Biomedical Public-Private Partnerships that End in Patent Disputes

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The U.S. government is not in the business of developing and commercializing innovative new drugs on its own -- it generally leaves that high-cost, high-risk, and potentially highly profitable endeavor to private companies. Nevertheless, the government has long played a significant role in pharmaceutical innovation, often through the funding of research that occurs at universities and non-profit institutions that results in discoveries and patents that the public sector then licenses and translates into FDA-approved medicines. Sometimes drug companies collaborate with federal agencies in research that can result in the development of new drugs or new uses for existing drugs, or in clinical trials that can speed the approval of new drugs and new indications. This government involvement with drug development efforts occurring in the private sector can be highly beneficial for all concerned, facilitating pharmaceutical innovation and commercialization that can provide tremendous benefits to patients.

For years there have been those who argue that the U.S. government has certain rights in the IP arising out of the government's involvement in the development of a drug and that those rights should be leveraged to render the drug more accessible, either by lowering the price of the drug, or allowing the government or some other third party to provide an alternate source of the drug.[1] This often occurs in the context of the Bayh-Dole Act, which provides certain retained rights for the U. S. government with respect to patents arising out of federally funded research, including but not limited to the march-in right. In this chapter, I will focus on a related phenomenon, which is when the government claims not just retained rights but actual ownership in patents arising out of public-private collaboration, and seeks to use patent ownership as a lever in the service of lower drug prices.

This chapter provides four case studies exemplifying this scenario. In the first three, government officials assert that government inventors should be listed as co-inventors on patents applied for and/or obtained by a drug company in relation to a previous collaboration, and that as a consequence the government is a co-owner of the patents. This alleged co-ownership is used leverage to pressure the drug company to change its practices in terms of the cost to charges for drugs, or the terms under which it licenses its technology to other companies. In the fourth case study, the U.S. government goes a step further, obtaining patents on the results of a successful public-private collaboration that name only government scientists as inventors, and then suing

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[1] Christopher M. Holman, *Government Involvement in Pharmaceutical Development Can Come Back to Haunt a Drug Company*, 40 Biotechnology L. Rep. 4 (2021).

the private company for infringement of the patents based on actions taken by the private company at the behest of federal officials. A significant aspect of all the case studies is that the government waited until the private company had expended a substantial amount of time, money, and other resources in bringing a successful medical product to market, and only after success was achieved was the purported ownership asserted. If the private companies had been cognizant of what the federal government would do with respect to these asserted patent rights, the companies might very well have made different decisions earlier on, and these decisions would not necessarily have been in the best interest of pharmaceutical innovation and public health policy.

The importance of public-private collaboration in drug development

A number of published studies have described the complementary roles of the public and private sectors in the development of medical treatments based on early-stage research funded by the federal government. For example, a study conducted by the NIH in 2001 concluded that of the 47 FDA-approved drugs having sales of more than $500M/year as of 1999, only four had been developed *in part* with technologies from NIH funding.[2] A 2022 analysis of 363 drugs approved between 2011 and 2020 similarly found that industry funded research (small and large) originated the IP of roughly 90% of all new medicines globally.[3] This study concluded that "NIH's CRADA and Intermural grants were directly responsible for the creation of 4 of the 363 new drugs" considered by the researchers.

An analysis of new drug approvals from 2010 – 2019 found that NIH funding contributed to 354 of the 356 drugs (99.4%), with a mean (SD) $1344.6 ($1433.1) million per target for basic research on drug targets and $51.8 ($96.8) million per drug for applied research on products.[4] In other words, a vast majority of the funding went toward basic research related to the biological targets for drug action rather than the drugs themselves. More recent studies show that, although basic research is important, 92% of patents underlying new medicines do not contain federal funding statements, and further, 90% of new medicines are derived from the private sector.[5] The findings of these studies supports the view that public and private funding enable each sector to leverage its strengths within the federally funded ecosystem: the public sector focuses on early-stage basic research to uncover new ideas, while the private sector provides the technical know-

[2] DEP'T OF HEALTH AND HUMAN SERVS. & NAT'L INSTS. OF HEALTH, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected (July 2001).
[3] Duane Schulthess, et al., *The US Ecosystem for Medicines* (Mar. 22, 2023), https://vitaltransformation.com/wp-content/uploads/2023/03/Where-do-new-medicines-originate_FINAL-HS-BIO-approved-2023_03_22-v3.pdf.
[4] Ekaterina G. Cleary, et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry*, 2010-2019, JAMA Health Forum. 2023;4(4):e230511. doi:10.1001/jamahealthforum.2023.0511 (April 28, 2023).
[5] Gwen O'Loughlin & Duane Schulthess, *March-in rights under the Bayh-Dole Act & NIH contributions to pharmaceutical patents*, VitalTransformation, at 8 (Nov. 30, 2023), https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf.

how and assumes the substantial financial risks needed to transform that research into marketable products.[6]

Moderna and its COVID-19 vaccine

The SARS and MERS coronavirus (CoV) epidemics of 2002-2003 and 2012, respectively had put the world on notice that there would likely be need for a vaccine solution to the next CoV pandemic, and research addressing this problem was being conducted in both the public and private sectors years prior to COVID-19. As part of these efforts, scientists at the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH), discovered ways in which they could introduce amino acid changes in CoV spike proteins that stabilized the proteins in their pre-fusion state.[7] The stabilizing mutations introduced by these scientists were shown to prevent structural rearrangement and to expose antigenically preferable surfaces, eliciting neutralizing antibody responses in animal models that were up to 10-fold higher than the wild-type protein. One of the amino acid substitutions identified by the inventors that generated a significantly stronger immune response entailed the introduction of two consecutive prolines in a specific region of the spike protein's amino acid sequence, i.e., the "2P" mutation. Significantly, this genetically engineered antigen was to prove amenable to delivery via mRNA technology.

Meanwhile Moderna, a biotechnology company focused on the design and delivery of mRNA molecules for therapeutic applications such as vaccines, had spent decades developing methods to design synthetic mRNAs encoding human or viral proteins. Some of the key advances they pioneered, such as the replacement of natural nucleosides with synthetic analogs, served to stabilize the mRNA molecule, reduce innate immune activation, and increase protein expression. Moderna also worked extensively on lipid nanoparticle (LNP) delivery systems for mRNA that protect the fragile molecule from degradation and enable it to be effectively delivered into cells. Prior to the pandemic Moderna already had mRNA vaccines in human trials, and these studies provided clinical data on safety, dosage, and immune responses for mRNA vaccines in people—crucial groundwork before attempting a COVID-19 vaccine. Furthermore, Moderna had opened a cGMP manufacturing facility in 2018 specifically designed for rapid production of mRNA vaccine candidates, which allowed Moderna to pivot to producing COVID-19 vaccine material almost immediately once the design of the vaccine had been determined.

Years prior to COVID-19 Moderna and NIH embarked upon an ongoing collaboration on vaccine development, which greatly facilitated their rapid response to the pandemic. When China released the DNA sequence of the SARS-CoV-2 genome in January 2020, Moderna scientists

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[6] See, also, Simoens S, Huys I. *How much do the public sector and the private sector contribute to biopharmaceutical R&D?* Drug Discov Today. 2022 Apr;27(4):939-945. doi: 10.1016/j.drudis.2021.11.027. Epub 2021 Dec 1. PMID: 34863932; Chakravarthy, R. et.al., Tufts Center for the Study of Drug Development. (2015). *Public and Private Sector Contributions to the Research & Development of the Most Transformational Drugs of the Last 25 Years*. Boston, Massachusetts: Tufts University School of Medicine.

[7] NIH Technology Transfer, *Prefusion Coronavirus Spike Proteins and Their Use*, TAB-3261, available at https://www.techtransfer.nih.gov/tech/tab-3261, last visited October 3, 2025.

were able to immediately combine the NIH's "2P" technology with the company's own technology to develop "mRNA-1273," a nucleoside-modified mRNA (modRNA) that encodes the full length SARS-CoV-2 spike protein, stabilized in its pre-fusion conformation using the 2P substitution. mRNA-1273 encapsulated in a Moderna LNP delivery system, i.e., Spikevax, carries the synthetic mRNA into human cells, which then transiently produce the engineered viral spike protein to stimulate an immune response. Spikevax entered clinical testing in March 2020, just 66 days after the viral genome became publicly available, and received FDA Emergency Use Authorization on December 18, 2020. Full FDA approval under the Spikevax brand name was achieved in January 2022**.** The vaccine was been shown to be highly effective at preventing symptomatic COVID-19, especially severe disease, and was widely deployed in the U.S. and internationally.

The partnership demonstrated the power of public–private collaboration: government scientists contributed fundamental discoveries and trial infrastructure, while Moderna brought cutting-edge platform expertise and rapid development capability. However, it also resulted in calls for the government to assert patent rights in the vaccine and to use those rights to address concerns about Moderna's pricing of the vaccine.

The dispute originated in Moderna's decision to file a patent application in 2020 claiming mRNA-1273 and naming only Moderna scientists as inventors, i.e., the "'215 application."[8] At some point NIH objected to Moderna's determination of inventorship, and asked Moderna to add three NIH scientists as co-inventors. Moderna declined to do so, informing the U.S. Patent and Trademark Office (PTO) that the company had "reached the good-faith determination that [the NIH scientists] did not co-invent the mRNAs and mRNA compositions claimed in the ['215] application."[9] Moderna has maintained its position that mRNA sequence was "selected exclusively by Moderna scientists using Moderna's technology and without input of [the NIH] scientists, who were not even aware of the mRNA sequence until after the patent application had already been filed."[10] On the other hand, a spokesperson for NIH said that "its own thorough review" had determined that three of its own scientists also deserved to be named as inventors.[11]

On August 27, 2021, the PTO allowed claims in the '215 application directed towards mRNA sequences that encode the SARS-CoV-2[12] spike protein with the double proline ("2P") mutation (K986P and V987P) relative to wild-type, and thus encompassing mRNA-1273. The allowance of these claims led to a letter dated November 2, 2021, from a group called Public Citizen urging

[8] U.S. Application No. 17/000,215.
[9] Letter from Peter Maybarduk, Public Citizen, Letter Urging NIH to Reclaim Foundational Role in NIH-Moderna Vaccine, (November 2, 2021), available at https://www.citizen.org/article/letter-urging-nih-to-reclaim-foundational-role-in-nih-moderna-vaccine/#_ftn1 (the "Public Citizen letter").
[10] Caitlin Grow, *United States v. Moderna: Explaining the Side Effects of the Patent Battle over the Moderna COVID-19 Vaccine*, Syracuse Law Review (March 3, 2022), available at https://lawreview.syr.edu/united-states-v-moderna-explaining-the-side-effects-of-the-patent-battle-over-the-moderna-covid-19-vaccine, (the "Syracuse Law Review article").
[11] Alexander Tin, *Moderna offers NIH co-ownership of COVID vaccine patent amid dispute with government*, CBS.com (November 15, 2021) available at https://www.cbsnews.com/news/moderna-covid-vaccine-patent-dispute-national-institutes-health (the "CBS article").
[12] SARS-CoV-2 is the virus that causes the COVID-19 disease.

the NIH to "publicly clarify the role of the NIH in the invention of the vaccine, and to explain the steps you intend to take to ensure the contributions of federal scientists are fully recognized, including any legal remedies,[13] and subsequent media coverage.[14]

The company decided not to pay the issue fee and allowed the '215 application to become abandoned. At the time Moderna explained that it was in talks with the NIH and it thought that payment of the issue fee would have sent a counterproductive signal that "could interfere with further discussions aimed at an amicable resolution."[15] Some speculated that Moderna might amend the claims in the patent application to "write out" any involvement by NIH.[16]

Moderna reportedly offered co-ownership of the patents to NIH, and would have allowed the government to "license the patents as they see fit."[17] This would in principle have given the government the same rights as would co-inventorship, but NIH refused the offer.[18]. Perhaps the NIH wanted the formal recognition of named inventorship for its scientists. NIH director Francis Collins stated that Moderna "has made a serious mistake here in not providing the kind of co-inventorship credit to the people who played a major role in the development of the vaccine that they're now making a fair amount of money off of."[19]

On November 3, 2021, the day after the Public Citizen letter and prior to abandonment of the '215 application, Moderna filed a continuation of the '215 application.[20] In the continuation application Moderna cancelled all of the previously allowed claims, substituting for them a new set of claims that seemed to focus on aspects of Spikevax more clearly attributable to Moderna, such as encapsulation in the LNP delivery vehicle. On December 30, 2022, however, prior to any substantive action by the PTO, Moderna expressly abandoned the continuation application, apparently deciding to forgo patent rights in aspects of Spikevax that the government might later claim co-inventorship in.

Moderna filed at least one other patent application relating to Spikevax that named NIH co-inventors and was and co-assigned to Moderna and the Department of Health and Human Services. This PCT application, WO2021159130-A3, was filed in 2021, prior to the public controversy over the '215 application's assignment of inventorship. The PCT application included claims directed to methods of inducing a neutralizing antibody response to SARS-CoV-2 spike protein through administration of a 25 mg or 100 mg dose of mRNA encoding pre-fusion stabilized spike protein in an LNP. However, Moderna apparently decided not to pursue this PCT

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[13] Public Citizen letter.
[14] Sheryl Gay Stolberg and Rebecca Robbins, *Moderna and US at Odds Vaccine Patent Rights*, New York Times (Nov 11, 2021); Christopher Rowland, *Moderna took NIH money and help for its covid vaccine. Now it wants to leave government scientists off a lucrative patent*, The Washington Post (Nov. 9, 2021).
[15] William Honaker, *NIH's Fight for Ownership of Moderna's COVID-19 Patent Highlights Hazards of Business Collaborations*, IP Watchdog (March 31, 2022), available at https://ipwatchdog.com/2022/03/31/nihs-fight-ownership-modernas-covid-19-patent-highlights-hazards-business-collaborations/id%3D148040/ (the (IP Watchdog article")..
[16] *Id.*
[17] CBS article.
[18] IP Watchdog article.
[19] Syracuse Law Review article.
[20] U.S. Application No. 17/518,542.

application—it never entered the national phase, and as far as this author can tell no patent has issued that claims priority to it.

This is not to say that the government was not able to obtain patent rights covering the Moderna vaccine. On March 30, 2021, prior to the inventorship dispute, a U. S. patent issued that was assigned to the U. S. government, Dartmouth College, and Scripps Research, U.S. Patent No. 10,960,070, which broadly claims as an immunogen spike protein comprising the "2P" modification. Another patent claiming priority to the same application, U.S. Patent No. 11,964,010, essentially recites nucleic acids encoding the immunogen, and is also co-assigned to the U.S., Dartmouth and Scripps.

In December of 2022 it was reported that Moderna had entered into a new royalty-bearing license agreement with NIH, Dartmouth College, and Scripps Research to access "certain patent rights concerning stabilizing prefusion coronavirus spike proteins," which included $400 million related to a "catch-up payment."[21] The agreement provides for low single-digit royalties on future COVID-19 vaccine sales.[22] Presumably this license encompasses the two patents described above.

Although Moderna decided to abandon the patent claims directed to the mRNA-1273 molecule per se, it did proceed to obtain a number of patents purported to cover Spikevax, and listing only Moderna inventors and Moderna as the assignee. Examples include U.S. 10,702,600; 10,933,127; 10,898,574; 12,409,347; 12,409,226; 12,404,232; 12,364,763; 12,357,708; 12,208,288; 11,622,972; 11,524,023; and 11,485,972.[23]

I did a search for any patents that were co-assigned to the government and Moderna, and was only able to find one, relating to HIV RNA vaccines.[24] The application appears to have been filed prior to the Spikevax inventorship dispute. At this point Moderna is on notice that its co-assigned HIV vaccine patent might be rendered useless if the government decides not to cooperate with the company, and one would suspect that in the future the company might avoid sharing patents with the government. As discussed more fully later in this article, this could pose a disincentive against future collaborative research with the government, given the importance private company's place on the ability to get patents on the results of its investment in research.

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[21] Benjamin Mueller, *After Long Delay, Moderna Pays N.I.H. for Covid Vaccine Technique*, The New York Times (February 23, 2023).

[22] Moderna Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Business Updates (Feb. 23, 2023), available at https://www.accessnewswire.com/740439/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2022-Financial-Results-and-Provides-Business-Updates; Eric Sagonowsky, *Moderna pays US government $400M 'catch-up payment' under new COVID-19 vaccine license*, Fierce Pharma (Feb. 24, 2023), available at https://www.fiercepharma.com/pharma/moderna-pays-us-government-400m-catch-payment-under-new-covid-19-vaccine-license.

[23] Moderna's "Patents" webpage, available at https://www.modernatx.com/en-US/patents.

[24] U.S. Patent No. 12,070,495.

Burroughs Wellcome and AZT for AIDS

In the mid-1980s, as part of its efforts to find an effective therapy for AIDS, Burroughs Wellcome Co. (BW) began screening chemical compounds for antiretroviral activity against murine and feline retroviruses. At the time BW was not working with live human immunodeficiency virus (HIV), and thus was only able to do the studies in animals analogs of HIV. These screening studies identified azidothymidine (AZT) as a compound having significant activity at low concentrations against the animal models. Based on these results, BW decided to file a patent application covering the use of AZT for the treatment of AIDS.

Meanwhile, scientists at the NIH were working with live HIV, which enabled them to develop an assay incorporating a human cell line capable of demonstrating a compound's effectiveness at inhibiting HIV replication. The NIH scientists let it be known that they were interested in obtaining compounds from private pharmaceutical companies to screen for activity against HIV. In response, shortly after deciding to file the patent application, BW sent a sample of AZT to NIH for testing under the code name "Compound S." In the letter accompanying the sample BW informed the NIH scientists that Compound S had been shown to inhibit HIV replication in murine and feline leukemia virus systems. The letter suggested specified concentrations at which BW scientists thought that NIH should screen the compound. The results of these tests of Compound S against live HIV demonstrated positive activity against HIV replication.

NIH informed BW scientists of the results, not knowing the actual identity of Compound S. Only later did BW inform NIH that Compound S was in fact AZT. Prior to this, none of the NIH scientists involved had ever thought of using AZT as a potential AIDS therapy.

Eventually, BW's patent application resulted in the issuance of six patents relating to the use of AZT for the treatment of HIV. These patents issued in 1988 and 1989, and all expired on the same day, February 9, 2005, as a result of terminal disclaimers.[25] The patents were assigned solely to BW and named five inventors, all of whom were employees of BW. Five of the patents claimed the use of AZT to treat patients infected with HIV or who have AIDS. The sixth patent claimed a method of using AZT to increase the T-lymphocyte count of persons infected with HIV.

On March 19, 1987, BW received FDA approval to market AZT for the treatment of HIV/AIDS under the brand name Retrovir®. Approval came just 20 months after the discovery of AZT's anti-HIV activity, making it one of the fastest drug approvals in FDA history at that time. It was also the first antiretroviral drug approved for the treatment of HIV/AIDS.

On March 19, 1991, exactly 4 years after the initial approval, Barr Pharmaceuticals filed an Abbreviated New Drug Application ("ANDA") with FDA seeking approval to manufacture and distribute a generic pharmaceutical capsule containing AZT. Barr's ANDA included a paragraph iv certification certifying that the BW patents were either invalid or not infringed by the product

[25] Burroughs Wellcome Co. v. Barr Lab'ys, Inc., 40 F.3d 1223 (Fed. Cir. 1994).

described in its ANDA. Barr promised to sell AZT for half the current annual price of $3,000 charged by Burroughs.

Also on March 19, 1991, Public Citizen, announced that it had filed a lawsuit against BW on behalf of AIDS patients seeking to revoke the AZT patents in the hope of getting less expensive versions of the drug on the market.[26] The suit claimed that BW did not "conceive, develop, or demonstrate the utility of AZT and failed to credit the NCI researchers who actually develop the drug." The suit also named as a defendant the U S. government because NIH scientists "were the actual inventors, or coinventors" of AZT as an AIDS therapy and could assert the rights to the patent, according to the lawsuit. At the time the lawsuit was filed, the acting director of the NIH issued a statement stating that the agency had been meeting with BW "over the past several months to discuss the inventorship of the patents relating to AZT," and that NIH believed that the NCI researchers should have been named as coinventors on these patents."[27] The lawsuit was reportedly filed in light of the fact that an unnamed foreign drug company had expressed its willingness to market the drug at half the price currently charged by BW. The complaint also alleged that BW was "less than candid" with the PTO when it failed to reveal that much of the research was done by federally-funded university studies and by the NIH.[28]

On May 28, the NIH director issued a statement accusing BW of unfairly taking credit for discovering the drug and said the agency was investigating ways to get government scientists who had collaborated with the company six years earlier included on the patent as co-inventors.[29] A Washington Post article stated that the NIH's action reflects a new commitment to asserting and protecting its commercial rights to scientific work conducted with public funds, and that if the NIH were to succeed, it would have the right to license any manufacturer it chose to produce the drug, which "could lead to dramatically lower prices for the costly AIDS treatment.".

On May 14, 1991, BW file a lawsuit against Barr alleging infringement of its patents under 35 U.S.C. § 271(e)(2)(A). In its answer to the complaint, Barr contended that two scientists employed by the NIH were coinventors of the subject matter of the BW patents but were not joined as inventors on the patents. The answer further stated that Barr and the NIH had entered into a nonexclusive licensing agreement in which Barr agreed to litigate the issue of the NIH's inventorship interest in the BW patents in exchange for a license from the NIH to manufacture and market AZT in the event that such rights were established.

On June 26, 1992, Novopharm Ltd., a Canadian corporation, filed an ANDA with the FDA seeking approval to manufacture and market a generic version of AZT. Like Barr, Novopharm asserted that two scientists employed by the NIH should have been named as coinventors on the BW Co. patents. But, unlike Barr, Novopharm did not have a licensing arrangement with the

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[26] Rob Stein, *Patent for AIDS drug challenged*, UPI Archives (March 19, 1991)("Stein"), available at https://www.upi.com/Archives/1991/03/19/Patent-for-AIDS-drug-challenged/4936669358800; see also Jonathan L. Mezrich, *The Patentability and Patent Term Extension of Lifesaving Drugs: A Deadly Mistake*, 6 J.L. & Health 111, n. 30 (1991-1992)("Mezrich")..

[27] Stein.

[28] Mezrich.

[29] Malcom Gladwell, *NIH May Seek to Void Firm's Patent on AZT: Success Could Cut AIDS Drug's Price*, The Washington Post (May 29, 1991).

NIH. Instead, Novopharm contended that BW had engaged in inequitable conduct before the PTO by failing to inform the agency of the identity of all of the proper inventors, and sought a declaration that the BW patents were invalid and unenforceable.

The district court granted BW's motion for judgment as a matter of law against all of the defendants, concluding that the BW inventors had conceived of the subject matter of the inventions at some time before February 6, 1985, without the assistance of NCI scientists.[30] On appeal, the Federal Circuit affirmed in part, holding that the NIH scientists were not coinventors with regard to the five BW patents encompassing compositions or methods of using AZT to treat AIDS.[31] As to the sixth patent, which claimed the use of AZT to increase number of T-lymphocytes in humans infected with HIV, the court determined that the proper assignment of inventorship was a question of fact for the jury. However, this was a moot point given that all six of the patents expired on the same day due to terminal disclaimers.

Chiron and the identification of the Hepatitis C virus

Hepatitis C virus (HCV) is a bloodborne virus that infects the liver and can result in chronic hepatitis, cirrhosis, and hepatocellular carcinoma. Prior to 1989, millions of people around the world were being diagnosed with what at the time was being called "non-A, non-B hepatitis" (NANBH). As was the case with Hepatitis A and B, NANBH was clearly transmissible via blood transfusion, but the pathogen was elusive — it could not be grown easily in cell culture and did not react with standard serological tests. Prior to the identification of HCV by a successful public-private partnership, NANBH caused serious transfusion-related epidemics; patients receiving blood products (e.g., hemophiliacs) were at especially high risk.

The collaboration between Chiron Corporation and the CDC that eventually solved the NANBH puzzle began in 1982. Founded in 1981 by prominent biochemists from UC Berkeley and UC San Francisco, Chiron was part of the first wave of biotech startups that emerged in the late 1970s and early 1980s aiming to commercialize the emerging technology of recombinant DNA. The CDC's Dr. Daniel Bradberry provided Chiron with samples containing the virus, and Chiron applied its cutting-edge expertise to clone the as-yet unidentified virus. Chiron's success in cloning a portion of the virus in 1987 resulted in a landmark article co-authored by CDC and Chiron scientists, and published in Science in 1989. The hepatitis C breakthrough is still pointed to as one of the groundbreaking triumphs of biotechnology, and some of the scientists who worked on the project were awarded the 2020 Nobel Prize in Physiology or Medicine for their contributions.

Using the cloned HCV material, Chiron developed a diagnostic assay for detecting the presence of HCV, and eventually vaccines and related technology. Chiron filed patent applications on these developments, naming only its scientists as the inventors. Thereafter the relationship between Chiron and the government deteriorated, with Dr. Bradley asserting that he should have been named as an inventor on the patent applications. Dr. Bradley would later state that while

[30] Burroughs Wellcome Co. v. Barr Lab'ys, Inc., 40 F.3d 1223 (Fed. Cir. 1994).
[31] *Id.*

this work was in progress the parties discussed the rights to any inventions that might result from the collaboration, but did not arrive at a resolution.[32]

In 1989 NIH filed its own patent application in which Dr. Bradley was named as an inventor along with three Chiron scientists. This application was filed in order to provoke an interference proceeding with the Chiron application, for the purpose of resolving issues of inventorship and ownership of these inventions. In 1990 Chiron entered into a settlement agreement with CDC and Dr. Bradley pursuant to which the government and the Dr. Bradley agreed to never bring a cause of action against Chiron relating to the collaboration, particularly "regarding the inventorship, ownership or control of Chiron Patents." CDC and Dr. Bradley also assigned to Chiron "any and all right title and interest in or to Chiron Patents and the inventions claimed therein." CDC and Dr. Bradley warranted that no patent application claiming subject matter interfering with the subject matter claimed in Chiron patents and patent applications would be maintained naming Dr. Bradley as an inventor or co-inventor. CDC and Dr. Bradley agreed to make supporting documents available to Chiron for the sole purpose of evaluating his claim to inventorship. Pursuant to the agreement, at the conclusion of such evaluation, Chiron could, "at its discretion, (i) add Dr. Bradley to one or more Chiron Patents as an inventor if in Chiron's opinion Dr. Bradley is an inventor or (ii) submit any material information regarding inventorship to the U.S. Patent and Trademark Office." If Dr. Bradley ended up being added as an inventor to a Chiron Patent, CDC and Dr. Bradley agreed to cooperate fully with and without charge to Chiron, and execute any and all necessary and proper documents related to the patent, and the assignment of the patent to Chiron. Pursuant to the agreement, Chiron agreed to pay CDC $1,912,500 and to pay Dr. Bradley $337,500 over five years. CDC dropped its pursuit of its patent application.

In December of 1994 Dr. Bradley filed a lawsuit seeking to rescind the settlement. The district court dismissed Dr. Bradley's second amended complaint with prejudice, and on appeal the Federal Circuit affirmed, holding that Dr. Bradley had failed to state a claim that would warrant recission of the agreement, and that the district court did not err in rejecting allegations in his second amended complaint as "false and sham."[33]

In 2004, 14 years after signing its agreement with Chiron, the CDC announced that it had decided to "review" the agreement.[34] A CDC spokesman stated at that time that "[t]here have been a number of individuals in the scientific community that are involved in the prevention, treatment and research of hepatitis C that have said the agreement is having an impact on the scientists' ability to address hepatitis C," and so "[w]e are looking into whether or not the agreement we have in place with Chiron is having an impact and, if so, what kind of impact." Within months of the CDC making this statement, Chiron announced that it would no longer demand that licensors pay upfront fees and make annual payments to obtain rights to the company's hepatitis C patents.[35] Chiron's CEO explained that he did not want Chiron to be

[32] Bradley v. Chiron Corp., 136 F.3d 1317 (Fed. Cir. 1998).
[33] *Id.*
[34] Paul Elias, *Feds review complaints that Chiron hinders HCV research* (Feb. 28, 2004), available at https://www.natap.org/2004/HCV/062804_14.htm?utm.
[35] Denise Gellene, *Chiron Relaxes Patent Licenses*, Los Angeles Times (June 22, 2004).

viewed as a company that blocked drug development, particularly in Washington, where the cost of medical innovation has become part of the broader discussion about pharmaceutical pricing.[36]

Gilead and pre-exposure prophylaxis (PrEP) for AIDs

Gilead has long been involved in efforts to identify and develop treatments for HIV/AIDS. The company's first success in this regard was the development of tenofovir disoproxil fumarate ("TDF"), a prodrug of tenofovir.[37] The FDA approved TDF for HIV treatment in 2001, and Gilead markets the drug as Viread®. While TDF has been shown to be effective, HIV can quickly develop resistance to a single drug. In light of this reality, Gilead continued to research potential drugs to treat HIV in combination with TDF and came up with emtricitabine ("FTC"),[38] which was approved by FDA in 2003 and is marketed by Gilead as Emtriva.

Because of HIV's tendency to develop resistance to any given drug, in the past patients were often required to take more than one drug at a time, sometimes requiring multiple pills taken multiple times a day. To simplify the drug therapy, Gilead developed "a fixed-dose combination," that combined TDF and FTC. That combination, marketed as Truvada®, received FDA approval for treatment in 2004.

Gilead invested a significant amount (more than a billion dollars) in developing TDF, FTC, and Truvada for treatment. To protect its investment, Gilead sought and received several United States patents covering these drugs. As a result of its patents, Gilead held the exclusive right to sell Truvada until September 30, 2020.[39]

Over the years Gilead has collaborated with the Center for Disease Control (CDC) in various research studies relating to the use of antiretroviral agents for the prevention of HIV. Beginning in 2004 CDC researchers approached Gilead for assistance in designing studies relating to HIV PrEP. According to Gilead, at the time studying drugs for HIV PrEP was controversial, and Gilead was hesitant to conduct clinical trials itself because "[t]here was concern about putting people onto clinical trials and the ethics of that, that it might expose them to more risk than [it was] actually helping." From a business standpoint, Gilead was concerned to avoid the appearance that it was encouraging disinhibition and unsafe sex practices. In spite of these concerns, Gilead and CDC entered into a collaborative relationship pursuant to which Gilead provided CDC with free pharmaceuticals and active compounds for use in experiments.

In connection with these studies, between 2004 and 2014 CDC and Gilead entered into a series of Material Transfer Agreements ("MTAs") wherein Gilead agreed to provide tenofovir, TDF, and/or FTC to CDC at no cost, for use in HIV research, and the CDC agreed to certain

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[36] *Id.*

[37] A prodrug is a pharmacologically inactive compound that is converted into an active drug within the body through metabolic processes. It is essentially a precursor to the active drug, designed to improve its properties or overcome limitations.

[38] The conventional abbreviation for emtricitabine is FTC, originating from the fact that it is the fluorinated cytidine analog related to the compound 3TC, i.e., lamivudine.

[39] Gilead Sciences, Inc. v. United States, 163 Fed.Cl. 104 (2022).

conditions, including to "promptly notify" Gilead of any claimed "Inventions" arising out of the MTAs, along with a promise to "give serious and reasonable consideration" to any request by Gilead for "a non-exclusive or exclusive license on commercially reasonable terms" for any intellectual property rights pertaining to claimed inventions arising out of use of the materials being provided by Gilead pursuant to the MTAs.

In 2004 the parties also entered into Clinical Trial Agreements ("CTAs") governing the provision of TDF and FTC in clinical trials studying the long-term safety and efficacy of TDF used as pre-exposure prophylaxis (PrEP) against HIV infection. As was the case with the MTAs, the parties engaged in a negotiation of language that would govern any intellectual property that resulted from the trials and the CTAs. Gilead initially proposed that it would "solely own any and all inventions, made, conceived, or reduced to practice during the course of the study that are directly related to the study drug." CDC represented that it could not grant such rights under a CTA and countered with language that it would "promise not to patent any invention that resulted from use of the partner's material but instead to publish the results, thus assuring unfettered access by the partner to any CDC subject invention." The parties ultimately agreed on the following text for the two CTAs' Intellectual Property clauses:

> Ownership of inventions from the Trial shall be determined in accordance with inventorship under U.S. patent law. The Study Drug and any related confidential information disclosed to CDC by Gilead will remain Gilead's property. *CDC agrees to put the results of the Trial, patentable or otherwise, in the public domain for all to use without obligation or compensation to CDC*. For clarity, *CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial*.

The trials proceeded using drugs donated by Gilead pursuant to the CTAs. The studies concluded that oral TDF was safe for long-term use in uninfected men, and that daily oral TDF-FTC prophylaxis (PrEP) prevented HIV infection in sexually active heterosexual adults.

In 2006, CDC filed a provisional patent application describing the results of a study in which a group of six rhesus macaques were injected once daily with tenofovir and FTC, and then subjected to weekly rectal exposure to a low dose of simian-HIV (SHIV). The study found that the combination of tenofovir and FTC provided a high level of protection against repeated virus challenges. This study employed tenofovir and FTC supplied by Gilead under the MTAs.

In 2007 CDC filed a non-provisional application claiming priority to the provisional application. This non-provisional application discloses a study in which rhesus macaques were divided into three study groups of six macaques each and treated with three different daily prophylaxis regimens, involving either subcutaneous or oral administration of FTC, TDF, and/or tenofovir. According to the application, the three studies concluded that each of the three prophylaxis regimens was "protective to a degree with a clear dose-response relationship being observed." These studies also employed drugs that Gilead freely provided to CDC under the MTAs.

Five patents (the "HHS Patents") eventually issued to the government claiming priority to these applications and naming as inventors CDC investigators specifically identified in the MTAs. The patents are generally directed to the use of tenofovir/FTC or Truvada for HIV PrEP.

While the patent applications were pending, the government (acting through FDA and CDC) encouraged Gilead to seek FDA approval to market Truvada for HIV PrEP. Despite its concern about a PrEP indication encouraging disinhibition, Gilead was persuaded, and on July 16, 2012, FDA approved the use of Truvada for PrEP. The CDC did not disclose at that time to either Gilead or FDA that it had filed a patent application for HIV PrEP compounds. It was this FDA approval of the use of Truvada for PrEP (as opposed to use of Truvada for the treatment of people who have AIDS, which was the originally approved indication) that was to ultimately serve as the basis for the government's contention that Gilead's sale of Truvada induced doctor and patients to infringe its PrEP patents.

Gilead has represented that, had it been aware of the pending applications, it might have taken different actions with respect to seeking approval for Truvada for PrEP. For example, Gilead could have chosen not to seek FDA approval for PrEP use of Truvada, at least absent assurance that the government would not turn around and sue it for patent infringement based on the newly approved use. If Gilead had not secured this FDA approval, instructions for PrEP would not appear on the label, eliminating the government's basis for its later assertion of induced patented infringement.[40] Although Gilead would not have been permitted to promote the drug for use in PrEP, Truvada was patented and the company could have sold the product for off-label use as PrEP.

On November 6, 2019, the government sued Gilead in the District of Delaware, alleging that Gilead was infringing the HHS patents by selling and promoting Truvada and a related drug, Descovy, for HIV PrEP, and seeking more than a billion dollars in damages, including royalties on Gilead's past sales of Truvada and Descovy for use in PrEP and an ongoing royalty for future sales of both products.

The government's lawsuit appears to have been prompted by calls from activists to use the HHS patents to force Gilead to agree to lower the price it charges for its drugs, and to obtain royalties from Gilead to be used to expand access of PrEP, by using the money to pay for the drug for those who cannot afford it.[41] These activists relied heavily on the argument that the government had funded much of the clinical research on the use of Truvada for PrEP, and that taxpayers should not be required to "pay twice."

On April 24, 2020 Gilead sued the U.S. government in the Court of Federal Claims in an action alleging that the CDC had, in seeking and obtaining the HHS patents, violated the terms of the MTAs and CTAs. On November 21, 2022, the Court of Federal Claims issued a decision holding

[40] *See generally*, Christopher M. Holman, *GlaxoSmithKline v. Teva: Holding a Generic Liable for an Artificial Act of Inducement*, 39 Biotechnology L. Rep. 425 (2020).

[41] *See, e.g.*, #BreakThePatent, https://breakthepatent.org [https://perma.cc/8FT5-Q7UV] ("The drug costs less than $6 a month to make but Gilead charges patients more than $1,600 for a 30 day supply."); *id.* ("The manufacturer of the Truvada, Gilead Sciences, has inflated the price by more than 25,000% . . . [w]hat Gilead charges for just two pills could pay for an entire year's supply of a generic equivalent.").

that the government had breached the MTAs by failing to properly notify Gilead of the inventions that the CDC patented. In particular, the government had not promptly notified Gilead of the patent applications, which were "made, conceived or reduced to practice" under the MTAs. The court also found that one of Gilead's rights under the MTAs was that the government was required to give Gilead "serious and regional consideration to [a] request for a… license," and that Gilead had been precluded from exercising this right because it was not informed of the existence of the government's patent applications.

In a subsequent decision the Court of Federal Claims held that the government had also breached the CTAs.[42] The court concluded that under the terms of the agreements, the government was bound, first, to place the clinical study "results" into the public domain and, second, not to seek patent protection for any inventions "derived from" the use of the donated drugs in the studies. Relying in part on findings from the parallel patent infringement litigation, the court concluded that the clinical studies conducted under the CTAs, and the conclusions of both studies with respect to humans, were necessary to support the patentability of inventions claimed in the HHS patents. "By supporting its [patent] application with sources citing the study results, the government removed those results from the public domain once the patent issued … As such, by pursuing the at-issue patents, the government removed the results of the clinical studies from the public and sought patent protection for inventions derived from the clinical studies in violation of both its obligations under the CTAs."

As to the patent infringement litigation, on March 22, 2024, the district court upheld a jury verdict that found all of the patent claims asserted by the government against Gilead to be invalid as anticipated, obvious, and/or not enabled.[43]

On January 15, 2025, Gilead announced it has reached a final settlement agreement with the U.S. government in both the breach of contract and patent infringement litigations.[44] In its press release, the company notes that "Gilead will receive a license to certain current and future government PrEP patents that will protect Gilead's freedom to operate for years to come." The company also states that it "continues to champion collaborations, including our efforts with HHS that span more than 15 years, as we all work together toward our common goal to end the HIV epidemic for everyone, everywhere."

What can we learn from these case studies?

The problem highlighted by these case studies is not so much that the government is asserting patent rights, as it is that those rights are only being invoked after the private company has committed substantial resources in the development of a successful product. This is a very different scenario than one in which a private company makes a decision to invest the resources

[42] Gilead Sciences, Inc. v. United States, 169 Fed.Cl. 210 (2024).
[43] United States v. Gilead Sciences, Inc., 722 F.Supp.3d 458 (2024).
[44] Gilead Statement on Successful Resolution with U.S. Department of Justice and the Department of Health and Human Services on Patents (January 15, 2025), available at https://www.gilead.com/company/company-statements/2025/gilead-statement-on-successful-resolution-with-us-department-of-justice-and-the-department-of-health-and-human-services-on-patents.

in developing a drug with full knowledge and notice of the potential that its ability to market the drug might in some way be constrained by the government's assertion of IP rights. For example, the Bayh-Dole Act provides for the retention of substantial rights by the government in patents arising out of federally funded research, and a private company that decides to commercialize an invention based on an exclusive license to a patent that arose out of federally funded research expects to live with those constraints. Similarly, sometimes the government owns a patent naming government scientists as inventors, and a private company willingly obtains a license to the patent in order to commercialize a product. And it is not uncommon that a public-private research collaboration under a cooperative research and development agreement (CRADA) will result in patents naming both government and private inventors, and thus presumptively co-owned by the company and the government. In such a case, the private company can decide to proceed with investing in the development of a drug that is covered by those co-owned patents, which might require the payment of substantial royalties to the government for the exclusive right to do so.[45] The problem arises when the government threatens to essentially move the goalposts and assert IP rights in a manner that would not have been reasonably anticipated by the private company.

In the first three case studies, the government asserted co-ownership of patents that the private companies had originally applied for on their own behalf. Co-ownership of a patent substantially weakens, and can potentially even nullify, the rights of a co-owner if the other co-owner decides not to cooperate in the management of the patent. Absent an agreement to the contrary, each co-owner has an equal undivided interest in the patent, and can unilaterally decide to license the patent to any third-party without accounting to the other co-owner. A co-owner also generally lacks standing enforce to enforce the patent in court if another co-owner declines to join in the suit, again, absent an agreement to the contrary.

The consequence of all this is that if a government scientist is named as a co-inventor on a patent covering the results of a public-private collaboration, the resulting co-ownership can effectively render the patent valueless. The threat of this can be used as leverage against the drug company. For example, one of the NIH scientists involved with the collaboration with Moderna commented shortly after the Pfizer-BioNTech and the Moderna COVID-19 vaccines became available for emergency use commented that the U. S.'s patent on the vaccine gave the government "leverage" over manufacturers that could "boost global access to Covid shots by compelling groups to share technology."[46] The fourth case study involving Gilead illustrates an even more substantial concern for the private company, where the government claims sole ownership of patents arising out of the collaboration and uses them as a cudgel in the purported service of "reasonable pricing" and expanded access. How should private companies respond to this potential downside to government collaboration?

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[45] See, for example, the exclusive patent license agreement between the NIH and Lixte Biotechnology Co. pertaining to co-owned patents arising out of a successful Cooperative Research and Development Agreement (CRADA) that involved the development of Lixte's proprietary compounds as potential cancer therapeutics, available at https://www.sec.gov/Archives/edgar/data/1335105/000149315224007784/ex10-1.htm.

[46] Erika Solomon, *Vaccine patent gives US government 'leverage' over manufacturers*, Financial Times (April 21, 2021).

One obvious response would be to avoid government collaboration in the development of medical products. But government involvement in drug involvement can be hugely beneficial to all concerned, including the patients that might ultimately benefit from the fruits of the collaboration. During the pandemic it was reported that Pfizer's efforts to bring its COVID-19 vaccines to market might have been hampered by the company's refusal to accept any federal money in the development of the vaccine.[47] If that is the case, it would certainly be a rational decision on Pfizer's part, but it also illustrates how penalizing drug companies for collaborating with the government on drugs might harm the public interest. Moderna did accept substantial federal funding in connection with the approval of its COVID-19 vaccine, and as would be expected, this resulted in Moderna becoming a prime target for scrutiny by those who would urge "the federal government to march in and pressure pharmaceutical companies over vaccine pricing.[48]

Another strategy that private companies need to consider is to take measures that allow it to obtain patents whose inventorship is unambiguously attributable to company scientists and assigned solely to the company. Note that Moderna and Burroughs Wellcome both had portfolios of patents that they clearly owned outright, which essentially rendered the patents in which the government claimed co-ownership redundant for purposes of excluding competitors. Companies should be diligent about documenting contributions of their own scientists in order to have better evidence in the event the government comes back and claims that its scientists were inventors on the company's patents. Companies should also consider maintaining some degree of separation between their own scientists and government scientists in order to fend off subsequent allegations of co-inventorship. In the cases of Moderna and Burroughs Wellcome, both companies' response to allegations of joint inventorship was that the company scientists conceived the invention prior to sharing the results with their government collaborators. Of course, the downside to this approach is it inhibits communication and collaboration between company and government scientists, to some extent undercutting the whole point of the collaboration.

Perhaps the best thing a company could do to protect itself is to enter into a formal agreement with the government prior to, or at least early in the collaboration, and sort out the ownership of resulting intellectual property. Inventorship on a patent is a purely legal question, and Moderna was right to point out that it was obligated to name as inventors those individuals that actually contributed to the conception of the claimed invention. Of course, the vagaries of the legal definition of conception and inventorship, combined with the realities of a dynamic and large-scale research collaboration, definitely allow reasonable and fair minds to come to different conclusions with respect to exactly who should be named as an inventor on any given patent or

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[47] Arlene Weintraub, *Feds rebuff Pfizer's pleas to speed up supplies of COVID vaccine raw materials*, Fierce Pharma (Dec 16, 2020), available at https://www.fiercepharma.com/pharma/feds-rebuff-pfizer-s-requests-for-speedier-supplies-covid-vaccine-raw-materials-reports.

[48] Lee Fang, *The Intercept: Last-Minute Trump Rule Would Let Vaccine Makers Hike Prices Unchecked* (April 2, 2021), available at https://doggett.house.gov/media/in-the-news/intercept-last-minute-trump-rule-would-let-vaccine-makers-hike-prices-unchecked. *See also*, Knowledge Ecology International, *Moderna*, available at https://www.keionline.org/moderna (providing links to various KEI Reports and Posts describing the group's examination of "issues and contracts related to Moderna's COVID-19 vaccine efforts.").

patent application. But although there is a presumption under the law that all of the inventors are co-owners of the patent, that presumption of ownership can be altered by agreement, and this occurs all the time. Private companies and the government are free to allocate patent ownership prior to the issuance of a patent or the filing of application, and even before the invention has been made. The problems in the first three case studies seem to have arisen in part because the parties simply just did not do that.

In the Chiron/HCV example, the allegedly omitted government inventor claimed that the parties had discussed allocation of patent ownership early in the collaboration, but had never reached an agreement. However, once the patent issued and the government raised its inventorship claim, Chiron and the government were able to enter an agreement that provided ownership of patents to Chiron irrespective of inventorship. The same sort of agreement could have been entered into much earlier in the relationship. Note that they agreement they did enter into stood up in court when the government scientist tried to rescind it and claim ownership of the patent.

In the cases of Moderna and Burroughs Wellcome, it appears the parties simply failed to reach an agreement on allocation of patent rights prior to the disputes arising. Of course, in both cases the partnership was addressing a compelling public health crisis, COVID-19 and AIDS, respectively, and so perhaps the parties can be excused for leaping into the collaboration without coming to an agreement regarding allocation of IP rights. But Moderna was reportedly working with the government scientists for years prior to the pandemic in anticipation of the next coronavirus epidemic, so it is not clear why they did not address the ownership of IP arising out of the collaboration earlier on. And it seems possible that Burroughs Wellcome could have addressed the issue before submitting its AZT sample to the government agency for testing. Perhaps in the future companies and government agencies will be more diligent.

The fourth case study involving Gilead really stands out in this regard. The facts that came out of the two litigations show that Gilead was very concerned about rights in any patents that might come out of the collaboration, and spent a great deal of time negotiating terms in the MTAs and CTAs that should have protected the company from what happened. The problem was that the government agencies blatantly breached their promises to Gilead. While the government's patenting of the results of the collaboration seems at least partly attributable to individual bad actors and a lack of communication and coherent policies within the agency, the government's decision to pursue the patent litigation against Gilead for so many years is harder to explain away. It seems that the government attorneys were bowing to pressure from activists to assert these patents against Gilead, regardless of the law and the assurances it had given to Gilead.

One really striking example of this was an amicus brief filed with the Federal Circuit by a group of academics, including law professors, in the appeal of district court decision finding the asserted patent claims to be invalid. The academics basically argued that the Federal Circuit should reverse the district and hold against Gilead, even though the government's patents were invalid. This is striking, I have never seen anything like it. It would be one thing to argue that the patent claims were actually not invalid. But the academics never tried to make that argument. Instead, they argued that Gilead should be forced to act like the patent was valid and bow to the government's demands, even though the patents are invalid.

Perhaps the government officials who decided to move forward with the litigation, to the point of appealing the adverse patent decision to the Federal Circuit, truly believed that an urgent need for greater access to anti-AIDS drugs justified its blatant disregard for the promises the government had made to Gilead. Unfortunately, the actions taken by the government against Gilead could easily cause a rational drug company to think twice before collaborating with a federal agency.

Private companies should be encouraged to invest in the expensive and high-risk endeavor of attempting to transform potential pharmaceutical agents identified by federally funded research into FDA approved medicines, not demonized and penalized by price controls imposed ex post facto. If the federal government deems it appropriate to introduce some sort of "reasonable pricing" or waiver of IP as a condition to government involvement in drug development, then this condition should be agreed to upfront, in the form of a formal agreement. This would permit the pharmaceutical company incorporate this restriction into the calculus when deciding whether to involve itself with federally funded research or federal funded researchers. However, history teaches us that efforts to leverage collaboration with the government as a means for regulating drug prices will cause the private sector to pull back from collaboration with government entities is substantiated by historical precedent.

For example, prior to 1962, private companies routinely collaborated with universities in the identification of new compounds of therapeutic interest through informal partnerships in which pharmaceutical firms screened compounds that arose out of NIH-funded research.[49] The industrial partners would pay the substantial costs required to perform the screening, with the understanding that the pharmaceutical company would obtain exclusive rights to patent and commercialize any product that might arise out of the endeavor. In 1962, the NIH announced a new policy blocking private sector actors from pursuing patent protection on these products without first obtaining consent from the government.[50] As would be expected, pharmaceutical firms responded to this change in policy by pulling back from collaboration with academic researchers, resulting in a "nearly complete blockage of testing" and an "insurmountable obstacle to the ultimate utilization" of any compounds with therapeutic potential.[51]

Later, in the years following passage of Bayh-Dole, members of Congress continued to express concerns that taxpayers were not receiving an appropriate monetary return on their investment in biomedical research. In response to these concerns, in 1989 the NIH adopted a policy stating that there should be "a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public."[52] It was applied in Cooperative Research and Development Agreement (CRADA) negotiations between NIH intramural laboratories and potential private collaborative partners interested in engaging in

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[49] *Harbridge House, Inc. Government Patent Policy Study: Final Report*. Prepared for the Federal Council for Science and Technology. Washington, DC: GPO, 1968, II- 19– II- 22, II- 40– II- 46.
[50] *Id.* at II.12.
[51] *Id.* at II.12, II-14, and II- 29.
[52] DHHS/NIH Report to Congress, *A Plan to Ensure Taxpayers' Interests are Protected* (July, 2001) 10, available at https://www.ott.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf

collaborative research. This "reasonable pricing" clause was required in exclusive licenses to inventions made under NIH CRADAs.

Not surprisingly, many companies withdrew from any further interaction with NIH rather than agree to the stipulation. Both NIH and its industry counterparts came to realize that this policy had the effect of posing a barrier to expanded research relationships and, therefore, was contrary to the purpose and policy behind Bayh-Dole. The NIH convened panels that included government scientists and administrators, industry, academia, and patient advocacy groups to review the "reasonable pricing" policy. Ultimately, the panels concluded that the policy did not serve the best interests of technology development and recommended that NIH rescind the requirement. NIH accepted the recommendation and revoked the policy in 1995.[53] The negative impact of NIH's "reasonable pricing clause" policy on collaborative research are evidenced in the relatively flat growth rate of CRADAs that occurred between 1990 and 1994, and the subsequent rebound in CRADAs following revocation of the policy.[54]

Conclusion

The four case studies examined in this chapter—Moderna's COVID-19 vaccine, Burroughs Wellcome's AZT, Chiron's hepatitis C breakthrough, and Gilead's PrEP litigation—illustrate both the promise and the peril of public–private collaboration in drug development. These examples confirm that partnerships between government agencies and pharmaceutical companies can accelerate lifesaving innovation, as when NIH's 2P mutation was paired with Moderna's mRNA platform, or when CDC samples enabled Chiron to identify hepatitis C. At the same time, they reveal a recurring pattern in which the government asserts intellectual property rights only after a company has invested substantial resources and achieved market success. Whether through belated claims of co-inventorship, disputed co-ownership, or the pursuit of patents despite contractual promises to the contrary, these actions introduce significant uncertainty and risk.

The resulting disputes have less to do with the legitimacy of government participation in research than with the unpredictability of its subsequent assertions of rights. Co-ownership of patents can undermine exclusivity; unanticipated infringement suits can chill investment. History shows that when the government seeks to impose "reasonable pricing" obligations or other restrictions retroactively, industry responds by retreating from collaboration—an outcome contrary to public health interests.

The lesson is not that companies should shun government partnerships, but that such collaborations must be governed by clear, upfront agreements that allocate patent ownership and licensing rights from the outset. Only with transparency and predictability can both sectors leverage their strengths: public institutions providing foundational science, and private firms

[53] *Id.*
[54] *Id.* at 11.

assuming the financial and technical risks required to transform research into widely available medicines.