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Response of The Regents of the University of California and Vysis, Inc., to Ventana Medical Systems' Petition to The Honorable Bill Richardson Secretary of Energy

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INTRODUCTION AND BACKGROUND

Ventana's petition concerns an invention made by two University of California scientists, Drs. Joe Gray and Dan Pinkel, in the mid-1980s at the Lawrence Livermore National Laboratory ("LLNL"). The invention was a fundamental breakthrough in the use of the biotechnology technique fluorescence in situ hybridization, or "FISH."[1]

FISH uses fluorescently-labeled probes to study or identify abnormalities in intact genes and chromosomes such as missing, extra or abnormally arranged genes and chromosomes. These abnormalities are frequently indicators of cancer, inborn genetic disorders, radiation damage, or other diseases. In FISH, nucleic acid probes labeled with colored fluorescent markers anneal to a specific target DNA in the chromosome to "light up" a particular chromosomal abnormality of interest, allowing relatively rapid and simple investigation through microscopic examination or with automated equipment. Examples of FISH photographs are included in the Vysis 1999-2000 Product Catalogue. Bishop Declaration Ex. B.

Critical to the successful use of FISH in most applications is preventing undesired signals (noise) caused by annealing of probes to non-target sections of the chromosome, particularly repeat sequences scattered throughout the genome. Prior to Drs. Gray and Pinkel's invention, the usefulness of FISH for unique targets was enormously limited by the inability to distinguish the signal generated by probes annealing to the target from background noise. Specifically, before Drs. Gray and Pinkel's invention, FISH could not be used to investigate genes and other unique portions of chromosomes.

After Drs. Gray and Pinkel successfully demonstrated in a laboratory setting that their invention indeed could enable the use of FISH to investigate genes and other unique portions of chromosomes, they published their work, including in the prestigious *Proceedings of*

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[1] The invention also is used in a similar technique that employs non-fluorescent probes. In those instances the technique is denominated "ISH."

the National Academy of Sciences (Gray Declaration Ex. A), and spoke about it at scientific conferences, thereby making their invention available for others to use. A list of some of their publications relating to their invention is attached to Dr. Gray's declaration as Exhibit B. In due course a patent, United States Patent No. 5,447,841, "Methods for Chromosome-Specific Staining," was issued encompassing the invention. The importance of Drs. Gray and Pinkel's work has been noted in the popular press (*see, e.g.*, Gray Declaration Ex. C, a videotape of news broadcasts describing the invention) and by the Department of Energy, which awarded Dr. Gray an Exceptional Service Award to recognize his work on this invention. Gray Declaration ¶ 5 and Ex. D.

After Drs. Gray and Pinkel successfully reduced their invention to practice, enormous effort and money were required to turn their laboratory technique into a commercial product. The promising, but nascent, nature of the original invention is captured in the reaction of a 1986 grant review committee of the United States National Institutes Of Health, composed of several distinguished experts in the field from research institutions throughout the country:

> Whole chromosome (FISH) and the proposed regional staining is highly innovative and presumably will be much more difficult to accomplish in practice than described, but has a high probability of resulting in important new techniques designed for specific uses, regions and genes.

Gray Declaration Ex. E at 3.

The risks of commercializing this invention are concretely evidenced by the failure of Becton Dickinson, which had the exclusive license to Drs. Gray and Pinkel's invention for prenatal testing between 1987 and 1994. Becton Dickinson provided over $650,000 in research funds, license fees, and equipment to the University and conducted a seven-year internal development effort, but nevertheless failed to commercialize any product. Voelker Declaration ¶¶ 7-25. While Vysis later succeeded, after investing tens of millions of dollars, that outcome was far from certain. *See* Ordover Report ¶¶ 48-49.

To move from Drs. Gray and Pinkel's "highly innovative" laboratory success to the anticipated "difficult to accomplish" commercial development, the University of California petitioned the Department of Energy, under then-existing law, to obtain ownership of the invention. In doing so, as detailed below, the University made no secret of its belief that commercial success would depend upon finding a commercial entity willing to *exclusively* license the technology and, in reliance upon those exclusive rights, make an anticipated large investment to develop the invention. Nor did the University make any secret of the intended scope of the patent it intended to seek to protect the invention. Among other things, copies of the patent applications were supplied to the Department.

The Department of Energy granted the University's request that it be permitted to license the technology, and the University commenced what proved to be a difficult, multi-year effort to find an entity willing to take the risk and make the investment necessary to commercialize the invention. This effort, detailed in the accompanying declarations of Candace L. Voelker and Joe W. Gray, included attempts to license the invention to small businesses, specifically including Ventana's predecessor Oncor; a failed attempt to exclusively license the invention to multiple companies which would exploit the invention in different fields; and careful consideration of the appropriateness of licensing a company that would continue to fund Drs. Gray and Pinkel's continuing research at LLNL and, after the relocation of their laboratory, other University facilities.

The result of the University's diligence is a model of successful transfer of government technology to the commercial sector. Drs. Gray and Pinkel's invention today is practiced in laboratories throughout the world pursuant to a royalty free sublicense that Vysis makes available for researchers making their own probes, and by laboratories using Vysis' products. Bishop Declaration ¶¶ 5, 6, 9 and 12 and Exs. B, C, H, I and J. More than ten thousand articles in scientific publications report the results of this FISH research from these laboratories. Schoonmaker Declaration Ex. A. Based upon an investment of over [redacted]

dollars in private money, a new business entity, Vysis, focuses on commercializing the patented technology. Bishop Declaration ¶ 3. In a February 1998 initial public offering ("IPO"), Vysis was spun off by Amoco (which then made clear it intended to provide no further services, support or funding to Vysis; Bishop Declaration Ex. A at 67), raised $36 million public investors' dollars, and now is publicly traded on the Nasdaq stock exchange. Bishop Declaration ¶ 2. Since that time Vysis has maintained a separate existence, operating out of it Downers Grove, Illinois, facility, and now employing about 175 people. *Id.* ¶ 2.

The patented FISH technology is a cornerstone of the Vysis product line. *Id.* ¶ 3. Vysis offers five FDA approved or cleared FISH products to detect cancer and genetic diseases and to provide genetic information regarding disease prognosis and predisposition. *Id.* ¶ 4. Vysis has ongoing or planned clinical trials to obtain FDA approval to offer another half dozen clinical products. *Id.* ¶ 4. Vysis also offers 190 additional products available for use by clinical laboratories under the FDA's Analyte Specific Reagents ("ASR") regulations (21 C.F.R. § 809.30), and about 300 products to researchers. Bishop Declaration ¶ 5. Vysis, like its corporate predecessor, continues to fund research by Drs. Gray and Pinkel, with total payments to date of [redacted] and another [redacted] illion committed through 2002. *Id.* ¶ 8. Finally, Vysis has made clear its willingness to license the invention to other commercial entities, by publishing an offer to do so in its Product Catalogue (the most recent version of which is Bishop Declaration Ex. B at 9), by licensing it to Ventana's predecessor and the University of Chicago, and by offering a license to Ventana on commercially reasonable terms. Bishop Declaration ¶¶ 6-7 and 10-11.

Ventana nevertheless asks the Department of Energy to take the unprecedented step of dictating the terms on which Ventana will receive a license, rather than requiring Ventana to negotiate the terms for a license with the University and its licensee. Ventana argues this unprecedented action is appropriate because, after purchasing certain Oncor assets that had been seized by Oncor's creditors, Ventana was not able to negotiate terms it prefers for a sublicense.

Ventana alleges the Department of Energy can grant its request because: (1) the University's license is being "exploited in an anti-competitive manner," (2) the University has not taken effective steps necessary to accomplish substantial utilization of the invention, (3) the University told material lies to the Department of Energy in obtaining the rights to the technology; and (4) the University failed to attempt to license the technology to small businesses.

Ventana is correct that its negotiations with Vysis have not resulted in an agreement. Although Ventana claims to have purchased Oncor's agreement with Vysis from Oncor's creditors, Ventana says the terms in that agreement are not acceptable to it. When informed of this, Vysis sought to negotiate with Ventana on different terms. These negotiations were continuing when Ventana filed its petition, and Vysis was awaiting a response from Ventana to Vysis' most recent counteroffer. Since Ventana filed its petition, Ventana stopped negotiating with Vysis. Bishop Declaration ¶ 7 and Exs. D-G.

Apart from its assertion that the parties' negotiations failed to reach an agreement, the remaining claims of Ventana's petition are each wrong. The reasons are discussed in detail in the following sections, and evidenced by the accompanying expert reports and declarations. In summary:

(1) As detailed by Dr. Janusz A. Ordover, a leading economist and formerly the Deputy Assistant Attorney General for Economics, the University's licensing of the invention to Vysis has been pro-competitive in its effect, conforms to the government's policy and goals for the licensing of its technology, and has not "tended substantially to lessen competition or result in undue market concentration." Vysis faces intense competition in its efforts to commercialize Drs. Gray and Pinkel's technology both from existing technologies, that now are the standard of care, and competing emerging technologies. Vysis has not tried to preclude others from exercising the invention through unreasonable royalty rates, but has negotiated and offered to sublicense the technology at royalty rates well within the range of reasonableness, as confirmed

both by the University's experience in licensing comparable technologies and the accompanying independent evaluation of PricewaterhouseCoopers' Aron Levko.

(2) Through the royalty-free sublicense Vysis has granted the research community, its extensive product offerings, its commercial sublicenses, and its continuing substantial investment in research to further develop Drs. Gray and Pinkel's invention, the University has "taken effective steps . . . to accomplish substantial utilization of the . . . invention." Assignment & Confirmatory License at 5. Even the overview of the technology attached to Ventana's own petition confirms that, "Today, FISH is used routinely in hundreds of laboratories worldwide."

(3) Ventana's claims that the University lied to the Department of Energy to obtain transfer of the technology are plainly false, and indeed, are disproven by the very documents Ventana myopically cites.

(4) Ventana also is wrong in its contention, made on the basis of unspecified "information and belief" (Petition at 17), that the University failed to fulfill its obligation to give consideration to licensing the technology to small businesses. The accompanying declarations of Ms. Candace Voelker and Dr. Joe W. Gray make clear the University diligently sought small businesses, including Ventana's predecessor Oncor, as licensees, but was unable to find a qualified small business willing and able to make the enormous investment necessary. Ventana's predecessor, Oncor, refused to respect the University's patent, and even after losing the point in litigation by summary judgment, insisted upon using the technology without payment of any part of the costs of developing it. Moreover, the Department's contract with the University makes clear that any failure to consider a small business licensee does not affect the University's rights in the technology.

I. THE GOVERNMENT'S WAIVER OF ITS RIGHTS IN DRS. GRAY AND PINKEL'S INVENTION HAS NOT TENDED TO SUBSTANTIALLY LESSEN COMPETITION OR RESULT IN UNDUE MARKET CONCENTRATION IN ANY SECTION OF THE COUNTRY IN ANY LINE OF COMMERCE TO WHICH THE INVENTION RELATES

Ventana first contends that the Department of Energy should take the unprecedented step of exercising march-in rights because, Ventana claims, the Department's license to the University has "tended to substantially lessen competition or result in undue market concentration in any section of the country in any line of commerce to which the invention relates." Ventana, however, nowhere seeks to demonstrate in meaningful economic terms that the license has tended to substantially lessen competition or that an undue market concentration has resulted. Instead, the petition alleges assorted Vysis misconduct that Ventana claims to find offensive.

Notwithstanding Ventana's utter failure to demonstrate any anticompetitive effect from the licensing of the patent, Vysis demonstrates in the following sections: (1) the granting of a license to Vysis has been procompetitive, and entirely consistent with the government's technology-transfer policy; (2) the misconduct alleged by Ventana has not occurred; and, (3) why the Department of Energy should make clear that modern technology-transfer policy, as set forth in the Bayh-Dole Act, and not some statutory provisions repealed decades ago, should govern this determination.

A. The License to Vysis Has Been Procompetitive, and Has Promoted the Goals of the Government's Technology-Transfer Policy

There should be no question that maintaining patent protection is essential to businesses investing in biotechnology products. Ventana fully understands this simple economic truism. For example, in its shareholder disclosures, Ventana regularly warns that Ventana's "success depends, in part, on its ability to obtain patents." Ventana 10-K405 Report for the year

ending Dec. 31, 1998, Tab 5, at 24.[2] The importance to Vysis of patent protection is evidenced by the $1.5 million it has reimbursed the University in patent prosecution fees for pursuing patents relating to Drs. Gray and Pinkel's invention, and improvements to it. Freeberg Declaration ¶¶ 4-5.

There also should be no question that Vysis and Ventana face fierce competition from a variety of products employing a variety of technologies. As Ventana bluntly explains in its annual shareholders' report:

> Competition in the diagnostic industry is intense and is expected to increase.

Ventana 10-K405 Report for the year ending Dec. 31, 1998, Tab 5, at 17. This "intense" competition arises, Ventana's shareholders' statement goes on to explain, not just from competitors employing the same technology, but from competitors offering competing technologies to achieve the same purpose:

> [T]he introduction of . . . alternative methods for diagnostic testing could hinder [Ventana's] ability to compete effectively and could have a material adverse effect on [Ventana's] business, financial condition and results of operations.

Id. at 17-18.

FISH, too, "intensely" competes with alternative technologies. Ordover Report ¶¶ 15-38. In the prenatal field, for example, notwithstanding extraordinary advances made possible by Vysis' prenatal test kit,[3] the standard of care continues to be karyotyping, in which

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[2] Copies of Securities and Exchange Commission filings cited in the response are included in the accompanying "Securities and Exchange Commission Filings Referred to in Response of The Regents of the University of California and Vysis, Inc., to Ventana Medical Systems' Petition to The Honorable Bill Richardson, Secretary of Energy." Cited page numbers for these documents refer to the reprint page numbers appearing in bottom right corner of the pages.

[3] One recent study of 3,150 patients finds that the Vysis test kit provides 24-hour results with no false positives or negatives, and concludes:

(Footnote Continued on Next Page.)

chromosomes are chemically stained. Bishop Declaration Ex. H; Ordover Report ¶¶ 31-35. For breast cancer testing, FISH testing competes directly with products based upon immunohistochemistry techniques.[4] Bishop Declaration Ex. I; Ordover Report ¶¶ 26-30. Moreover, FISH is not the only new technology being promoted for prenatal and cancer testing; among other nascent technologies is testing based upon polymerase chain reaction (PCR), promoted by Hoffman-LaRoche. Bishop Declaration Ex. J; Ordover Report ¶¶ 29, 34.

Ignoring both the "intense" competition among competing technologies and companies in medical diagnostics and the shared view that patent protection is essential if large investments in technology are to be made, Ventana's Petition simplistically contends that the licensing of Drs. Gray and Pinkel's invention to Vysis has "tended to substantially lessen competition or result in undue market concentration" just because it is exclusive. Ventana, however, nowhere identifies any relevant market or line of commerce, and nowhere explains how competition has been lessened. Ventana instead appears to assert, contrary to its and every other biotechnology company's actual experience, that the mere existence of patent protection eliminates competition. The assertion is nonsense.

The accompanying report of Dr. Janusz A. Ordover, a leading economist and former Deputy Assistant Attorney General for Economics in the Antitrust Division, explains in

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(Footnote Continued from Previous Page.)

> In most analyses, the FISH result is normal and provides rapid relief to the pregnant woman. This effect should not be underestimated, especially regarding the anxiety whereby a most distressing period can be ended within 24 h.

Bishop Ex. G, first document, at 906.

[4] This is a field that Ventana claims to monopolize, having an "installed base that is several times as large as the combined installed base of all the company's current competitors." Ventana Petition at 9.

detail the errors in Ventana's simplistic notion that an exclusive license under a patent is per se anticompetitive. Based upon his extensive analysis, Dr. Ordover concludes, in part:

> a) Licensing arrangements rarely create competitive concerns. In principle, as long as the licensing provision does not significantly weaken dynamic competition relative to what that competition would have been had the license not been issued, the license provision likely does not harm competition in any relevant antitrust market. In cases such as the one under review, where the innovator has no downstream interest, *i.e.*, is not a producer, an especially wide latitude should be allowed in choosing a licensing strategy.
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> b) My review of the evidence in this case to date indicates that the University of California's (UC) exclusive license of the '841 patent to Vysis has not harmed competition in any relevant market.
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> c) Since receiving the license from UC, Vysis has undertaken significant investments in technology development, marketing, distribution, and regulatory compliance. Vysis has developed and commercialized products in several different applications that utilize the IP embodied in the '841 patent, and continues to conduct research to advance and expand its product line. In short, Vysis has been a procompetitive force in the marketplace.
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> d) The evidence shows that Vysis does not possess significant market power within any reasonably defined relevant market. To the contrary, the FISH technology claimed in the '841 patent is one of many technologies either currently used or under development in the field of DNA diagnostics. Even were Vysis to refuse to license the '841 patent, I conclude that this would likely not create any anticompetitive harm.
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> e) Vysis does not possess significant market power even when market definitions are artificially limited to those diagnostic fields within which Vysis currently markets FDA-approved products. None of the Vysis products represents the standard of care in its respective application, several are approved for marketing only as adjunct products, and in every case, they confront competitive offerings whose sales far outpace those of Vysis.
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> f) Finally, Vysis has offered to license to Ventana and others the technology embodied in the '841 patent. The fact that Vysis refused to accept the licensing terms for the '841 patent demanded by rivals does not suggest that Vysis has arbitrarily withheld the technology, or acted in a manner deleterious to competition.

Ordover Report ¶ 5 (footnote omitted).

B. The Allegations of Misconduct Relating to Negotiations and Settlement with Oncor

In place of any genuine effort to show that the government's waiver of its rights in Drs. Gray and Pinkel's invention has "tended to substantially lessen competition or result in undue market concentration," Ventana's petition asserts, without evidentiary support, misconduct by Vysis, mostly relating to its sublicensing of the technology. These allegations of misconduct in any event could never demonstrate lessening of competition or undue market concentration. They also are false.

Several of Ventana's false allegations surround the litigation brought by the University and Vysis to force Ventana's predecessor, Oncor, to stop its patent infringement. The actual facts relating to this litigation and its settlement are very different from the unsupported allegations in Ventana's petition.

Asserting valid patent infringement claims against an infringer is hardly anticompetitive conduct. Ordover Report ¶ 41. That the University and Vysis had valid grounds to bring the suit against Oncor cannot be questioned; the federal district court granted the University and Vysis summary judgment on most issues, finding no trial was necessary to establish that Oncor infringed the patent, and that Oncor's invalidity claims based upon anticipation and obviousness were meritless. *The Regents of the University of California and Vysis, Inc. v. Oncor, Inc.*, 44 U.S.P.Q.2d 1321, 1997 U.S. DIST. LEXIS 15068 (N.D. Cal. 1997). Shortly before the scheduled trial, Oncor additionally admitted that it had failed to produce documents it had been required to produce in discovery, and that as a result Oncor wrongly had denied that certain of its products do not infringe the patent.

Thus, on the eve of trial in the spring 1998, the situation, as described by Oncor in a securities law filing, was:

> In August 1997, the Court granted Vysis' motion for summary judgment on novelty and non-obviousness with respect to the patent, and granted in part and denied in part Vysis' motion for summary judgement that the patent in suit is infringed .... On February 3, 1998, the Company notified the Court that it intended

> to concede that the Company's probes, when used with metaphase chromosomes infringed the Vysis patent. On March 20, 1998, Vysis filed a motion requesting that the Court (i) establish that use of the Company's INFORM(TM) product infringes the patent in suit, or alternatively that the Company be precluded from presenting evidence that such use would infringe the patent in suit, (ii) permit Vysis to present to the jury at trial evidence concerning the Company's alleged failure to produce documents and false statements .... A failure to successfully defend against or settle this suit may result in damages being assessed against the Company and an injunction against the sale of most of the Company's probes and genetic test kits, either of which would likely have a material and adverse effect on the Company's business, financial condition or results of operations.

Oncor 10-K Report for the year ending December 31, 1997, Tab 1, at 24.

At the outset of the litigation, long before it had been put to the burden and expense of demonstrating that Oncor infringed the Gray and Pinkel patent, Vysis had sought to settle the case. This offer was conveyed to Oncor in a letter sent immediately after the suit was filed. Bishop Declaration ¶ 10 and Ex. K. To facilitate that settlement, Vysis offered to avoid publicity regarding the filing of the lawsuit, to grant Oncor additional time to respond, to stay the lawsuit, or to take "other reasonable steps" that Oncor might suggest. *Id.* Ex. K.

No settlement was reached at the outset of the litigation, however. Bishop Declaration ¶ 10. Instead, Oncor continued to infringe the patent, even after the Court decided by summary judgment that it was doing so. The result was that as Oncor neared trial it faced liability for willful infringement of the patent, and therefore a likelihood that it would be required to pay up to treble damages and the University and Vysis' multi-million dollar attorneys' fees, and that it would be enjoined from selling infringing products, much of Oncor's product line. *See* 35 U.S.C. §§ 283, 284, 285.

At the same time, Oncor faced unrelated financial problems. By the first quarter of 1998 Oncor was losing money at the rate of $12.3 million per quarter, adding to its cumulative loss of $145 million. Oncor 10-Q Report for the period ending March 31, 1998, Tab 2, at 13,

Item 2, Risk Factors, History of Operating Losses. On December 31, 1997, Oncor received its first FDA approval to market a clinical FISH product.[5] Oncor however, lacked the financial resources to do so, particularly in light of the drain of less productive parts of its business. Oncor therefore proposed to Vysis that Oncor sell the non-strategic, money-losing portion of its business to Vysis, and use the proceeds of that sale to compensate Vysis for some of the damages and attorneys' fees Oncor owed in the litigation. The parties eventually negotiated such a transaction. Oncor described the transaction to its shareholders as follows:

> Effective April 10, 1998, the Company conveyed its non-oncology genetic probe business unit and cash of $0.5 million to Vysis, Inc. as consideration for obtaining certain key royalty-bearing licenses and for settling claims of past patent infringement and related claims made against the Company. As a result of this transaction, beginning in the second quarter of 1998, the Company will report significantly reduced sales, costs of sales and selling, general, administrative, research and development expenses of the Company. 1997 revenues for this business unit were approximately $3 million. The Company believes that the total costs and expenses associated with the business unit in 1997 were greater than $3.0 million. As a result, the Company expects that results of operations starting in the second quarter of 1998 will reflect the decreased sales and expenses attributable to that business unit. The Company is currently seeking a purchaser for its non-strategic research products business unit . . . . Collectively, these two units are referred to as the non-strategic operating units of the Company.

Oncor 10-Q Report for the period ending March 31, 1998, Tab 2, at 9, Item 2, Overview.

Ventana asserts Vysis' acceptance of Oncor's settlement overture as evidence of Vysis' anticompetitive nature. Ventana's mischaracterizations of this settlement are many. So

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[5] Ventana's claim that this occurred in 1995, before Vysis had received FDA clearance to market FISH products, is wrong. *See* Oncor 10-K Report for the year ending December 31, 1997, Tab 1, at 3.

that the Department of Energy can judge the true nature of the Vysis-Oncor agreement, Vysis submits a copy with this response.[6] Bishop Declaration Ex. L.

Apart from its misstatement of the transaction itself, Ventana's arguments mischaracterize the reasons for and effect of the transaction. Ventana first ignores that Oncor proposed the transaction, Vysis did not demand it. Bishop Declaration ¶ 11. Ventana ignores that the business Oncor sold to Vysis lost money, earning revenues of about $3 million with expenses in excess of that amount, as Oncor explains in the shareholder disclosure quoted above. Ventana ignores that the sold business was non-strategic to Oncor, and that Oncor wanted to dispose of it, as again confirmed by Oncor's shareholder disclosure. Finally, Ventana misstates the relationship of the timing of the settlement agreement, the commencement of litigation, and the history of Oncor's efforts to obtain FDA approval of its breast cancer product. Specifically, Ventana asserts (Ventana Petition at 8) that the FDA approval was received by Oncor in 1995, a date Ventana tries to relate to the litigation filing and asserts was before Vysis had received FDA clearance to market its first FISH product. In fact, Oncor received FDA approval two years later, on December 31, 1997. *See* Oncor 10-K Report for the year ending Dec. 31, 1997, Tab 1, at 3. This was after Vysis already had received its first FDA clearance. Bishop Declaration ¶ 4.

A specific provision of the Vysis-Oncor agreement that Ventana finds anticompetitive is the covenant not to compete. Ventana's petition mischaracterizes this provision as being part of the parties' agreement relating to the patent license. Petition at 12. This, too, is wrong. The agreement unequivocally provides otherwise:

> 14.1 Covenant Not to Compete. *In connection with the transfer of the Business to Vysis*, for the period from the date of Closing until the fifth anniversary of the date of the closing, Oncor will not (a) engage in business in the Restricted Fields . . . .

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[6] Ventana has consented to this submission. The parties request that the agreement be maintained in confidence due to the proprietary information contained within it.

Bishop Declaration Ex. L at 20 (emphasis added). Such a covenant not to compete is both common and entirely proper in connection with the sale of a business. *E.g.*, 1 ABA Section of Antitrust Law, *Antitrust Law Developments* at 124-26 (4th ed. 1997)("Covenants not to compete often appear . . . in contracts for the sale of a business"). Contrary to Ventana's suggestion, the covenant not to compete was not demanded by Vysis, but offered by Oncor in its initial written proposal setting forth its offer to sell non-strategic portions of its business to Vysis. Bishop Declaration at ¶ 11. Because this covenant not to compete was given in connection with the sale of a business, not in connection with a patent license, Ventana's arguments regarding covenants not to compete given in exchange for patent licenses are irrelevant.[7] As Dr. Ordover confirms, there is no evidence that Vysis has engaged in conduct that resulted in competitive harm. Ordover Report ¶ 39. This particularly is true because, at least in Vysis' view, neither Ventana nor any other business is now bound by the covenant.

Ventana again is wrong in its allegation that Vysis left "a void in the market" for Oncor products after the settlement. Since no product is identified by Ventana, the allegation cannot be answered specifically. Generally, however, Vysis has continued to offer a broad selection of probe products for which it obtained rights from Oncor. Apart from Oncor probes for which there is no significant demand, Vysis has continued to offer probes for all the purposes for which the probes acquired from Oncor were used, either in the form acquired from Oncor or in a form that incorporates superior technology. Bishop Declaration ¶ 12.

C. The Allegations of Misconduct Relating to Negotiations with Ventana

Ventana, presumably because it saw commercial value in the agreement between Vysis and Oncor, purchased this asset from Oncor's creditors after the creditors seized Oncor's

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[7] Ventana is also wrong in its claim that the University and Vysis patents licensed to Oncor would not be infringed were Oncor to engage in the Restricted Fields without a license.

assets in November 1998. Oncor 10-K Report for the year ending December 31, 1998, Tab 4, at 4. Following that purchase, Ventana informed Vysis of its position that Ventana is entitled to exercise Oncor's rights under the agreement, a position that Vysis disputes. Ventana also informed Vysis that, rather than comply with the terms of the Vysis-Oncor agreement it contends it acquired, Ventana wanted to renegotiate those terms.

Notwithstanding their difference of views regarding the claimed assignment of Oncor's rights to Ventana, Vysis and Ventana entered into negotiations regarding a potential license of Drs. Gray and Pinkel's technology, together with additional Vysis technology, to Ventana. Following a meeting in April 1999, the parties exchanged several offers and counteroffers through June 1999. Bishop Declaration ¶ 7 and Exs. D-G. The last of these offers, a June 7, 1999, Vysis counteroffer to which Ventana never responded, would allow Ventana to license the Gray and Pinkel technology, in addition to several patents encompassing technology that Vysis developed, for a six percent royalty. Bishop Declaration Ex. G.

In order to negotiate a royalty rate substantially less than the rate Oncor and Vysis agreed upon, Ventana proposed to Vysis, and Vysis agreed, that Vysis would take as part of the consideration for a license several probe products that Ventana received from Oncor's creditors, and is not presently exploiting. Bishop Declaration Ex. D. Remarkably, Ventana now asserts that Vysis' acceptance of Ventana's offer of these probes as partial consideration for a license is evidence of anticompetitive conduct by Vysis. In fact, nothing in Vysis' negotiations with Ventana constitute anticompetitive conduct. Ordover Report ¶ 40.

D. Vysis' Proposed Royalty Rates Are Reasonable

Ventana contends that Vysis' agreements to obtain royalties and negotiations seeking royalties in excess of four percent are further evidence of its anticompetitive conduct. This, Ventana argues, is because in 1989 the University licensed the technology to Vysis' predecessor for four percent, and because an article in the *Genetic Engineering News* includes in a cryptic table for a category labeled "Diagnostics, in vitro" a range of royalties of "2-6%."

As Dr. Ordover explains, licensing agreements seldom have anticompetitive effects, and Vysis' agreements certainly have had none. Ordover Report ¶ 5(a). Even were Vysis to refuse to license the '841 Patent at all, the result would not be anticompetitive. *Id.* ¶ 5(d). Ventana's decision not to accept a particular royalty rate – at least until it can attempt to obtain a lower one through its petition to the Department of Energy – certainly does not suggest that Vysis has arbitrarily withheld the technology, or acted in a manner deleterious to competition. Ordover Report ¶ 5(f). Nor is it anticompetitive that Vysis refuses to license at a rate that ignores the tens of millions of dollars invested in the technology, and provide Ventana free use of that investment. *Id.* ¶¶ 46-49.

> Understandably, Vysis is reluctant to license the '841 patent on terms that, in its view, do not adequately reflect the market potential of FISH nor the substantial value added from Vysis' own investments. Vysis has already invested substantial resources in the technology and is showing an ongoing commitment to expanding the market potential for FISH applications. This is precisely the kind of social benefit that is consistent with the grant of an exclusive license.

Id. ¶ 49.

That the University licensed an important laboratory discovery to Vysis' predecessor in 1989 for a four percent royalty demonstrates literally nothing about the current reasonable royalty rate. By undertaking the risk and financial burden of investing over $75 million and spending a decade of effort to develop and commercialize this technology, including the $6.5 million paid to fund further research by Drs. Gray and Pinkel, Vysis and its corporate predecessor plainly have made the technology more valuable. Businesses that make such investments obviously expect to obtain financial benefits not available to those who do not, either in the form of the product exclusivity that results from a patent or in the form of royalties in excess of those that would be reasonable had the investment not been made. *See* Ordover Report ¶ 46. To allow Ventana to obtain rights to Drs. Gray and Pinkel's invention without paying any part of the tens of millions of dollars subsequently invested by Vysis and its

predecessor would be to give Ventana a "free ride" on Vysis substantial investment, a result that would substantially *harm*, not promote, competition. Ordover Report ¶ 46 and n.46.

The *Genetic Engineering New* article that Ventana attaches to its Petition makes clear that the issue is more complex than the cryptic table Ventana would have the Department of Energy rely upon. For example, the article explains that several of the special factors present in this situation lead to higher up-front payments than those listed in the table. These special factors include "hot technology in a developing field," a "claim of infringement by the licensor against the licensee," and "the importance of the developing market." Ventana Petition Exhibit 10 at 1, 2. Moreover, the *Genetic Engineering News* article makes clear that its generalizations apply poorly in the field of biotechnology, where the complications of FDA approval, rapid technological obsolescence, and the high risks of untested technology "significantly complicate attempts to establish reasonable royalty rates." *Id.* at 2.

To provide more realistic royalty rate information, the University and Vysis have obtained data from two sources. First, the University's Office of Technology Transfer reviewed its nonexclusive licenses to government funded research to determine whether other royalty rates of eight percent or more exist. Second, the University and Vysis retained PricewaterhouseCoopers to conduct an independent examination of a reasonable royalty rate for Drs. Gray and Pinkel's technology.

Ms. Voelker details the information from the University's licensing experience. Voelker Declaration ¶ 44. Among the University's non-exclusive licenses to government funded technology are those with the following royalty rates[8]:

[8] Where a single license has multiple royalty rates, it may be included multiple times.

Royalty Rate	Number of Licenses
[redacted]	

Expert reports prepared by PricewaterhouseCoopers' Aron Levko confirm the reasonableness of the royalties Vysis negotiated with Oncor and offered Ventana. Mr. Levko initially provided Vysis his expert opinion regarding a reasonable royalty for the '841 Patent in September 1996, before Vysis negotiated an agreement with Oncor. To render an opinion, Mr. Levko evaluated methodologies for determining a reasonable royalty rate based upon Vysis' reagent profitability, Oncor's reagent profitability, and a comparison with the University of California agreement with Vysis. After considering the results of these three different

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[9] Includes one license which provides for an 8 percent rate prior to FDA approval of the company's PMA.

[10] Includes two licenses which provides for royalty bases of "bulk licensed product" and non patented derived products, respectively, and one which provides for a 10 percent rate prior to patent issuance.

[11] Includes one license which provides for a 15 percent rate until royalties of $10,000 are paid, and one which provides for royalties on patent pending products.

methodologies, Mr. Levko concluded that a reasonable royalty rate for the '841 Patent would be 14.54 percent. At the request of the University and Vysis, Mr. Levko reviewed his opinion, and in his recent supplement report he rendered the opinion that a reasonable royalty rate for the '841 Patent in light of current Vysis financial information[12] would be 14.75 percent. These reasonable royalty rates, of course, far exceed the six percent royalty rate offered Ventana. Copies of Mr. Levko's reports accompany this response.[13]

Thus, the royalty rates negotiated and offered by Vysis have been reasonable.

E. Licensing the Technology to Vysis Had the Pro-Competitive Result Sought by the Government's Modern Licensing Policies

Some of the technology-transfer laws and policies in place when the Department of Energy and University of California entered the 1982 contract under which Drs. Gray and Pinkel made their invention have long since been superseded. As demonstrated above, even under the competition standards set forth in the Assignment and Confirmatory Licenses, however, no action is merited here.

But, were this not the case, the government's modern technology-transfer laws make clear it still would be improper for the Department to intervene in the University's licensing of Drs. Gray and Pinkel's invention. This is because some of the laws on which the Assignment and Confirmatory License are based were repealed decades ago as inconsistent with modern technology-transfer policies, and subsequently statutory amendments and an Executive Order require the Department of Energy to exercise its discretion in accordance with modern, not historic, technology-transfer policy.

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[12] To avoid possibly prejudicing his opinion, Mr. Levko was not informed of the terms of the agreement between Vysis and Oncor.

[13] Confidential sales information, and calculations from which that information might be derived, are redacted from the attached copy of Mr. Levko's initial report.

The provisions of the Assignment and Confirmatory Licenses relating to lessening competition and market concentration were taken directly from the former statutory provisions in section (h)(7) of the Federal Non Nuclear Energy Research and Development Act of 1974, P.L. 93-577 (formerly 42 U.S.C. § 5908). These statutory provisions were repealed in 1980 by section 7 of the Patent and Trademark Laws of 1980, the same laws that separately enacted the Bayh-Dole Act. The repeal of this provision, Congress explained, was "necessary to implement the provisions of new chapter 38 of title 35, United States Code [the Bayh-Dole Act]." H. Rep. No 96-517, pt. 2, *reprinted in* 1980 U.S.C.A.A.N. 6460, 6505.

Notwithstanding the repeal of these provisions, between 1980 and 1984 the Bayh-Dole Act was not directly applicable to the University's contract with the Department of Energy. The original Bayh-Dole provisions excepted from its application agreements for the operation of government-owned research or production facilities. P.L. 96-517, ch. 38 § 202(a)(i) (1980 version of Bayh-Dole).

In 1984 Congress eliminated the exception for government-owned research or production facilities. Uniform Patent Protection Act, P.L. 98-620 § 501(3). Congress made unequivocally clear that its intent in extending Bayh-Dole to government-owned facilities was to assure that the demonstrated benefits of the Bayh-Dole provisions applied to all government-financed inventions:

> T]he amendments are designed to improve the functioning of the 1980 Act and to further extend the principles of that Act to the operations of Government laboratories . . . . After nearly four years of experience with P.L. 96-517, it is clear that the Act is accomplishing what it was intended to do.

House Rep. No. 98-1062, *reprinted in* 1984 U.S.C.A.A.N. 5708, 5799-800.

Thus, in 1984, Congress extended to the Department of Energy's national laboratories the policies of the Bayh-Dole Act. By doing so, Congress sought to achieve exactly what has occurred here:

> encourage private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application.

House Report No. 96-1307, Part 1, at 3, *reprinted in* 1980 U.S.C.A.A.N. 6460, 6462. In enacting the 1984 amendments, Congress particularly sought to extend the uniform policy of the Bayh-Dole Act to the national laboratories. *See* Senate Report No. 98-662, *reprinted in* 1984 U.S.C.A.A.N. 5799, 5807 ("This will result in uniform treatment of all domestic nonprofit organizations regardless of where they perform their Federally-funded work and *is particularly important to organizations that manage Department of Energy laboratories*" (emphasis added)).

Congress' goal of a uniform national technology-transfer policy later was confirmed by Executive Order. In December 1987, President Reagan sought to assure "uniform treatment of federally funded inventions" by promulgating Executive Order 12618. 52 F.R. 48661 (Dec. 22, 1987), *amending* Executive Order 12591, 52 F.R. 13414 (Apr. 10, 1987). The December 1987 Executive Order again reiterates the importance of establishing a single national policy governing technology transfer, making the finding:

> [T]he ability of the United States to achieve the statutorily prescribed policy (35 U.S.C. § 200 [the Bayh-Dole Act]) of using the patent system to promote the utilization of inventions arising from federally supported research or development requires that Federal agencies follow uniform policies in administering patents and licenses conceived or first reduced to practice during the course of federally funded research . . . .

In evaluating the Ventana Petition, it would not matter whether the Department of Energy were to use the standard of the provisions of the Federal Non Nuclear Energy Research and Development Act repealed in 1980 (incorporated into the Assignment and Confirmatory Licenses), or the United States' modern march-in policy as set forth in the Bayh-Dole Act (35 U.S.C. § 203(1)). Other cases, however, may not be so easily resolved. The University and Vysis therefore urge the Department of Energy to make clear that the governing standard is that

of the Bayh-Dole Act, and provide those risking private capital to commercialize federally-funded technology the certainty that Congress and the President have sought.

II. THE UNIVERSITY AND VYSIS HAVE TAKEN EFFECTIVE STEPS NECESSARY TO ACCOMPLISH SUBSTANTIAL UTILIZATION OF THE INVENTION

Ventana also claims that the University has not "taken effective steps, or within a reasonable time [redacted] . . . expected to take such steps, necessary to accomplish substantial utilization" of Drs. Gray and Pinkel's invention. Again, Ventana's Petition wholly fails to make any showing that this is true. Instead, the Petition makes an assortment of claims about Vysis, none of which shows lack of utilization of the invention.

Even Ventana's Petition demonstrates there is no question that Drs. Gray and Pinkel's FISH invention is substantially utilized. The attached Exhibit I(B) to the Petition says just that:

> The usefulness of these methods for routine cytogenetic analysis was demonstrated by Pinkel and his colleagues, who developed a relatively straightforward procedure for fluorescence *in situ* hybridization (FISH) . . . . This procedure has been modified and adapted by scientists at various companies and institutions to allow the detection of specific DNA sequences on individual human chromosomes. . . . Today, FISH is used routinely in hundreds of laboratories worldwide. . . .

Ventana's Exhibit is correct. Vysis allows research institutions making their own probes (as many do) to use Drs. Gray and Pinkel's invention royalty free, and hundreds have taken advantage of that offer. This is confirmed by the resulting scientific publications, numbering well over ten thousand. Schoonmaker Declaration Ex. A. This use constitutes "substantial utilization" of the invention.

But there is more. As previously explained, Vysis offers five FDA approved or cleared diagnostic FISH products (three of these are probes for highly repetitive chromosomal targets, and therefore do not fall within the patent); 190 products for use by diagnostic laboratories under the FDA's ASR regulations; and over 300 products for use by researchers.

Bishop Declaration ¶¶ 4-5 and Ex. B. Vysis also has underway or planned clinical trails to obtain FDA approval or clearance for another half dozen diagnostic FISH products. *Id.* ¶ 41. To assure effective distribution of these products, Vysis has established a direct sales operation in the United States and Europe, and a worldwide distribution network covering 51 countries. *Id.* ¶ 5. Vysis' FISH-related revenues are in excess of $1[redacted]. *Id.* ¶ 5. Beyond the products available today, Vysis and its predecessor have invested over $75 million dollars to exploit this technology, including funding about $6.5 million in research by Drs. Gray and Pinkel at LLNL and the University. *Id.* ¶¶ 3, 8. Vysis also is developing Drs. Gray and Pinkel's technology by funding and participating in research collaborations with other leading research institutions, including the Mayo Clinic, the University of Chicago, the NIH's National Human Genome Research Institute, Eos, Digital Scientific, and the Institute of Pathology at the University of Basel, Switzerland. Bishop Declaration ¶ 8. This extensive activity plainly constitutes "tak[e] effective steps . . . necessary to accomplish substantial utilization" of the invention.

And still there is more. The only FDA-approved FISH diagnostic product encompassed by the patent that was developed by a company other than Vysis, Oncor's breast cancer probe, was sublicensed by Vysis notwithstanding that Vysis was seeking FDA approval of a directly competitive product. As a result of Vysis' willingness to sublicense this technology to a direct competitor, the Oncor breast cancer probes continued to be sold by Oncor until Oncor's assets were seized by its creditors. Pending resolution of negotiations between Vysis and Ventana, that product continues to be sold by Ventana. Here, too, effective steps have been taken to accomplish substantial utilization of the invention.

Ventana's allegations regarding Vysis' utilization of Drs. Gray and Pinkel's technology address none of this plainly substantial use of the technology. Instead Ventana first notes that Vysis is a spin off of Amoco, next points out that Amoco since was acquired by British Petroleum, and concludes with the observation that, like many young biotechnology companies, Vysis does not have unlimited financial resources.

None of these observations regarding Vysis' history or financial situation suggests any failure to "tak[e] effective steps . . . to accomplish substantial utilization" of the invention. Indeed, Vysis does have to maintain itself as a viable, separate financial entity. Surprisingly, Ventana questions whether cash assets of [redacted] million are sufficient. Ventana, however, reports as of June 1999 its "principal source of liquidity consisted of cash and cash equivalents of just [redacted] million," an amount less than the $2.7 million cash used by the Ventana in the prior six months. Ventana 10-Q Report for the period ending June 30, 1999, Tab 7, at 10. In truth, there is no reason for concern about the viability of either company; if necessary, presumably either could raise additional money through sales of additional stock, loans, or other business transactions.

Equally irrelevantly, Ventana argues that Vysis' settlement with Oncor was unfair, repeating again its charges – directly contradicted by the Oncor's shareholder reports discussed above – that Vysis extracted an unfair agreement. This, however, ignores that Vysis successfully licensed Oncor to sell a diagnostic product incorporating the invention, a product that Ventana continues to sell.

Finally, Ventana argues that Vysis has licensed no distributors of equipment to prepare samples to perform FISH. This, too, is irrelevant since the Gray and Pinkel patent (which has claims addressed only to performance of FISH with blocking DNA) would not be infringed by the sale of generic sample-preparation equipment.

Ventana's arguments do not show any failure to "tak[e] effective steps . . . to accomplish substantial utilization" of the invention, but only reiterate its desire to obtain a free ride on the enormous investment made by others now that the path to commercialize Drs. Gray and Pinkel's invention is clear. Ventana's arguments do not even demonstrate that granting it a license will result in any further utilization of the invention. Ventana's sole contribution to the

technology is that it continues to sell a product it purchased from Oncor's creditors. Finally, it is clear that the University[14] and Vysis continue to seek to commercialize this technology as quickly as possible; thus, "within a reasonable time [they are] . . . expected to take such steps, necessary to accomplish substantial utilization," even beyond what they already have accomplished.

III. THE UNIVERSITY DID NOT OBTAIN WAIVERS THROUGH MATERIAL MISSTATEMENTS OR FAILURE TO DISCLOSE MATERIAL FACTS

Ventana's Petition claims that the Department of Energy should further license Drs. Gray and Pinkel's inventions because, Ventana claims, the University lied to the Department of Energy to obtain waiver of the government's rights in the invention. Ventana claims there were two lies: (1) the University failed to disclose the full scope of the claimed invention; and (2) the University claimed it would use the intellectual property to promote free competition, which Ventana asserts is a representation by the University that it intended to enter into only non-exclusive licenses.

To justify action by the Department, Ventana must demonstrate:

> [T]he request for waiver . . . of rights . . . contain[s] false material statements or nondisclosure of material facts, and such were specifically relied upon in reaching the waiver determination . . . .

Assignment and Confirmatory License at 5. Ventana cannot possibly satisfy this standard, because both of its charges of lying are groundless.

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[14] As Ventana's petition points out (Petition at 8), when the technology was licensed to Vysis in 1989, the University also took the precaution of reserving the right to grant additional licenses if Vysis is unable to fill market demand for the licensed product. This care by the University confirms its diligence in fulfilling its responsibility to take effective steps to accomplish substantial utilization of the invention.

A. The Department of Energy's Statement of Considerations Makes Clear It Knew of the Patent Application that Ventana Contends the University Withheld to Hide the Full Scope of the Invention

Ventana first argues that the University lied to the Department of Energy by not disclosing in its Petition for Waiver the scope of the invention, as set forth in the claims of the patent application filed by the University. Petition at 15. Indeed, Ventana claims these patent claims were "hidden from the DOE." *Id.* Ventana also claims that, because the Department's Statement of Considerations refers back to the description in the Petition for Waiver, the Department must have relied upon the alleged hiding of information. *Id.*

The University's Petition for Waiver summarized the invention by using the short description in the "Abstract" of Dr. Gray's Disclosure and Record of Invention. *Compare* Voelker Declaration Ex. D at 2 *with* Voelker Declaration Ex. A at 2. This sensible approach did not defraud the Department of Energy or preclude it from learning the content of the University's then-patent application. To the contrary, in the Department's Statement of Consideration cited by Ventana – indeed, in sentences directly adjoining the sentence Ventana cites – the Department of Energy quoted, and thus makes clear that it was fully aware of, claim 1 of the very patent application that Ventana asserts was hidden from the Department. Specifically, the Statement of Considerations for case W(I)-86-070 (a copy is attached to Ventana's Petition as Exhibit 4(a)) explains the Department's understanding of the scope of the invention in these terms:

> The invention relates generally to the field of cytogenetics, and more particularly to methods for identifying and classifying chromosomes. As identified in the above-referenced patent application, the invention is *a chromosome-specific staining reagent comprising a heterogeneous mixture of labeled nucleic acid fragments, the labeled nucleic acid fragments being derived from the same chromosome type, and being substantially free of repetitive nucleic acid sequences having hybridization capacity.* Item 2 of the Petition for Waivers sets forth further description of the invention.

The initial patent application's claim 1 (a copy is attached to Ventana's Petition as Exhibit 2), which Ventana contends the University successfully lied about and hid from the Department, claimed exactly what the Statement of Considerations recites:

> 1. A chromosome-specific staining reagent comprising a heterogeneous mixture of labeled nucleic acid fragments, the labeled nucleic fragments being derived from the same chromosome type and being substantially free of repetitive nucleic acid sequences having hybridization capacity.

Thus, it is plain that the University did not hide the scope of the pending patent claims from the Department of Energy. It also is clear that the Department used its knowledge of the actual scope of the pending patent claims, not the shorthand description in the Petition for Waiver.[15]

B. The University Made Very Clear It Intended to Grant Exclusive Licenses

Quoting portions of the University's requests for waiver out of context, Ventana attempts to construct an argument that the University misled the Department of Energy by not disclosing the University's intention to grant an exclusive license. This omission, Ventana then claims, amounts to a lie when combined with the University's statement it intended to license the technology to "promote free competition." In truth, the University fully disclosed its intention to license the technology through exclusive licenses.

First, in its Request of Waiver the University disclosed its belief that "a tremendous amount of development work . . . needed to be done to make the invention useful."

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[15] Ventana does not claim that the other Petition for Waiver involved in this matter was false. The second Petition for Waiver was filed, as shown on its face, before a patent application was filed. *See* Ventana Petition Ex. 3(b) at 1. Between its filing and the time the Department of Energy prepared its Statement of Considerations, a patent application was filed and brought to the attention of the Department. This is evidenced by the Statement of Considerations, which includes the number of the application and refers to the invention "as claimed in the above-referenced patent application." Ventana Petition Ex. 4(b).

Petition for Waiver, Voelker Declaration Ex. D at 1.[16] This work, the petitions explained, "must be undertaken by private industry if the benefits of the subject invention are to be enjoyed by the public sector." *Id.* at 3. With this background, the University explained:

> Petitioner's experience in the transfer of new technology spans approximately forty years and shows that the incentives afforded by a period of exclusivity under a "private" patent are usually prerequisite to attracting venture capital for the commercial development of new technology which require substantial risk capital. If Petitioner's request for greater rights is acted upon favorably, *Petitioner will be in a position to offer the prospective licensee a period of exclusivity* to encourage investment of time and funding necessary to bring the invention to a point of practical application.

Id. at 4 (emphasis added). Through such licenses, the University told the Department of Energy, the laboratory invention made by Drs. Gray and Pinkel could be made a "successful development" "result[ing] in expanded business opportunities for industrial concerns and ultimate public benefit." *Id. at 5.* This course of events, the University noted, matched the objectives of Congress in enacting the Bayh-Dole Act. *Id.*

Thus, the University made clear to the Department that it intended to attempt to enter into the exclusive licenses in order to attract the substantial capital necessary to commercialize Drs. Gray and Pinkel's invention. The University also made clear that it believed successful commercialization of the technology in this manner would promote free competition. The University made no material misstatement in setting forth its plans and belief about the impact of those plans on competition.

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[16] The second Petition for Waiver describes the University's licensing plans in nearly identical language. *See* Ventana Petition Ex. 3(b).

IV. THE UNIVERSITY GAVE APPROPRIATE CONSIDERATION TO SMALL BUSINESSES, INCLUDING ONCOR, BUT IN ANY EVENT THE UNIVERSITY HAD DISCRETION TO LICENSE THE INVENTION AS IT DETERMINED APPROPRIATE

Ventana finally complains that the University, according to Ventana's unexplained "information and belief," failed to give appropriate consideration to potential small business licensees. Ventana asserts the University took no reasonable efforts to attract small company licensees; again complains that, in settlement of litigation in 1998, Oncor paid a royalty rate greater than that offered Vysis' predecessor a decade earlier; and complains that it cannot now obtain the same rate being paid by Vysis.

The Department of Energy did not require that the University license the technology to a small business. Instead, its contract with the University provided:

> The University agrees that it will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the University determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms;[17] *provided, that the University is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the University.* However, the University agrees that DOE may review the University's licensing program and decisions regarding small business applicants, and the University will negotiate changes to its licensing policies, procedures, or practices with DOE when the review discloses that the University could take reasonable steps to implement more effectively the requirements of this subparagraph (q)(2).

Department of Energy Contract No. W-7405-ENG-48, paragraph 35(q)(2)(emphasis added).

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[17] The claimed quote of the governing contractual provision that appears in Ventana's Petition (pages 16-17) ends at the point of this footnote indicator, and does not include the portion of the provision that follows, including the italicized portions.

The University's efforts to fulfill this obligation are detailed in the accompanying declarations of Candace L. Voelker and Joe W. Gray. Among the companies they contacted, and contacted repeatedly, was Oncor, but it declined the University's offer to negotiate. Voelker Declaration ¶ 16 and Ex. J; Gray Declaration ¶¶ 10-11. Other then-small companies unsuccessfully solicited by the University included Bio-Rad Laboratories (Gray Declaration ¶¶ 8-9 and Exs. F-G), Cetus (Voelker Declaration ¶¶ 27, 32), Chiron (*id.* ¶ 27), and IG Labs (*id.* ¶¶ 27, 36). Still another small business, CW Group (*id.* ¶¶ 28-31; Gray Declaration ¶¶ 12-13 and Ex. H), was seriously considered by the University, but determined to be too risky, a conclusion that was hardly unreasonable in light of the failure of Becton Dickinson to commercialize the technology despite a seven-year effort requiring the expenditure of hundreds of thousands of dollars. *See* Voelker Declaration ¶¶ 7-25. These constitute reasonable efforts under the circumstances to license the technology to a small business.

Moreover, paragraph 35(q)(2) makes clear that in any event the consequence of a failure of the University to properly consider a small business licensee is not that the Department of Energy may grant additional licenses. Recognizing that in any specific case enormous subjective judgments would be necessary, the contract provides, "The decision whether to give a preference in any specific case will be at the discretion of the University." Thus, even if there were an error by the University in judging a small business potential licensee – and there was none here -- that error would not justify the relief Ventana seeks.

Ventana is not entitled to a license because the University was unsuccessful in finding an appropriate small business willing to pay for a license to Drs. Gray and Pinkel's invention.

CONCLUSION

Having purchased certain Oncor assets following their seizure by Oncor's creditors, Ventana demanded a bargain royalty rate to use Drs. Gray and Pinkel's technology. Having found that it could not negotiate the final few percentage points it desired off the royalty

rate being offered by Vysis, Ventana asks the Department of Energy to take the unprecedented step of providing it a license to Drs. Gray and Pinkel's technology.

Ventana has demonstrated none of the events that would permit the Department of Energy to grant the extraordinary relief requested:

- The University's license to Vysis has not "tended substantially to lessen competition or result in undue market concentration"; rather, Vysis is engaged in competition, described by Ventana itself as "intense," against other companies and their technologies.
- The University has not failed to "take effective steps . . . to accomplish substantial utilization of the . . . invention"; rather, through its license to Vysis, the University has obtained an investment of tens of millions of dollars that is being used to substantially utilize the technology, including through a royalty free license to researchers, extensive product offerings (five clinical products (and additional products in clinical trials), 190 ASR products, 300 research products), extensive marketing efforts, commercial sublicenses, and continuing substantial research to further develop Drs. Gray and Pinkel's invention.
- The University did not defraud the Department of Energy to obtain rights in the technology; rather, the University disclosed the scope of the patent application's claims as well as its intention to engage in the exclusive licensing the University believed necessary to incentivize the required enormous investment.
- And the University did not fail to give appropriate consideration to potential small business licensees; rather, none was found, in part because, until forced by litigation to do otherwise, Oncor preferred to infringe the University's patent rather than pay royalties under it.

To provide Ventana the free ride it seeks on the tens of millions of dollars that have been invested by Vysis to commercialize Drs. Gray and Pinkel's invention would be legally wrong, contrary to the government's technology-transfer goals, and extraordinarily harmful to Vysis and its shareholders. As sought by the expressed goals of the government's technology-transfer program, for a decade Vysis and its shareholders – first Amoco and more recently the public investors who provided Vysis with $36 million in funds – invested the $75 million of high-risk capital necessary to turn Drs. Gray and Pinkel's important invention into useful commercial products. After a decade of investing and work, those products are coming to market

and Vysis has an opportunity to offer them in competition with the products based upon other technologies, new and old.

Ventana's only contribution to has been to purchase Oncor's assets from the creditors who seized them from Oncor. Ventana asks that it now can be permitted to avoid the enormous expense and decade of work and risks that Vysis and its shareholders undertook. If, as Ventana's petition seeks, Ventana can obtain equal rights to the technology for [redacted] fee and a four percent royalty, the result will be economically disastrous for Vysis. Vysis' $75 million investment would be immediately devalued to the cost others must pay to duplicate it. And Vysis opportunity to ever earn any return on the $75 million investment would largely disappear. The result would be equally disastrous for the government's technology transfer program, as few companies ever again would risk investing in technology with so uncertain a future.

For the reasons discussed, the Department should deny the petition. Moreover, it should do so in a manner that makes clear that licensees of Department of Energy funded patents need not fear the Department will permit competitors to obtain free rides on the often huge investments they make. The path to these technologies must be through sublicenses from those who have invested time and money to develop them, not end runs around licensees' rights. As Congress and the President long ago recognized, providing certainty to those who develop transferred technology is critical to successfully attracting private capital to commercialize government funded research.

DATED: September 11, 1999.

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