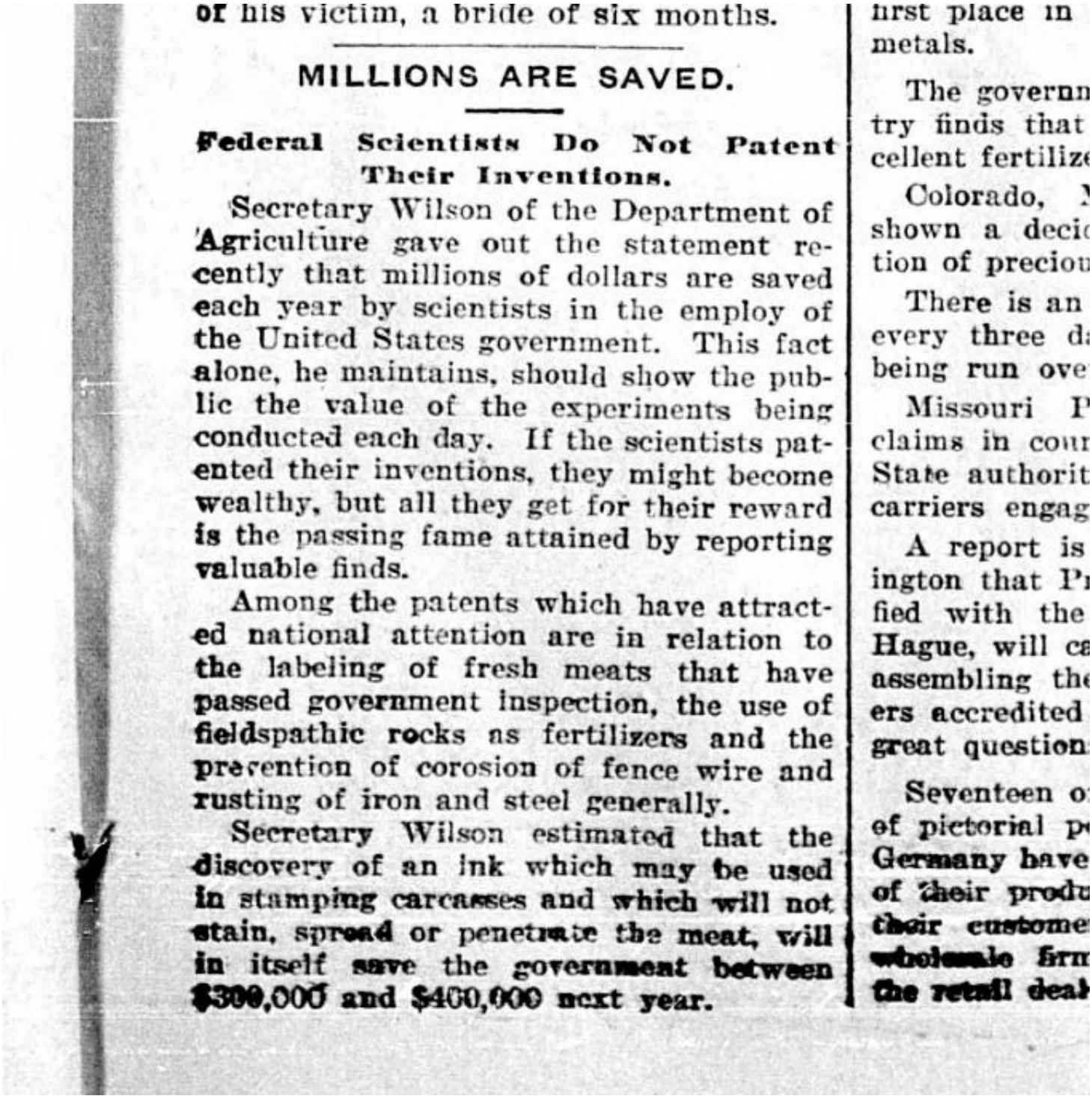
What point is the creator trying to make with this source?

What was happening in the U.S./world during this time period?

What else do you wonder about this source? **Questions?**

ROBERT J. DOLE INSTITUTE OF POLITICS
The University of Kansas

Dakota farmers' leader. (Canton, S.D.) 1890-19??, October 04, 1907, Image 3



of his victim, a bride of six months.

MILLIONS ARE SAVED.

Federal Scientists Do Not Patent Their Inventions.

Secretary Wilson of the Department of Agriculture gave out the statement recently that millions of dollars are saved each year by scientists in the employ of the United States government. This fact alone, he maintains, should show the public the value of the experiments being conducted each day. If the scientists patented their inventions, they might become wealthy, but all they get for their reward is the passing fame attained by reporting valuable finds.

Among the patents which have attracted national attention are in relation to the labeling of fresh meats that have passed government inspection, the use of fieldspathic rocks as fertilizers and the prevention of corosion of fence wire and rusting of iron and steel generally.

Secretary Wilson estimated that the discovery of an ink which may be used in stamping carcasses and which will not stain, spread or penetrate the meat, will in itself save the government between $300,000 and $400,000 next year.

first place in metals.

The governm try finds that cellent fertilize

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Missouri claims in cou State authorit carriers engag

A report is ington that P fied with the Hague, will c assembling th ers accredited great question

Seventeen o of pictorial p Germany have of their produ their custome wholesale firm the retail deal

News from Senator

BOB DOLE

(R - Kansas) 2213 Dirksen Building, Washington, D.C. 20510

FOR IMMEDIATE RELEASE
WEDNESDAY, MAY 16, 1979

CONTACT: BILL KATS, BRENDA LEVENSON
202-224-8947, -7563

'PUBLIC THE VICTIM' FOR LACK OF LIMITED PATENT RIGHT POLICY, DOLE SAYS

WASHINGTON -- Sen. Bob Dole (R-Kan.) said today that the American public suffers because of the government's current patent policies, which "act to stifle the development and marketing of inventions emanating from federally funded research." Dole made his statement during hearings on the University and Small Business Patent Procedures Act in the Judiciary Committee's subcommittee on constitution. Dole along with Sen. Birch Bayh (D-Ind.) are original sponsors of the bill.

The bill was introduced last fall following Dole's charges that the Department of Health, Education and Welfare was suppressing lifesaving drugs and medical devices developed under support from the National Institutes of Health. He stated that HEW's refusal to relinquish ownership of inventions developed by university scientists with NIH support "precludes the possibility of these drugs and medical devices ever reaching the public." As a result of Dole's actions, some of the inventions in question were freed for further development. But an HEW patent counsel who cooperated with Dole aides in formulating a new patent policy lost his department job as a result.

Following is Sen. Dole's hearing statement:

"Mr. Chairman, the present patent policy generally encourages retention by the government of rights to inventions it sponsored. This policy has resulted in a reluctance by universities and industry to invest the necessary funds for the development and marketing of inventions emanating from federal funded research. This is understandable in view of the fact that the development process is not only risky but expensive, and estimated to cost ten times the cost of the initial research.

"By obstructing patent rights and innovations, the government increases the factor of uncertainty in an already uncertain area, that of technology end result. By denying the modicum of protection that the granting of patent rights for a limited period of time would afford, the government removes the incentive that would stimulate the private sector to develop and market inventions.

IMPACT OF FEDERAL POLICY

"The effect of this policy is twofold, bearing on the consumer as well as on the economy in general. In both cases, the public is the victim. When large amounts of taxpayers' money are directed to the research field, the public expects and deserves to reap the benefit of its investment in the form of products available for its consumption. When this fails to materialize, it is obvious that the government has reneged on its promise. This is evidenced by the fact that, of the 28,000 inventions funded by the government, only about 5% have been used.

"The damaging impact of the federal patent policy on the economy is dramatic. That we have lost our leadership role to Japan in the fields of electronics and shipbuilding is no accident. Without short-term exclusive rights, small firms cannot take the risk of bringing innovations to the commercial market, but large foreign firms can and are doing so, with ideas gleaned from U.S. funded research. That the richest nation on earth has a trade deficit with Japan amounting to $13 billion leaves room for reflexion, when one considers that fact that Japan has no natural resources on her mainland. Our annual growth is 3% as opposed to 8% in Japan. Our newly established ties with China make the People's Republic a candidate for emulation of the Japanese example. With a population of 900 million people, through the potential use of U.S. technology to which its access is now guaranteed, China could become a most formidable competitor.

"The development of technological innovation by government and industry in countries such as Japan and Germany, is a contributing factor in their dominance of world trade.

WHAT IS THE ANSWER?

"Protectionism is not what I am advocating. Such a theory would be counterproductive and one I do not adhere to on general principles. What I am rather suggesting is that the answer to foreign competition lies neither in an increase of export subsidies, nor in an increase of tariffs, but in an increase in productivity. I believe that the protection that patent rights for a limited amount of time would guarantee to American business would be a giant step towards providing incentives for greater productivity.

"Our economy is one which has always run on America's innovative genius. This resource must not be allowed to waste away on account of unnecessary delays and red tape. Complex rules and regulations devised by federal agencies are detrimental to stimulating productivity and enterprise. They are particularly harmful to small businesses from which, traditionally, innovative and creative programs have emanated. In the field of medical innovation, the obstruction of patent rights by federal agencies is an extremely serious problem. Indeed, when medical inventions, offering potential cures for diseases are withheld, it is the very lives of Americans which are affected.

"The almost adversarial relationship that now exists between business and government must be replaced by a true and genuine partnership, a partnership in which the government will act as impresario in bringing industry and universities together with new fields of knowledge, and their practical implementation.

GOAL OF LEGISLATION

"The University and Small Business Patent Procedures Act that Senator Bayh and I have introduced would establish a uniform policy, guaranteeing rights for a limited period to inventions made under federally sponsored research. Such a policy would help promote the utilization of inventions and would encourage the participation of contractors in government sponsored R & D. By doing this, the public investment in R & D would be protected, and the public interest would be served, according to the direction given by the Constitution in Article One, Section Eight.

"Before concluding, I should like to ask that the text of an article published in the Washington Post on April 8, 1979, titled Patent Bill Seeks Shift to Bolster Innovation be inserted for the Record, following the text of my statement.

THE BAYH-DOLE ACT

OVERVIEW

In 1980, Congress amended the Patent and Trademark Act with what is commonly referred to as th Bayh-Dole Act. In short, the Act gave universities title to patents they developed with federal dollars. In turn, universities could develop licensing arrangements with industry.

Prior to Bayh-Dole, technology transfer from universities to the public sector was virtually nonexistent, as there was no clear government policy regarding ownership of inventions made with federal dollars. It was bad business to base a product on a federal patent when that patent conveyed no rights. Especially, when one factors in that R&D represented less than 25% of the total cost necessary to bring a new product to market. As a result, the public was denied access to new medicines and technologies derived from federally-funded research.

Bayh-Dole is credited with helping create the Biotech Industry. In addition to making possible the development of new drugs and treatments of diseases, it has also created a better economic environment by providing the incentive needed to develop new companies with high-paying professional jobs. In simple terms, the Act has made a national resource more accessible and thereby has sparked innovation, job growth, and public good.

IMPACT OF BAYH-DOLE ACT

According to Dr. Allan L. Goldstein, Chairman of George Washington Universities Department of Biochemistry and Molecular Biology, the economic impact of the Act as of 1994 resulted in the creation of markets of between $9 and 13 billion dollars in product sales, between 50,000 and 100,000 new jobs, and federal, state, and local tax revenues of over $2 billion.

o In the 1980's, 25% of university patents were biomedical or health related inventions -- Compare that with 8% in the 1970's.

o In 1981, universities were issued less than 250 patents per year. A decade later, that number jumped to 1,600 and almost 80% of these were through federally-funded research.

o Industrial support for University research has jumped from 2% to more than 10% in the last decade and is continuing to grow.

o Licensing arrangements provide universities with royalties that can be plowed back into research -- $350 million last year alone.

o It has also put some in a position to be philanthropists. Dr. Herbert Boyer, a professor and UC San Francisco School of Medicine, and co-founder of Genentech, recently gave his home university $25 million -- the largest gift in the school's history.