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Maximizing Pharmaceutical Industry Profits at the Taxpayers' Expense:

Construing FOIA Exemption Four to Allow Secret License Agreements between Pharmaceutical Companies and Federally-funded Laboratories in *Public Citizen Health Research Group v. National Institutes of Health*

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I. ABSTRACT

The federal government's technology transfer program encourages federally-funded laboratories to license their newly developed technologies to the private sector. However, the laboratories are required by law to report their licensing activities to the federal agency charged with allocating public funds to them. In March 2002, the United States District Court for the District of Columbia held that the essential term (royalty rate) of a license agreement between a federally-funded laboratory and a pharmaceutical company is exempt from the Freedom of Information Act (FOIA). In other words, federal agencies may choose to hide the royalty information from the public. This Note argues that the Court has misconstrued the FOIA by failing to address several important factors. The bigger picture tips the balance in favor of releasing the royalty information to the public.

II. INTRODUCTION

Several factors contribute to the high price of pharmaceuticals. These include (1) selling prescription drugs in a captive market where consumers cannot choose to forego important medical treatments, (2) bringing a new drug to market requires substantial research and development, and (3) some investors demanding large returns.

But what happens when a pharmaceutical company utilizes federally-funded scientific research to assist the process of bringing a new drug to market? Does this lower the company's costs? If so, does the company respond in kind by lowering the price it charges consumers? Or do the investors merely achieve larger returns? These are the questions to which the Plaintiff wants the public to demand answers.[1]

II-A. Litigants

The plaintiff is Public Citizen Health Research Group (PCHRG). Public Citizen is a non-profit consumer advocacy group located in Washington, D.C. devoted to health care issues.[2] The mission of PCHRG is to fight for health care and prescription drugs that are safe, effective, and affordable.[3]

The defendant is the National Institutes of Health (NIH).[4] The NIH is a very large federal agency under the U.S. Department of Health and Human Services. It conducts medical, behavioral, and pharmaceutical research.[5] The NIH is comprised of 27 separate components, and its main campus consists of 75 buildings located on 300 acres in Bethesda, Maryland. The NIH intramural research program allocates funds to federally-owned laboratories, and the NIH extramural research program awards competitive grants to university-owned laboratories throughout the nation. Both research programs are financially supported by the taxpayers. In the year 2001, Congress appropriated \$20.5 billion to the NIH.[7]

The intervenor-defendant is Johnson & Johnson, a for-profit business organization that manufactures and sells pharmaceuticals (45% of total sales), medical devices (34% of total sales), and hygiene products (21% of total sales).[8] Its pharmaceutical segment is one of the most profitable enterprises within the pharmaceutical industry. In the year 2001, Johnson & Johnson's pharmaceutical segment generated \$14.9 billion in sales and \$4.9 billion in operating profits, while holding \$11.6 billion in identifiable assets.[9]

II-B. Background

A number of prescription drugs have been developed in part by financial support from taxpayers. The process begins with a federally-funded laboratory making an initial drug discovery.[10] At this early stage of development, the taxpayers are the investors who bear the risk of failure. Afterwards, the federal government's technology transfer program makes the drug discovery available to for-profit business organizations.[11] At this stage, the role of a pharmaceutical company is to design a method to scale-up production of the drug and perform the clinical trials necessary to achieve FDA-approval for sale of the drug to the public. Here, the pharmaceutical company bears the risk of failure. However, it is becoming more common for federal funding to assist with the clinical trials as well.[12]

II-C. Reason for Filing an FOIA Request

PCHRG has been lobbying Congress to place price controls on prescription drugs for which financial support from taxpayers played a major role in research and development.[13] PCHRG believes it is an intolerable situation to force working middle-class Americans to subsidize the development of new prescription drugs when they cannot afford to purchase them.[14]

The pharmaceutical industry has counter-lobbied that prices are high because investment and production costs are high.[15] To respond to the pharmaceutical industry's explanation, PCHRG has begun a quest to map-out which prescription drugs were developed in part with public funds, and the cost each pharmaceutical company incurred in bringing those particular drugs to market.[16] This includes learning how much each pharmaceutical company paid to license technology from the federal government's technology transfer program.

II-D. Dispute and Outcome

PCHRG asked the NIH to make the following information accessible to the public: 1) the royalty rate (defined as a percentage of gross sales revenues) of each license agreement between the NIH and a pharmaceutical company, and 2) the amount of royalties each pharmaceutical company paid pursuant to each license agreement during the period from 1986 to 1998.[17] The NIH refused to reveal the information.[18] PCHRG filed suit against the NIH in federal district to obtain the records of a federal agency under the Freedom of Information Act (FOIA).[19] Johnson & Johnson, a company with active license agreements, intervened on the side of the NIH.[20]

The Court held in favor of NIH and Johnson & Johnson.[21] The Court reasoned that the royalty information should be protected, because the possibility of NIH and Johnson & Johnson experiencing harm outweighs the public's need to know.[22]

II-E. Direction

This Note argues that the public interest is more important, and therefore the Court's decision should be overturned.[23] The Note begins with an overview of the laws that control the federal government's technology transfer program and shows examples of technology transfers to Johnson & Johnson. Then, the Note demonstrates the link between the technology transfer laws and the Freedom of Information Act (FOIA), and introduces the balancing analysis that courts perform under Exemption Four of the FOIA. The Note presents the interests of each party, offers a better method for assigning weight to those interests, and performs the balancing analysis with the new weights.

III. TECHNOLOGY TRANSFER

Congress created the technology transfer program to encourage movement of the federal government's scientific and technical information to the private sector.[24] Commercialization of new technologies should stimulate the economy and improve the quality of life.

III-A. Technology Transfer Statutes

When a federally-funded scientific research institution creates a patentable invention, the federal government retains a partial ownership interest in the resulting patent. The institution may choose to achieve partial ownership as well. The institution

can apply for patents, and license the patents to the private sector, but this power is subject to many restrictions described below.

Situations that Give Rise to Federally-Owned Patents

The federal government retains a property interest in a newly issued patent under three different scenarios. In the first situation, a federally-owned laboratory is the sole creator of the patentable invention. The patenting and licensing is governed by a portion of the Bayh-Dole Act (35 U.S.C §§ 207-209). In the second situation, a federally-owned laboratory collaborates with a for-profit business organization, and together they create a patentable invention. The collaboration is referred to as a “CRADA” (Cooperative Research and Development Agreement),^[25] and is governed by the Federal Technology Transfer Act (15 U.S.C. §§ 3710a-d). In the third situation, a university-owned laboratory receives a federal research grant, and uses the money to create a patentable invention. In this case, the patenting and licensing is governed by a different portion of the Bayh-Dole Act (35 U.S.C. §§ 202-204).

Federally-owned Laboratories Bayh-Dole Act (35 U.S.C §§ 207-209)

In the first situation, the individual inventor, the federally-owned laboratory, and the federal government, share property interests in the patent.^[26] The federally-owned laboratory (or the federal agency overseeing the laboratory) may negotiate license agreements with private companies.^[27] To start the negotiation process, the private company must submit a proposal describing how the company plans to develop and market the invention.^[28] The private company must demonstrate that the license agreement will serve the public interest,^[29] and that manufacture of the resulting consumer product will occur within the United States to promote jobs.^[30] Also, the royalty payments received by the federally-owned laboratory (or the federal agency) must be used to support further research and development projects.^[31]

The federally-owned laboratories prefer to enter non-exclusive license agreements in an effort to achieve maximum usage of the technology. However, if a private company insists on obtaining an exclusive license, this requires a public notice-and-comment period.^[32] Even if an exclusive license agreement is achieved, the federal government still retains the right to use the invention for research purposes.^[33] Also, the federal government retains the right to investigate the effort the private company has made toward bringing the product to market; Congress frowns on hoarding and shelving exclusive license agreements merely to thwart others in the same general industry.^[34]

CRADAs - Federal Technology Transfer Act (15 U.S.C. §§ 3710a-d)

In the second situation, the individual inventor, the federally-owned laboratory, the federal government, and the private company, share property interests in the patent.^[35] The federally-owned laboratory retains the right to negotiate license agreements with other private companies.^[36] The private company who is joint owner of the patent (and any licensees) must manufacture the resulting consumer product within

the United States.[37] The federal government retains the right to use the invention for research purposes.[38] The royalty payments received by the federally-owned laboratory must be used to support further research and development projects.[39] The formation of the CRADA does not require a public notice-and-comment period.[40]

University-Owned Laboratories - Bayh-Dole Act (35 U.S.C. §§ 202-204)

In the third situation, the individual inventor, the university, and the federal government, share property interests in the patent.[41] The university may negotiate license agreements with private companies. However, the federal agency that allocated the research funds retains the right to terminate any of the university's license agreements, and to license the patent to others instead.[42] All licensees must manufacture the resulting consumer product within the United States.[43] The federal government retains the right to investigate the effort a licensee has made toward bringing the product to market.[44] The federal government also retains the right to use the invention for research purposes.[45] The royalty payments received by the university must be used to fund further scientific research at the university.[46]

Restrictions on Royalty Rates

The technology transfer statutes do not place any restrictions on royalty rates; the law allows royalty rates to be as low as zero percent.[47] However, the NIH has adopted a policy of trying to negotiate royalty rates that are reasonable.[48]

III-B. Reporting Requirements

The federally-owned laboratories, CRADAs, and university-owned laboratories receiving federal research grants, are required to report their patenting activities to the federal agency that allocated federal funds to the laboratories.[49] The laboratories are also required to submit annual reports about any license agreements they have made. The reports are to include the status of product development, date of first commercial sale or use, and gross royalties received.[50]

Biomedical laboratories, which have been allocated funds by the NIH, are required to report their patenting and licensing activities to the NIH. The NIH has created a database called "Interagency Edison" to manage this information.[51] However, the data is not accessible to the public. The database can only be searched by staff in the NIH Office of Technology Transfer.[52]

III-C. Examples of Technology Transfers to Johnson & Johnson

Sometimes the existence of a license agreement leaks to the news media. Here are some examples of how the federal government's technology transfer program has benefited the intervenor-defendant, Johnson & Johnson.

Procrit® and Ortho Biotech

Erythropoietin is a natural growth factor found in humans, which stimulates the production of red blood cells. Columbia University utilized NIH funding[53] to develop a process that produces erythropoietin in the laboratory.[54] Columbia University licensed the resulting patent to Amgen.[55] Amgen sub-licensed to Ortho Biotech of Raritan, New Jersey.[56] Ortho Biotech is a subsidiary of Johnson & Johnson.[57] Ortho Biotech obtained FDA approval to sell erythropoietin under the name Procrit® as a treatment for anemia (low red blood cell count) associated with chemotherapy in cancer patients and with zidovudine-therapy in HIV patients.[58] The sale of Procrit® produces more revenue for Johnson & Johnson than any of its other products. In the year 2001, sales of Procrit® reached \$3.43 billion.[59] Consumers pay about \$120 for each dosage of Procrit®.[60]

Leustatin® and Ortho Biotech

Cladribine (2-chlorodeoxyadenosine) is a nucleotide analog that inhibits DNA replication. The Brigham Young University utilized NIH funding[61] to develop a procedure to chemically synthesize cladribine.[62] Brigham Young University licensed the resulting patent to Ortho Biotech (subsidiary of Johnson & Johnson).[63] The General Clinical Research Center (GCRC) of The Scripps Research Institute (TSRI) utilized NIH funding to perform clinical trials on cladribine.[64] Ortho Biotech obtained FDA approval to sell cladribine under the name Leustatin® as a treatment for hairy cell leukemia.[65] Consumers pay about \$2400 for chemotherapy treatment with Leustatin®.[66]

ReoPro® and Centocor

Abciximab is a monoclonal antibody that binds to a glycoprotein receptor on the surface of platelets, thereby preventing platelets from sticking together and forming a blood clot. The State University of New York at Stony Brook (SUNY-SB) utilized NIH funding[67] to create abciximab.[68] SUNY-SB licensed the resulting patent to Centocor of Malvern, Pennsylvania.[69] Centocor is a subsidiary of Johnson & Johnson.[70] The company obtained FDA approval to sell abciximab under the name ReoPro® as a treatment to prevent the formation of blood clots during and after surgery for clogged arteries.[71] In the year 1999, ReoPro® generated \$447 million in sales.[72] Consumers pay about \$1100 for each dosage of ReoPro®.[73]

Remicade® and Centocor

Infliximab is a monoclonal antibody that binds to tumor necrosis factor alpha, thereby hindering the inflammatory process. The New York University Medical Center (NYU-MC) utilized NIH funding to create infliximab.[74] The project was done in collaboration with Centocor (subsidiary of Johnson & Johnson). NYU-MC and Centocor became joint owners of the resulting patent.[75] Centocor obtained FDA approval to sell infliximab under the name Remicade® as a treatment for both Crohn's disease and rheumatoid arthritis.[76] In the year 2001, Remicade® generated \$721 million in sales.[77] Consumers pay about \$1800 for each dosage of Remicade®.[78]

IV. FREEDOM OF INFORMATION ACT

The Freedom of Information Act (FOIA) requires federal agencies to disclose their records to the public upon request.[79] However, not all records are fair game. The FOIA has nine different exceptions that give federal agencies the power to refuse disclosure.

IV-A. FOIA Exemption Four

One of these exceptions is referred to colloquially as Exemption Four. It gives federal agencies the ability to protect “trade secrets and commercial or financial information obtained from a person and privileged or confidential.”[80] This statutory language is construed as applying to two types of information: 1) trade secrets, and 2) commercial or financial information, provided by a non-governmental third party, received by a federal agency, and privileged or confidential.

The technology transfer statutes expressly reference FOIA Exemption Four and directly mimic its statutory language in all three federally-funded settings (federal laboratories,[81] CRADAs,[82] and university laboratories[83]). The main issue in the *PCHRG* case is whether the NIH can use FOIA Exemption Four as an excuse to hide royalty information from the public.[84] Therefore, each component of FOIA Exemption Four must be carefully evaluated.

Trade Secrets versus Commercial or Financial Information

Royalty rates and royalty payments are not trade secrets.⁸⁵ They are financial information.[86]

Provided by a Non-Governmental Third Party

Within the setting of a technology transfer program, the non-governmental third parties are the business organizations that enter into license agreements with federal entities.

PCHRG has argued that a royalty rate is not information “provided by” (or obtained from) a third party, but instead is merely one term in a contract “negotiated with” a third party, and royalty payments are merely the performance of that negotiated agreement.[87] Therefore, the royalty information does not fall under FOIA Exemption Four; the information must be released to the public.

But the *PCHRG* Court concluded otherwise. The technology transfer program requires that licensees provide the initial offer.[88] Then the licensees provide counter-offers during negotiation. And the licensees must agree to the final value. Therefore, the licensees are the ultimate source of the royalty information.[89]

Received by a Federal Agency

The law requires that the NIH receive the royalty information.[90] Either the NIH directly negotiates a license agreement with a business organization, or a federally-funded laboratory negotiates a license agreement and reports the information to the NIH.

Privileged or Confidential

In the *PCHRG* case, the royalty rates and royalty payments are not protected by a privileged relationship, such as attorney-client or doctor-patient.[91] So, the issue narrows to whether they are confidential.[92]

IV-B. Balancing Test Defines Confidential

The statutory language of the FOIA does not define confidential. Congress has left to the courts the responsibility of determining when commercial or financial information is confidential.[93] The D.C. Circuit, which handles the largest number of FOIA cases, has stated repeatedly since the 1970's that all FOIA exemptions must be construed narrowly, in such a way to provide maximum access to agency records consistent with the overall purpose of the FOIA.[94] In other words, a party's subjective desire to hide information from the public does not automatically deem the information confidential. And signed confidentiality agreements are not particularly persuasive.[95]

The D.C. Circuit has created a balancing test to determine when commercial or financial information is confidential under FOIA Exemption Four.[96] The test balances the public interest versus the interests of the federal agency and the third party. The analysis contains a presumption that the public interest is strong. Information is declared confidential when the combined weight of the federal agency's and third party's interests overcomes the strong public interest.[97]

Mandatory versus Voluntary Information

A different set of factors is used to evaluate the interests depending upon whether the information was provided to the federal agency on a voluntary or mandatory basis. Information is considered mandatory when submitting the information is either required by law or required to maintain the relationship between the third party and the federal agency.[98]

In the *PCHRG* case, all parties agree that the federal agency (NIH) obtained royalty information from the third parties (licensees such as Johnson & Johnson) on a mandatory basis.[99] A royalty rate is a required term in a license agreement, and laboratories are required to report licensing information to the NIH.

Factors Defining the Federal Agency's Interests

The interests of the federal agency are rather similar in the voluntary and mandatory situations. If the third-party submitted the information on a voluntary basis, the issue is whether revealing the information to the public would jeopardize the federal agency's ability to ensure that the information is readily available to the agency in the future.[100] If the third-party submitted the information on a mandatory basis, the issue is whether revealing the information to the public would jeopardize the federal agency's ability either to carry out its statutory mandate[101] or to ensure that the acquired information is accurate and reliable.[102]

Factors Defining the Third Party's Interests

The interests of the third party are rather different between the voluntary and mandatory situations. If the third party submitted the information on a voluntary basis, the issue is whether it is objectively the normal custom of the third party to hide the information from others.[103] If the third party submitted the information on a mandatory basis, the issue is whether revealing the information to the public would create a substantial risk of competitive harm by placing the third-party at a significant disadvantage compared to his competitors.[104] There is no need to show actual competitive harm; all that is required is demonstrating actual competition and the likelihood of substantial competitive injury.[105]

V. INTERESTS OF THE LICENSEES

Since the royalty information was submitted to the NIH on a mandatory basis, a significant factor that must be considered when evaluating the licensees' interests is whether revealing the royalty information to the public would create a substantial risk of competitive harm to the licensees.

V-A. Actual Competition Faced by the Licensees

Licensing agreements create three different competitive situations: 1) a licensee with an exclusive license, 2) multiple licensees with non-exclusive licenses to the same technology, or 3) the presence of both licensees and non-licensees. In the first situation, there is no competition. A single licensee has exclusive rights to the technology. In the second situation, competition may arise among the various licensees. However, the presence of competition is not an absolute certainty in the pharmaceutical industry. Sometimes different licensees use the same underlying technology to develop different drugs, or they use the same drug to target different markets (i.e., obtain FDA-approval to treat different illnesses). In the third situation, competition arises between a licensee and a non-licensee. Here, a non-licensee enters the fray with a medication that is markedly different to avoid infringing the patent being licensed, but is sufficiently similar to act as an effective market substitute (i.e., obtained FDA-approval to treat the same illness).

Criticism of the Court's Finding of Actual Competition

The *PCHRG* Court declared that the licensees face actual competition.[106] Yet, the Court did not specify the particular situations, companies, or products in which the actual competition was found.

It is interesting to note that during the course of the litigation the NIH revealed that it does not receive many overlapping offers for the same technology. In the year 2000, only about 10 percent (33 out of 298) of the technologies had more than one offer for a license agreement.[107] This data suggests that the pharmaceutical industry is using careful planning when choosing among the various technologies. The companies are not blindly stumbling into license agreements only to worry about future competition. Instead, they are cherry picking the technologies that they believe will face the least competition.

V-B. Likelihood of Competitive Injury to the Licensees

Johnson & Johnson argued that royalty rates and royalty payments are the kind of information that a competitor could unfairly use to his advantage.[108] When a particular product is associated with a license agreement, the royalty rate is the product's only cost variable; the other costs are standard throughout the industry.[109] A competitor could easily use the royalty information to estimate Johnson & Johnson's cost structure. And the cost structure could be used to estimate the amount the competitor needs to lower his prices to capture Johnson & Johnson's market.[110] In addition, a competitor could use the royalty information to gain insight into Johnson & Johnson's strategic plans. The royalty information could indicate how much Johnson & Johnson values the technology, thereby pointing a competitor in the direction of Johnson & Johnson's most fruitful markets.[111]

Criticism of the Court's Finding of the Likelihood of Competitive Injury

The *PCHRG* Court declared it was likely that the licensees would experience competitive injury if the royalty information were released to the public.[112] However, it is interesting to note here the relationship between Amgen and Johnson & Johnson. As mentioned earlier, Columbia University licensed the process to produce erythropoietin to Amgen, and Amgen sub-licensed to a subsidiary of Johnson & Johnson.[113] Amgen's knowledge of Johnson & Johnson's royalty rates and royalty payments did not cause Johnson & Johnson to lose profits; the arrangement merely pushed Johnson & Johnson to plan for different markets. Amgen obtained FDA approval to sell erythropoietin under the name Epogen® as a treatment for anemia associated with chronic kidney failure in dialysis patients.[114] In contrast, Johnson & Johnson's subsidiary obtained FDA approval to sell erythropoietin under the name Procrit® as a treatment for anemia associated with chemotherapy in cancer patients and with zidovudine-therapy in HIV patients.[115] The behavior of the two licensees suggests that they are strategically avoiding competing with each other.

V-C. Assigning the Appropriate Weight to Competitive Harm

The *PCHRG* Court viewed the risk of competitive harm as so important that it chose to evaluate the federal agency's factors merely in the interest of thoroughness.[116] Moreover, the Court did not address the public interest factor. The Court's eagerness to end its analysis after checking for competitive harm raises the question of how much weight should be attached to competitive harm.

Assigning weight to an individual factor requires that the factor be evaluated within the appropriate context. Business organizations submit commercial or financial information to federal agencies on a mandatory basis in many different situations. The most common setting is the "regulatory" context. For example, the Department of Transportation requires motor carriers to file annual financial and safety reports,[117] and U.S. Customs requires importers to file entry documents showing the value of the goods being imported into the United States.[118] In the regulatory context, the basis of the relationship between a federal agency and a business organization is that Congress has charged the federal agency with regulating the activity of that business organization. The direct benefactor of the relationship is the public.

The "public funds" context is a completely different setting. Here, the basis of the relationship between a federal agency and a private company is that the company is somehow acquiring or using government property, rights, or funds. The direct benefactor of the relationship is not the public, but the individual company. Since the company's needs are already being served by the relationship, there is no justification for increasing the company's benefits by weighing competitive harm heavily. The weight on competitive harm in the public funds context should be applied with moderation.

The facts of the *PCHRG* case fall into the public funds context; the basis of the relationship between the NIH and the pharmaceutical companies is based on the pharmaceutical companies' desire to acquire technology developed with public funds. If the context theory is correct, the *PCHRG* Court applied too much weight to competitive harm.

V-D. National Trends within the Public Funds Context

To test the context theory, it is useful to compare the outcome of the *PCHRG* case with the national trends among various FOIA Exemption Four cases that similarly address the public funds context. These cases can be divided into four categories: 1) business organizations that enter into contracts to provide goods and services to the federal government, 2) business organizations that receive loans either provided by or guaranteed by the federal government, 3) healthcare business organizations that are reimbursed for their services by the Medicare or Medicaid programs, and 4) business organizations that purchase, lease, or license property or rights in which the federal government has an ownership interest. The trends indicate that only in the first category is competitive harm weighed heavily.

In the first category, the competitive bidding process dominates the balancing analysis. Here, the federal government advertises for bids, and then chooses the contractor with the best proposal. The typical FOIA scenario involves a losing bidder asking the federal agency to disclose to the public the details of the other bid proposals. The trend here has been for the courts to protect the other bidders; the federal agency is not required to release the information to the public.[119] A bid proposal goes right to the heart of what a company does to operate and survive. The competition is obvious and imminent.

In contrast, the second and third categories have the opposite trend; courts favor release of the information to the public. For example, courts have required the Small Business Administration (SBA) to disclose the amount borrowed and balance due of each company who received an SBA loan.[120] In addition, a court allowed the Farmers Home Administration (FHA) to disclose the audit reports of each company that received an FHA loan.[121] Similarly, courts have upheld the decision of the U.S. Department of Health and Human Services to disclose the cost reports of hospitals that receive Medicare and Medicaid payments.[122] Here, business competition plays a smaller role. Public scrutiny of the business organizations that receive direct distributions of public funds becomes more prominent.

In the fourth category, courts also tend to favor release of the information to the public. In the following cases, the courts either made a finding of no competitive harm or failed to address it. For example, after the Department of Energy (DOE) sold a piece of land containing a naval petroleum reserve, a court required the DOE to release to the public the name of every company that had made an offer and the amount of each offer.[123] In another example, a court required the Department of Interior to release to the public the audit reports of some of the companies that leased concession space (for providing food, lodging, and entertainment to the tourists) within the national parks system.[124] In yet another example, a court required an Indian tribe that entered into a cooperative management agreement with the Department of Interior to release to the public the royalty rates that the tribe charges utility companies to license oil and gas extraction rights on the Indian reservation.[125]

The facts of the *PCHRG* dispute match the fourth category of cases in the public funds context; a consumer advocacy group asked the NIH to reveal to the public the amount each pharmaceutical pays to license technology in which the federal government has a partial ownership interest. Ironically, the *PCHRG* Court allowed the federal agency to hide the information. The U.S. Supreme Court's decision is out of step with the national trends. The Court failed to place the facts of the case within the appropriate context, and in so doing placed too much weight on competitive harm.

VI. INTERESTS OF THE NIH

Since the royalty information was submitted to the NIH on a mandatory basis, the factors to consider when analyzing the federal agency's interests are whether revealing the information to the public would jeopardize the federal agency's ability: 1) to carry out

its statutory mandate, or 2) to ensure that the acquired information is accurate and reliable.

VI-A. Ability of the NIH to Carry Out its Statutory Mandate

The NIH argued that it feared a retaliatory boycott by the pharmaceutical industry if it revealed the royalty information to the public.[126] Johnson & Johnson verified that it would refuse to enter into any future license agreements.[127] The boycott would result in the failure of the NIH to carry out the Congressional mandate of the Bayh-Dole Act and Federal Technology Transfer Act to encourage and promote technology transfers to the private sector.[128]

The NIH bolstered its argument by claiming it would be easy for the pharmaceutical industry to topple the technology transfer program. The program is not as popular as NIH would like it to be. In the year 2000, NIH received only 298 offers to enter license agreements, but they have about 2000 technologies available.[129]

Criticism of the Court's Finding of the Failure to Carry Out the Mandate

The *PCHRG* Court declared that revealing the royalty information to the public would substantially impair the ability of NIH to carry out its statutory mandate.[130] Although the threat of boycott is a serious concern, there are two problems with allowing the defendant to describe one of its interests as fearing retribution from the intervenor-defendant.

First, the threat of boycott due to competitive harm does not create a separate and unique interest for the NIH. One party in the litigation is merely stretching the same issue to another party in the litigation. To count competitive harm under the intervenor-defendant's interests, and to count fear of boycott due to competitive harm under the defendant's interests, would be to count the same problem twice. Only if the intervenor-defendant was not a party to the litigation would it be appropriate to count NIH's fear of boycott by the licensees as its own unique interest. Once a licensee enters as a party, the NIH should be required to present an independent reason why revealing the information would harm the viability of the technology transfer program.

Second, the sincerity of NIH's self-deprecating stance in regard to the popularity of its own program should be questioned. Given the nature of basic scientific research, it is quite remarkable that the NIH is producing about 300 biomedical technologies per year that can be easily converted into consumer products. This is almost one per day. In addition, given the lengthy and detailed language of the technology transfer statutes, it is clear that Congress intended to place numerous restrictions upon the licensees. Despite these restrictions, many companies have been willing to forego some autonomy in exchange for profitable opportunities. Although the NIH would like to downplay the importance of its own work, the technology transfer program is rather successful.

VI-B. Ability of the NIH to Receive Accurate and Reliable Information

The *PCHRG* Court did not address whether revealing the royalty information to the public would impair NIH's ability to receive accurate and reliable royalty information from the federally-funded laboratories. Interestingly, the U.S. General Accounting Office (GAO) published a study performed in 1999 that showed a significant number of laboratories were failing to comply with the reporting requirements.[131] The reports from the laboratories were often inaccurate and incomplete.

Since it appears that the law alone is having little impact on the laboratories, a different approach would be to give the public access to the royalty information. Being under public scrutiny could create the impetus to comply with the law. It is easy to envision a scenario where the existence of a license agreement leaks to the news media, but the corresponding royalty information is missing from NIH's database because the laboratory failed to report it. Public awareness that the laboratory is violating the law could cause substantial embarrassment to both the laboratory and the licensee.

VII. INTERESTS OF THE PUBLIC

The purpose of the FOIA is to promote and ensure the democratic process. Emphasis is placed on full disclosure of federal agency records.[132] The drafters of the FOIA hoped that public scrutiny of the activities of federal agencies would prevent special interest groups from capturing those agencies.[133]

The pharmaceutical industry represents a special interest group that has strived to achieve substantial political influence. In the year 2001, the pharmaceutical industry spent \$78.1 million on federal lobbying activities, and employed a total of 623 different individual lobbyists, more than six for every member of the Senate (100) and more than one for every member of the House (435).[134] The pharmaceutical industry also created an organization called PhRMA for the purpose of spreading an anti-price-control message to the public,[135] and filing lawsuits to overturn any price-lowering legislation.[136]

Political pressure from the pharmaceutical industry has forced the NIH to adopt an official policy of no longer requesting that licensees charge consumers reasonable prices.[137] Since the NIH now prefers to avoid getting involved in socio-economic issues,[138] the tasks of determining whether it is technically feasible for the pharmaceutical industry to lower prices, and calling the legislature's attention to the results, have become the responsibility of citizen watchdog groups. *PCHRG* wants to respond to PhRMA's explanation[139] for high prices. But *PCHRG* cannot formulate an intelligent response when the NIH is withholding the evidence supporting PhRMA's premise. The democratic process is being thwarted.

VIII. BALANCING THE INTERESTS

The interests of each party have been presented and critiqued. Now the interests need to be compared in the balancing analysis.

First, the interests of the licensees will be weighed. On one hand, the pharmaceutical industry can be very competitive, because it is lucrative enough to attract many takers. And by threatening to boycott the technology transfer program, the licensees have expressed how serious they believe the competitive harm would be if the royalty information were released to the public. On the other hand, the ability of the licensees to cherry-pick the right technologies, and to use the FDA-approval process to segregate markets, indicate that the licensees have the business savvy to avoid some of the competition. Therefore, upon initial evaluation, the risk of competitive harm to the licensees is medium. But the facts of the *PCHRG* case fit within the “public funds” context; the licensees are the direct benefactors of their relationship with the NIH. There is no reason to maximize the weight on the licensees’ interests, because the operation of the technology transfer program already serves the needs of the licensees. Therefore, the weight on the interests of the licensees should be adjusted downward from medium to low.

Second, the interests of the NIH will be weighed. The NIH did not articulate an independent reason why revealing the royalty information to the public would impair its ability to carry out its statutory mandate. Although the NIH has experienced problems with getting laboratories to comply with the reporting requirements, providing public access to royalty information in the NIH database could actually improve compliance. Therefore, the weight on the interests of the NIH is low.

Third, the balancing analysis presumes the public interest is strong; the mandate of the FOIA is to favor disclosure. *PCHRG* seeks the royalty information to participate more fully in the democratic process.

The combined weight of the licensees’ interests (valued low) and the NIH’s interests (valued low) do not overcome the public interest (valued high). Therefore, the royalty information should not be declared confidential; the public should have access to the information.

IX. CONCLUSION

The technology transfer statutes govern the licensing of technology developed with public funds. The statutes are detailed in length; yet they defer to the Freedom of Information Act (FOIA) to determine when information deserves to be protected from public scrutiny. The case law interpreting the FOIA uses a balancing test. The *PCHRG* Court applied too much weight to the interests of the licensees by failing to place the situation in the appropriate context. And the NIH did not articulate a separate and unique interest. The FOIA disclosure mandate favors release of the royalty information.

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[FN1] *Pub. Citizen Health Research Group v. Nat'l Inst. of Health*, 2002 U.S. Dist. LEXIS 7457, 8 (D.D.C. 2002) (“Plaintiff seeks the withheld information to evaluate whether the government is receiving a reasonable rate of return on the taxpayers' investment in the valuable research done by the NIH. This evaluation is of particular relevance because of the current debate over the pricing of medical products.”).

[FN2] <http://www.citizen.org> (website for Public Citizen).

[FN3] <http://www.citizen.org/hrg> (website for Public Citizen Health Research Group).

[FN4] <http://www.nih.gov> (website for the National Institutes of Health).

[FN5] <http://www.nih.gov/about/almanac/index.html> (“NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.”).

[FN6] National Cancer Institute (NCI), National Eye Institute (NEI), National Heart, Lung, and Blood Institute (NHLBI), National Human Genome Research Institute (NHGRI), National Institute on Aging (NIA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Biomedical Imaging and Bioengineering (NBIB), National Institute of Child Health and Human Development (NICHD), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute on Drug Abuse (NIDA), National Institute of Environmental Health Sciences (NIEHS), National Institute of General Medical Sciences (NIGMS), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Nursing Research (NINR), National Library of Medicine (NLM), Center for Information Technology (CIT), Center for Scientific Review (CSR), John E. Fogarty International Center (FIC), National Center for Complementary and Alternative Medicine (NCCAM), National Center on Minority Health and Health Disparities (NCMHD), National Center for Research Resources (NCRR), and Warren Grant Magnuson Clinical Center (CC).

[FN7] <http://www.nih.gov/news/budgetfy2003/2003NIHpresbudget.htm> (National Institutes of Health, *Press Release for the FY 2003 President's Budget*, February 4, 2002).

[FN8] <http://www.jnj.com/home.html> (website for Johnson & Johnson).

[FN9] http://www.jnj.com/investor/annual_reports/2001/2001_Report.htm (Johnson & Johnson's Annual Report to the Shareholders for the Year 2001).

[FN10] See Gerard O'Neill, *Public Handouts Enrich Drug Makers and Scientists*, THE BOSTON GLOBE, April 5, 1998, at A1; Jeff Gerth & Sheryl Gay Stolberg, *Medicine Merchants: Birth of a Blockbuster; Drug Makers Reap Profits on Tax-Backed Research*, NEW YORK TIMES, April 23, 2000, at 1.

[FN11] See generally Bayh-Dole Act, 35 U.S.C §§ 200-212 (2003); Federal Technology Transfer Act, 15 U.S.C. §§ 3710(a-d)(2003).

[FN12] See <http://www.cptech.org/pharm/pryor.html> (website for Consumer Project on Technology) Ralph Nader & James Love, *Federally Funded Pharmaceutical Inventions*, Testimony before the Special Committee of the United States Senate on the Aging, February 24, 1993.

[FN13] *Id.*

[FN14] See <http://www.citizen.org/hrq> (website for Public Citizen Health Research Group) Public Citizen's Congress Watch, Report Number c9021, *America's Other Drug Problem: A Briefing Book on the Rx Drug Debate*, copyright 2002.

[FN15] See <http://www.phrma.org/publications/publications/profile02/chapter2.pdf> ("The PhRMA Industry Profile - Chapter 2: R&D - The Key to Innovation").

[FN16] See Nader, *supra* note 12, at 2.

[FN17] Pub. Citizen Health Research Group v. Nat'l Inst. of Health, 209 F. Supp 2d. 37, 41 (D.D.C. 2002) ("After having conferred by telephone on October 25, 2000, counsel for both parties agreed that only two categories of information are at issue in this case: 1) the request for NIH revenues from royalties based on NIH inventions, from both intramural and CRADA research, and 2) the request for records concerning the percentage of sales that NIH received as royalties, both for the period of 1986-1998").

[FN18] *Id.* ("On October 26, 2000, after having narrowed the scope of the request for purposes of this case, Defendant formally denied Plaintiff's September 29, 1999, and June 22, 2000, requests under FOIA exemptions 4 and 5").

[FN19] Freedom of Information Act, 5 U.S.C. § 552(a)(4)(B) (2003) ("On complaint, the district court of the United States . . . in the District of Columbia has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such case the court shall determine the matter de novo . . . and the burden is on the agency to sustain its action").

[FN20] See Pub. Citizen Health Research Group, 209 F. Supp 2d. at 49 ("Intervenor-Defendant almost never releases royalty rate and payment information contained in its licensing agreements. . . . The rule, rather than the exception, is that pharmaceutical companies go to great lengths to maintain the confidential and proprietary nature of such

information”); *Id.* at 45, n9 (“The Court notes that Defendant takes confidentiality of this information very seriously because every licensing agreement contains a confidentiality clause”).

[FN21] *Id.* at 54 (“ . . . the Court concludes that the NIH appropriately withheld, pursuant to exemptions 3 and 4 of the Freedom of information Act, the information relating to NIH revenues . . .”).

[FN22] *Id.* at 51 (“while the Court is extremely cognizant of the mandate underlying the Freedom of Information Act for public disclosure, in conducting the balancing of private and public interests, the Court determines that the private interests favoring withholding the information dominate the balancing”); *Id.* at 48 (“The Court concludes that in balancing the public interest in disclosure against the private interest in withholding information, the private interest prevails.”).

[FN23] Before proceeding with an argument that is contrary to the Court’s decision, the author would like to resolve some confusion about the written language of the *PCHRG* case. The author believes there are two sentences that contain serious “typos,” because the meaning of the sentences does not match the Court’s overall viewpoint. Page 38, fourth sentence: “From the overwhelming evidence submitted by Defendant and Intervenor-Defendant, the Court finds as a matter of law that release of the information would **not** pose a substantial competitive harm to the licensees.” Page 49, third sentence: “Based on the record considered in evaluating the private interest in this case, the Court concludes as a matter of law that the strong public interest in disclosure under the Freedom of Information Act **outweighs** the private interest in withholding the information.”

[FN24] Bayh-Dole Act, 35 U.S.C. § 200 (2003) (“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . to promote collaboration between commercial concerns and nonprofit organizations, including universities . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.”).

[FN25] Federal Technology Transfer Act, 15 U.S.C. § 3710a(d)(1) (2003) (“ . . . the term "cooperative research and development agreement" means any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory . . .”).

[FN26] Bayh-Dole Act, 35 U.S.C. § 207(a)(1) (2003) (“Each Federal agency is authorized to apply for, obtain, and maintain patents or other forms of protection in the

United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest.”).

[FN27] Bayh-Dole Act, 35 U.S.C. § 207(a)(2) (2003) (“Each Federal agency is authorized to grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions . . .”); Federal Technology Transfer Act, 15 U.S.C. §3710a(a)(2) (“Each Federal agency may permit the director of any of its Government-operated Federal laboratories . . . to negotiate licensing agreements under 35 U.S.C. §207 . . . for inventions made or other intellectual property developed at the laboratory . . .”).

[FN28] Bayh-Dole Act, 35 U.S.C. §209(f) (2003) (“No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention . . .”).

[FN29] Bayh-Dole Act, 35 U.S.C. § 209(a)(2) (2003) (“A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under §207(a)(2) only if the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant’s intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention’s utilization by the public . . .”).

[FN30] Bayh-Dole Act, 35 U.S.C. § 209(b) (2003) (“A Federal agency shall normally grant a license under §207(a)(2) to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.”).

[FN31] Federal Technology Transfer Act, 15 U.S.C. § 3710c(a)(1) (2003) (“In general . . . any royalties or other payments received by a Federal agency . . . from the licensing of inventions of Federal laboratories under 35 U.S.C §207 or under any other provision of law, shall be retained by the laboratory which produced the invention . . .”).

[FN32] Bayh-Dole Act, 35 U.S.C § 209(e) (2003) (“No exclusive or partially exclusive license may be granted under §207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice . . .”).

[FN33] Bayh-Dole Act, 35 U.S.C. § 209(d)(1) (2003) (“Any licenses granted under § 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions retaining a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States.”).

[FN34] Bayh-Dole Act, 35 U.S.C. § 209(d)(2) (2003) (“Any licenses granted under §207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions: requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with . . .”).

[FN35] Federal Technology Transfer Act, 15 U.S.C. § 3710a(a)(1) (2003) (“Each Federal agency may permit the director of any of its Government-operated Federal laboratories . . . to enter into cooperative research and development agreements on behalf of such agency . . . with . . . industrial organizations . . .”); 15 U.S.C. §3710a(b)(1) (“Under an agreement entered into pursuant to subsection (a)(1) of this section, the laboratory may ... agree to grant in advance to a collaborating party patent . . . assignments . . . in any invention made . . . by a laboratory . . . for reasonable compensation when appropriate.”).

[FN36] Federal Technology Transfer Act, 15 U.S.C. § 3710a(b)(1)(B) (“If a laboratory assigns title or grants an exclusive license to such an invention, the Government shall retain the right - (i) to require the collaborating party to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive license to use the invention in the applicant's licensed field of use, on terms that are reasonable under the circumstances; or (ii) if the collaborating party fails to grant such a license, to grant the license itself.”).

[FN37] Federal Technology Transfer Act, 15 U.S.C. § 3710a(c)(4)(B) (2003) (“The laboratory director in deciding what cooperative research and development agreements to enter into shall ... give preference to business units located in the United States which agree that products embodying inventions made under the cooperative research and development agreement or produced through the use of such inventions will be manufactured substantially in the United States . . .”).

[FN38] Federal Technology Transfer Act, 15 U.S.C. § 3710a(b)(1)(A) (2003) (“In consideration for the Government's contribution under the agreement, grants under this paragraph shall be subject to the following explicit conditions: A nonexclusive, nontransferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.”).

[FN39] Federal Technology Transfer Act, 15 U.S.C. § 3710c(a)(1) (2003) (“In general ... any royalties or other payments received by a Federal agency from the licensing and assignment of inventions under agreements entered into by Federal laboratories under 15 U.S.C. § 3710a . . . shall be retained by the laboratory which produced the invention ...”).

[FN40] Bayh-Dole Act, 35 U.S.C § 209(e) (2003) (“This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under 15 U.S.C. § 3710a”).

[FN41] Bayh-Dole Act, 35 U.S.C. § 202(a) (2003) (“Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention . . .”); 37 C.F.R. § 401.14 (f)(4) (“The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, ‘This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.’”).

[FN42] Bayh-Dole Act, 35 U.S.C. § 203(a) (2003) (“With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself . . .”).

[FN43] Bayh-Dole Act, 35 U.S.C. § 204 (2003) (“Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.”).

[FN44] Bayh-Dole Act, 35 U.S.C. § 202(c)(5) (2003) (“Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following: [t]he right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees . . .”).

[FN45] Bayh-Dole Act, 35 U.S.C. § 202(c)(4) (2003) (“Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following: [w]ith respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world . . .”).

[FN46] Bayh-Dole Act, 35 U.S.C. § 202(c)(7)(C) (2003) (“Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following: In the case of a nonprofit organization . . . a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions . . . be utilized for the support of scientific research or education . . .”).

[FN47] Bayh-Dole Act, 35 U.S.C. § 207(a)(2) (2003) (“Each federal agency is authorized to grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration . . .”) (emphasis added).

[FN48] See Rex Rhein, *NIH Makes Royalties, Not Price Major Factor in Issuing CRADAs*, FEDERAL TECHNOLOGY REPORT, April 27, 1995, at 11 (“After six years of vainly trying to convince companies to sign cooperative R&D agreements and exclusive licenses containing a controversial pricing clause, the National Institutes of Health threw in the towel and threw out the clause. From now on, the major factor in negotiating CRADAs will be royalties.”).

[FN49] Department of Commerce Regulations, 37 C.F.R. § 401.14(c)(1) (2003) (“The contractor will disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention.”).

[FN50] Department of Commerce Regulations, 37 C.F.R. § 401.14(h) (2003) (“The Contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify . . .”).

[FN51] <http://www.iedison.gov> (website for Interagency Edison database); <http://www.gao.gov> (website for the U.S. General Accounting Office) Report Number RCED-99-242, *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision*, page 14 (“NIH in October 1995 deployed Edison, an on-line computer system for reporting inventions. Edison uses the Internet to (1) allow the organizations NIH funds to enter data, including the required reports and notifications, in the system and (2) give NIH the ability to review and analyze the activity on any particular invention at any time”).

[FN52] Department of Commerce Regulations, 37 C.F.R. § 401.14(h) (2003) (“...As required by 35 U.S.C. §202(c)(5), the agency agrees it will not disclose such information to persons outside the government without permission of the contractor.”).

[FN53] Richard Axel, *The Isolation and Transfer of Specific Genes*, CRISP Database, NIH Grant Number: P01CA023767, (1978-1983), at [http:// www-commons.cit.nih.gov/crisp](http://www-commons.cit.nih.gov/crisp).

[FN54] Richard Axel, *Processes for Inserting DNA into Eucaryotic Cells for Producing Proteinaceous Materials*, Patent Database, Patent Number: 4399216, (1983), at <http://www.uspto.gov/patft/index.html>.

[FN55] See Anthony Shadid, *A US Share of Royalties on Research is Opposed: NIH Report Warns of Focus on Profit*, THE BOSTON GLOBE, August 22, 2001, at A1; Lisa Seachrist, *Washington Roundup: Columbia Patent Provision Still Alive in AG Appropriation Bill*, BIOWORLD TODAY, July 10, 2000.

[FN56] See Joseph Brown, *Like no other*, MED AD NEWS, September 1, 2000, at 148.

[FN57] See <http://www.jnj.com> (website for Johnson & Johnson).

[FN58] See <http://www.orthobiotech.com/products/procrit.html>.

[FN59] <http://www.jnj.com/investor/presentations/presentations.pdf> (Johnson & Johnson's Annual Report to the Shareholders) (sales of Procrit®/Eprex® accounted for 10.4% of total company revenues in the year 2001).

[FN60] See <http://www.rxusa.com/cgi-bin/db/db.cgi> (this is an online pharmacy that provides a current price list).

[FN61] Roland Robins, *Inhibitors of ADP-Ribosylation as Antitumor Agents*, CRISP Database, NIH Grant Number: R01CA034384, (1983-1986), at <http://www-commons.cit.nih.gov/crisp>.

[FN62] Roland Robins, *Method for the Production of 2'-Deoxyadenosine Compounds*, Patent Database, Patent Number: 4760137, (1988), at <http://www.uspto.gov/patft/index.html>.

[FN63] See Kristen Grough, *Office Helps Market Professors' Creations*, BYU MAGAZINE, Summer 1997 at <http://magazine.byu.edu>; *BYU Honors 4 Faculty Researchers*, THE DESERET NEWS (Salt Lake City, UT), October 21, 1996, at 3.

[FN64] Ernest Beutler, *General Clinical Research Center*, CRISP Database, NIH Grant Number: M01RR000833, (1977-1995), at <http://www-commons.cit.nih.gov>; Ernest Beutler, *Chlorodeoxyadenosine Therapy for Human Hematopoietic Malignancies*, NIH grant number: 5M01RR000833-150089, (1988-1989); Mika Ono Benedyk, *Of Drugs and Diseases: GCRC Provides Site for Clinical Studies*, THE SCRIPPS RESEARCH INSTITUTE NEWS & VIEWS, Volume 1, Issue 11, April 16, 2001, at <http://www.scripps.edu/newsandviews>.

[FN65] See <http://www.orthobiotech.com/products/leustatin.html>.

[FN66] See <http://www.rxusa.com/> (this is an online pharmacy that provides a current price list).

[FN67] Barry Coller, *Biochemistry and Physiology of Platelet Membrane Receptors*, CRISP Database, NIH Grant Number: R01HL019278, (1976-1989), at <http://www-commons.cit.nih.gov/crisp>.

[FN68] Barry Coller, *Method of Inhibiting Thrombus Formation by the 7E3 Monoclonal Antibody*, Patent Database, Patent Number: 5387413, (1995), at <http://www.uspto.gov/patft/index.html>.

[FN69] See Gerard O'Neill, *Public Handouts Enrich Drug Makers and Scientists*, THE BOSTON GLOBE, April 5, 1998, at A1.

[FN70] See <http://www.jnj.com> (website for Johnson & Johnson).

[FN71] See http://www.centocor.com/cgi-bin/site/products/prod_reopro.cgi (last visited Feb. 08, 2003).

[FN72] See Tim Searle, *New Therapies for Cardiovascular Disease: Getting to the Heart of the Matter*, BIOVENTURE VIEW, November 1, 2000, at 8.

[FN73] See <http://www.rxusa.com/> (this is an online pharmacy that provides a current price list).

[FN74] Junming Le, *Synthesis & Roles of TNF & IL-6 in T-Cell Activation*, CRISP Database, NIH Grant Number: R01AI028993, (1990-1995) at <http://www-commons.cit.nih.gov/crisp>.

[FN75] Junming Le, *Methods of Treating TNF-alpha-mediated Crohn's Disease using Chimeric anti-TNF Antibodies*, Patent Database, Patent Number: 5656272, (1997), at <http://www.uspto.gov/patft/index.html> (last modified Jan. 17, 2003); Junming Le, *Methods of Treating Rheumatoid Arthritis using Chimeric anti-TNF Antibodies*, Patent number: 5698195, (1997), at <http://www.uspto.gov/patft/index.html> (last modified Jan. 17, 2003).

[FN76] See http://www.centocor.com/cgi-bin/site/products/prod_remicade.cgi (last visited Feb. 08, 2003).

[FN77] See Amy Barrett, *Johnson & Johnson: A Shopping Spree Waiting to Happen*, BUSINESS WEEK, June 17, 2002, at 58.

[FN78] See <http://www.rxusa.com/> (this is an online pharmacy that provides a current price list).

[FN79] Freedom of Information Act, 5 U.S.C. § 552(a)(3)(A) (2003) (“...each agency, upon any request for records, ... shall make the records promptly available to any person”).

[FN80] Freedom of Information Act, 5 U.S.C. § 552(b)(4) (2003) (“This section does not apply to matters that are trade secrets and commercial or financial information obtained from a person and privileged or confidential”).

[FN81] Bayh-Dole Act, 35 U.S.C. § 209(f) (2003) (“No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention, except that any such plan shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under 5 U.S.C. § 552”); Bayh-Dole Act, 35 U.S.C. § 209(d)(2) (“Any licenses granted under § 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions: requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with, except that any such report shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under 5 U.S.C. § 552.”).

[FN82] Federal Technology Transfer Act, 15 U.S.C. § 3710a(c)(7)(A) (2003) (“No trade secrets or commercial or financial information that is privileged or confidential, under the meaning of 5 U.S.C. § 552(b)(4), which is obtained in the conduct of research or as a result of activities under this chapter from a non-Federal party participating in a cooperative research and development agreement shall be disclosed”); Federal Technology Transfer Act, 15 U.S.C. § 3710a(c)(7)(B) (“The director, or in the case of a contractor-operated laboratory, the agency, for a period of up to 5 years after development of information that results from research and development activities conducted under this chapter and that would be a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party participating in a cooperative research and development agreement, may provide appropriate protections against the dissemination of such information, including exemption from subchapter II of chapter 5 of title 5 [5 U.S.C. §§ 551-559]”); Federal Technology Transfer Act, 15 U.S.C.

§ 3710a(b)(1)(A) (“In consideration for the Government's contribution under the agreement, grants under this paragraph shall be subject to the following explicit conditions: A nonexclusive, nontransferable, irrevocable, paid-up license from the collaborating party to the laboratory to practice the invention or have the invention practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. § 552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party.”).

[FN83] Bayh-Dole Act, 35 U.S.C. § 202(c)(5) (2003) (“The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: Provided, That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under § 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under 5 U.S.C. § 552.”).

[FN84] Pub. Citizen Health Research Group v. Nat’l Inst. of Health, 209 F. Supp 2d. 37, 43 (D.D.C. 2002) (“Thus, the sole issue left for adjudication is whether the agency may prevent the release of the information by citing exemption 4 of FOIA, 5 U.S.C. § 552(b)(4)”).

[FN85] *Id.*, (“Here, neither party contends that the requested information is a trade secret and thus the Court must look to the second kind of information protected under exemption 4.”).

[FN86] *Id.*, (“[I]t is undisputed that the information that Plaintiff wishes to obtain is commercial or financial information. The terms ‘commercial’ and ‘financial’ should be given their ordinary meaning . . .”).

[FN87] *Id.* at 44 (“Plaintiff contends that the requested information was not obtained from outside the government since the royalty rate is negotiated between the licensee and the government.”).

[FN88] *Id.* at 44-45 (“If the licensee wishes to become involved with a certain technology, it must submit proposed royalty information. If it fails to submit any information it cannot license the technology. While the final royalty rates may reflect negotiation between the agency and the licensee, the licensee still must provide the information in the first instance.”).

[FN89] *Id.* at 44 (“Even though the final royalty rate is arrived at through negotiation, this does not alter the fact that the licensee is the ultimate source of this information.”).

[FN90] Department of Commerce Regulations, 37 C.F.R. § 401.14(h) (2003) (“The Contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify . . .”).

[FN91] Pub. Citizen Health Research Group, 209 F. Supp 2d. at 45 n.5 (“Defendant also argues that the information was privileged. However, because the Court finds the withheld information to be confidential, it need not reach the question of whether the information is also privileged.”).

[FN92] *Id.*, (“Thus, as Plaintiff noted in its original motion, the only issue for resolution by this Court is whether the material is confidential within the meaning of exemption 4.”).

[FN93] *See generally* Robert B. Kelso, *A Practitioner's Guide to "Confidential Commercial and Financial Information" and the Freedom of Information Act*, 1990 ARMY LAW. 10; Lawrence Kaplan, *What Constitutes "Trade Secrets And Commercial Or Financial Information Obtained From A Person And Privileged Or Confidential" Exempt From Disclosure Under Freedom of Information Act*, 139 A.L.R. FED. 225 (1997).

[FN94] *Vaughn v. Rosen*, 484 F.2d 820, 823 (D.C. Cir. 1973) (“The Freedom of Information Act was conceived in an effort to permit access by the citizenry to most forms of government records. In essence, the Act provides that all documents are available to the public unless specifically exempted by the Act itself. This court has repeatedly stated that these exemptions from disclosure must be construed narrowly, in such a way as to provide the maximum access consonant with the overall purpose of the Act.”).

[FN95] *Petkas v. Staats*, 501 F.2d 887, 889 (D.C. Cir. 1974) (“Nor can a promise of confidentiality in and of itself defeat the right of disclosure”); *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1287 (D.C.Cir. 1983) (“But Congress has made clear both that the federal courts, and not the administrative agencies, are ultimately responsible for construing the language of the FOIA, see 5 U.S.C. § 552(a)(4)(B) (1976), and that agencies cannot alter the dictates of the Act by their own express or implied promises of confidentiality.”).

[FN96] *Pub. Citizen Health Research Group v. Nat'l Inst. of Health*, 209 F. Supp 2d. 37, 45 (D.D.C. 2002) (“[O]ur circuit has reaffirmed the central role a rough balancing must play between the private and public interests when considering a withholding under exemption 4. . . . The Court is therefore charged with balancing the public interest in disclosure against the private interest in withholding the information”); *GC Micro Corp. v. Defense Logistics Agency*, 33 F.3d 1109, 1115 (9th Cir. 1994) (“We agree with the D.C. Circuit that, in making our determination, we must balance the strong public interest in favor of disclosure against the right of private businesses to protect sensitive information.”).

[FN97] *Washington Post Co. v. Dep't. of Health and Human Services*, 865 F.2d 320, 325 (D.C. Cir. 1989) (“When we refer to a ‘rough balancing’ under exemption 4, we mean that information will be withheld only when the affirmative interests in disclosure on the one side are outweighed by the factors identified in *National Parks I* (and its progeny) militating against disclosure on the other side. More simply put, minor disadvantages flowing from disclosure ‘cannot overcome the disclosure mandate of FOIA.’”).

[FN98] *McDonnell Douglas Corp. v. NASA*, 895 F. Supp. 319, 326 (D.D.C. 1995) (pricing information submitted in response to NASA's Request for Proposals ("RFP") in a

competitive bidding situation was "required" and mandatory; its omission would result in the disqualification of the bidder from the competition); *Lykes Bros. Steamship Co. v. Pena*, 1993 U.S. Dist. LEXIS 20279, *11 (D.D.C. 1993); *Chemical Waste Mgmt. v. O'Leary*, 1995 U.S. Dist. LEXIS 2586, *8 (D.D.C. 1995) (bid "would not have won plaintiff the subcontract" without the pricing data. Plaintiff "had no choice but to submit the unit price information once it chose to submit its proposal."); *Pub. Citizen Health Research Group v. FDA*, 964 F. Supp. 414 n.1 (D.D.C. 1997) (drug manufacturer's submission of protocol for post-marketing study of drug was necessary in order to obtain FDA approval to market, and therefore "required" under National Parks analysis).

[FN99] *Pub. Citizen Health Research Group*, 209 F. Supp 2d. at 45 ("In this case, the parties have proceeded under the assumption that the information in question was, in fact, required to be submitted and the Court agrees.").

[FN100] *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 767 (D.C. Cir. 1974) ("Unless persons having necessary information can be assured that it will remain confidential, they may decline to cooperate with officials and the ability of the Government to make intelligent, well informed decisions will be impaired"); *Id.* at 770 ("[C]ommercial or financial matter is confidential for purposes of the exemption if disclosure of the information is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future . . .").

[FN101] *Judicial Watch, Inc. v. Export-Import Bank*, 108 F. Supp 2d. 19, 30 (D.D.C. 2000) ("This Court has held that impairment of an agency's ability to carry out its statutory purpose is sufficient cause to justify a finding of confidentiality within the context of Exemption 4.") (internal citations omitted).

[FN102] *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878 (D.C. Cir. 1992) ("[W]hen information is obtained under duress, the Government's interest is in ensuring its continued **reliability**; when that information is volunteered, the Government's interest is in ensuring its continued **availability**." (emphasis added)).

[FN103] *Id.* at 879 ("[W]e conclude that financial or commercial information provided to the Government on a voluntary basis is confidential for the purpose of Exemption 4, if it is of a kind that would customarily not be released to the public by the person from whom it was obtained . . . [The test] is objective... [T]he agency invoking Exemption 4 must meet the burden of proving the provider's custom.").

[FN104] *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974) ("[C]ommercial or financial matter is confidential for purposes of the exemption if disclosure of the information is likely to have either of the following effects . . . (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.").

[FN105] *Gulf & Western Indus., Inc. v. United States*, 615 F.2d 527, 530 (D.C. Cir. 1979) ("In order to show the likelihood of substantial competitive harm, it is not necessary to

show actual competitive harm. Actual competition and the likelihood of substantial competitive injury is all that need be shown.”).

[FN106] *Pub. Citizen Health Research Group*, 209 F. Supp 2d. at 47 (“In this case, there is evidence that the licensees face actual competition. . . . The evidence reveals that the licensees are engaged in actual competition such that if the proprietary information was released it could be used by the licensees’ competitors to their advantage. The pharmaceutical industry is a highly competitive market where companies routinely attempt to discover a possible advantage over their competitors. Thus, in this case the Court determines that the licensees face actual competition.”) (internal citations omitted).

[FN107] *Id.* at 54 (“[F]or most technologies the market operates with only one interested participant. The vast majority of NIH inventions require active marketing by the OTT and it is often the case that the OTT has but one firm interested in licensing a specific technology. In fact in Fiscal Year 2000, forty-five applications for exclusive licenses were received. Of these forty-five applications, only two technologies had two applications each. Thus, forty-one of the applications had no competition. Furthermore, in applications for nonexclusive licenses, Defendant received two hundred fifty-three applications; only thirty-one of which had more than one application.”) (internal citations omitted).

[FN108] *Id.* at 41 (“Defendant argues that the release of this information would substantially impair the competitive position of the licensees.”).

[FN109] *Id.* at 47 (“With the exception of royalty rates, the other fixed costs and competitive market conditions involving a product can generally be predicted with significant accuracy by companies in the pharmaceutical industry.”).

[FN110] *Id.* (“Royalty rates are also one of the truly unknown factors in the cost structure. . . . If this information is disclosed, J&J’s cost structures and profit margins for products that are the subject of its NIH licensing agreements would be known with much greater precision, and other companies would be able to undermine J&J’s efforts to market such products.”).

[FN111] *Id.* at 49-50 (“[T]he Court notes that if a competitor realized information about how much a licensee was paying for a royalty, it would immediately know the value the firm placed on that particular technology. This knowledge, in turn, would certainly help competitors know which technologies and which areas of the market the licensee found particularly fruitful.”).

[FN112] *Id.* at 46 (“First, the licensees would be placed at a substantial competitive disadvantage if the information was released. . . . The Court concludes that Defendant has shown that release of the information at issue in this case would likely cause substantial competitive harm to the licensees.”); *Id.* at 26 (“Based on the evidence in the record, the Court also concludes that there is a likelihood that the licensees would face substantial competitive harm”); *Id.* at 36-37 (“As the Court in *Gulf Western* noted, the test is

whether the withheld information would likely cause substantial competitive harm. As amply demonstrated above, the competitive harm to the licensees has been clearly demonstrated.”); *Id.* at 38 (“Simply put, the Court finds that there is actual competition present and that there is the substantial likelihood of competitive harm if the withheld information was to be released.”); *Id.* at 39 (“The licensees would likely suffer substantial competitive harm if this information was released.”).

[FN113] See Anthony Shadid, *A US Share of Royalties on Research is Opposed: NIH Report Warns of Focus on Profit*, THE BOSTON GLOBE, August 22, 2001, at A1; Lisa Seachrist, *Washington Roundup: Columbia Patent Provision Still Alive in AG Appropriation Bill*, BIOWORLD TODAY, July 10, 2000; Joseph Brown, *Like no other; Johnson and Johnson; Statistical Data Included*, MED AD NEWS, September 1, 2000, at 148.

[FN114] See <http://www.amgen.com/product/AboutEpogen.html>.

[FN115] See <http://www.orthobiotech.com/products/procrit.html>.

[FN116] *Pub. Citizen Health Research Group*, 209 F. Supp. at 57 (“While the Court is extremely cognizant of the mandate underlying the Freedom of Information Act for public disclosure, in conducting the balancing of private and public interests, the Court determines that the private interests favoring withholding the information dominate the balancing. The licensees would likely suffer substantial competitive harm if this information was released. . . . While the Court conceivably could stop the analysis at this point and grant Defendant and Intervenor-Defendant's motions, it nevertheless analyzes the remaining basis cited by Defendant for withholding the information in the interest of thoroughness.”).

[FN117] See 49 U.S.C. § 14123 (2003).

[FN118] See 19 U.S.C. § 1485 (2003).

[FN119] See generally *Honeywell Information Systems v. NASA*, 1976 U.S. Dist. LEXIS 15894 (D.C. Cir. 1976); *Audio Technical Services v. Dep't. of Army*, 487 F. Supp. 779 (D.C. Cir. 1979); *Gulf & W. Indus. v. United States*, 1979 U.S. App. LEXIS 10667 (D.C. Cir. 1980); *Shermo Indust. v. Secretary of United States Air Force*, 613 F.2d 1314 (5th Cir. 1980); *BDM Corp. v. SBA*, 1981 U.S. Dist. LEXIS 18610 (D.C. Cir. 1981); *Fidell v. USCG*, 1981 U.S. Dist. LEXIS 18429 (D.D.C. 1981); *Professional Review Organization v. US Dept of Health & Human Services*, 607 F. Supp. 423 (D.C.Cir. 1985); *AT&T Information-Systems v. General Services Admin.*, 810 F.2d 1233 (D.C. Cir. 1987); *Raytheon Co. v. Dep't. of Navy*, 1989 U.S. Dist. LEXIS 18281 (D.C. Cir.. 1989); *Environmental Technology v. US EPA*, 822 F. Supp. 1226 (E.D. Va. 1993); *Mallinckrodt v. West*, 140 F. Supp 2d. 1 (D.C. Cir. 2000); *MCI Worldcom v. GSA*, 163 F. Supp 2d. 28 (D.C. Cir. 2001).

[FN120] *Miami Herald Pub. Co. v. U.S. Small Bus. Admin.*, 670 F.2d 610 (5th Cir. 1982); *Buffalo Evening News, Inc. v. Small Business Admin.*, 666 F. Supp. 467 (W.D.N.Y. 1987).

[FN121] *Sharyland Water Supply Corp. v. Block*, 755 F.2d 397, 398 (5th Cir. 1985).

[FN122] *Westchester Gen. Hosp. v. Dept. of Health, Educ. & Welfare*, 464 F. Supp. 236 (M.D. Fla. 1979); *St. Mary's Hosp. v. Harris*, 604 F.2d 407 (5th Cir. 1979); *Humana of Virginia, Inc. v. Blue Cross of Virginia*, 622 F.2d 76 (4th Cir. 1980); *South Hills Health System v. Bowen*, 864 F.2d 1084 (3d Cir. 1988).

[FN123] *Ctr. for Pub. Integrity v. U.S. Dept. of Energy*, 191 F. Supp 2d. 187 (D.D.C. 2002).

[FN124] *Nat'l Parks & Conservation Ass'n v. Kleppe*, 547 F.2d 673 (D.C. Cir. 1976).

[FN125] *Merit Energy Co. v. U.S. Dep't. of Interior*, 180 F. Supp 2d. 1184 (D. Colo. 2001).

[FN126] *Pub. Citizen Health Research Group v. Nat'l Inst. of Health*, 209 F. Supp 2d. 37, 53 n.8 (D.D.C. 2002) (“Scores of licensees have already stated they would be much less willing to work with the NIH if royalty information was disclosed. This, in and of itself, is sufficient for the Court to find that Defendant's effective management of the license program would be impaired if the royalty information was released”); *Id.* at 48 (“As a result, the Court concludes that there will be a diminution in the number of firms willing to engage in partnership with Defendant to license new technologies. . . . In this case, the agency has substantially demonstrated that the effectiveness of the licensing program would be critically impaired if the royalty information was released.”).

[FN127] *Id.* at 53-54 (“Additionally, Intervenor-Defendant notes that such disclosure would chill all future dealings between J&J and the NIH. Intervenor-Defendant contends that having the royalty and revenue information disclosed would essentially defeat the commercial goals of J&J and its affiliates. Thus, the Court determines that the licensees would not wish to partner with Defendant and therefore the agency would have significant difficulty fulfilling its statutory mandate.”).

[FN128] *Id.* at 51 (“[D]efendant argues that the licensing program's effectiveness would be diminished if the information was released. Essentially, Defendant contends that its ability to fulfill its statutory mandate under the Bayh-Dole Act would be seriously deterred by the release of the royalty information to Plaintiff”); *Id.* at 45 (“The Court, therefore, agrees with Defendant's observation that if the government were compelled to disclose the information in dispute in this case, ‘it would seriously impair OTT in carrying out its public health responsibilities, since NIH would cease to be an attractive or viable licensor of patented technology’ (*citing* Freire Decl. P. 24) (‘licensees will not negotiate with NIH without an expectation that the financial terms of the licenses will

remain confidential.’). Such a result obviously would hinder the agency in fulfilling its statutory mandate.”).

[FN129] *Id.* at 54 (“[I]n fact in Fiscal Year 2000, forty-five applications for exclusive licenses were received. . . . Furthermore, in applications for nonexclusive licenses, Defendant received two hundred fifty-three applications Currently, OTT has approximately two-thousand technologies available for licensing”) (internal citations omitted).

[FN130] *Id.* at 46 (“Second, disclosure of the royalty information would impair the efficient and effective performance of Defendant’s licensing program”); *Id.* at 52 (“The Court finds that if the royalty information were disclosed, the effectiveness of Defendant’s licensing program would be impaired.”).

[FN131] <http://www.gao.gov> (website for the U.S. General Accounting Office) Report Number RCED-99-242, *Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision*, page 2 (“Federal agencies and their contractors and grantees are not complying with provisions on the disclosure, reporting, retention, and licensing of federally sponsored inventions under the regulations implementing the Bayh-Dole Act and Executive Order 12591. In our review of more than 2,000 patents issued in calendar year 1997 as well as an Inspector General’s draft report on 12 large grantees of the National Institutes of Health, we found that the databases for recording the government’s royalty-free licenses are inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all”); *Id.* at 12 (“In July 1999, the Inspector General submitted a draft report to NIH on the most recent review and concluded that compliance with Bayh-Dole requirements remained insufficient.”).

[FN132] *EPA v. Mink*, 410 U.S. 73, 80 (1973) (“Without question, the Act is broadly conceived. It seeks to permit access to official information long shielded unnecessarily from public view and attempts to create a judicially enforceable public right to secure such information from possibly unwilling official hands. . . . As the Senate Committee explained, it was not an easy task to balance the opposing interests, but it is not an impossible one either. . . . Success lies in providing a workable formula which encompasses, balances, and protects all interests, yet places emphasis on the fullest responsible disclosure.”).

[FN133] *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978) (“The basic purpose of FOIA is to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed.”).

[FN134] <http://www.citizen.org/hrg> (website for Public Citizen Health Research Group) Public Citizen’s Congress Watch, Report Number c9021, *America’s Other Drug Problem: A Briefing Book on the Rx Drug Debate*, copyright 2002, page 65.

[FN135] <http://www.phrma.org> (The Pharmaceutical Research and Manufacturers of America, known as PhRMA, posts its political viewpoints on this website).

[FN136] *See* PhRMA v. Concannon, 249 F.3d 66 (1st Cir. 2001); *PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001).

[FN137] Baruch Brody, *Public Goods and Fair Prices: Balancing Technological Innovation with Social Well-Being*, 26 Hastings Center Report 5 (1996) (“[T]he announcement on 11 April 1995 by Harold Varmus, the director of the National Institutes of Health, that the NIH would no longer insist on a "reasonable pricing clause" in Cooperative Research and Development Agreements and in Exclusive license Agreements between industry and government in the process of technology transfer.”).

[FN138] Rex Rhein, *NIH Makes Royalties, Not Price Major Factor in Issuing CRADAs*, Federal Technology Report, April 27, 1995, at 11 (“[B]oth Varmus and his immediate predecessor, Bernadine Healy, had consistently maintained that NIH should not have to administer an economic policy since its primary role was to further biomedical research.”).

[FN139] *See* <http://www.phrma.org/publications/publications/profile01/index.phtml> (“The PhRMA Industry Profile - Chapter 2: R&D - The Key to Innovation”).