IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
BALTIMORE DIVISION

RON L. LACKS, PERSONAL REPRESENTATIVE OF THE ESTATE OF HENRIETTA LACKS
5409 Daywalt Avenue
Baltimore, Maryland 21206

PLAINTIFF

VS-

ULTRAGENYX PHARMACEUTICAL, INC
60 Leveroni Court
Novato, CA 94949

DEFENDANT

Civil Case No.: 1:23-cv-2171

CIVIL COMPLAINT AND REQUEST FOR JURY TRIAL

Plaintiff Ron L. Lacks, personal representative of the Estate of Henrietta Lacks, by and through their undersigned counsel, brings this Complaint against Defendant Ultragenyx Pharmaceutical, Inc. ("Ultragenyx") and states as follows:

INTRODUCTION

1. This case is about a multibillion-dollar biopharmaceutical corporation, Ultragenyx, making a conscious choice to commercialize the living genetic material of Henrietta Lacks, a Black woman, grandmother, and community leader, despite the corporation's knowledge that Mrs. Lacks's tissue was taken from her without her consent or knowledge by physicians at Johns Hopkins Hospital. Ultragenyx has made a fortune by using Mrs. Lacks's stolen cells as a factory to make its "proprietary" gene therapy products.

2. Medical research has a long, troubled racial history. The exploitation of Henrietta Lacks represents the unfortunately common struggle experienced by Black people throughout American history. Indeed, Black suffering has fueled innumerable medical progress and profit, without just compensation or recognition. Various documented and undocumented studies have thrived off the dehumanization of Black people.

3. In the 1950s, a group of white physicians at Johns Hopkins preyed on Black women with cervical cancer. While treating Black women in racially segregated wards, white physicians would cut away tissue samples from their patients' cervixes without their patients' knowledge or consent (informed or otherwise). A leading figure in this unseemly and unlawful practice—Dr. George Gey, then head of tissue culture research at Johns Hopkins—once proclaimed himself "the world's most famous vulture, feeding on human specimens almost constantly."

4. Tissue samples were not taken for purposes of genuine medical treatment.

5. Henrietta Lacks was one of the victims of this misconduct. Mrs. Lacks was admitted to the racially segregated ward at Johns Hopkins Hospital—one of the only hospitals that would treat Black patients—for a malignant tumor on her cervix. On February 5, 1951, during a surgical procedure and with her under anesthesia, a white physician at Johns Hopkins used a sharp knife to cut two parts of Mrs. Lacks's cervix away under the guise of treating her cervical cancer with radium. This surgical procedure to harvest Mrs. Lacks's tissue was not medically necessary and was not an operation to which Mrs. Lacks had consented. Nor was she warned about the risks of the aggressive course of treatment she was subjected to, which left her infertile. Months later, when Mrs. Lacks was told that the course of treatment for her cancer had left her infertile, she stated clearly that she would never have agreed to be treated had she been informed of the risk of

infertility. Moreover, the "treatment" was completely ineffective. Henrietta Lacks ultimately died of cervical cancer on October 4, 1951.

6. The cells taken from Henrietta Lacks have unique properties. While most cell samples die shortly after they are removed from the body, Mrs. Lacks's cells survived and reproduced in the laboratory. This exceptional quality meant that it was possible to cultivate Mrs. Lacks's cells into a cell line that could reproduce indefinitely in laboratory conditions—an immortal cell line. Indeed, Mrs. Lacks's cells were the first known immortalized human cell line. Medical researchers refer to Henrietta Lacks's cultivated cell line as the HeLa cell line, using the first letters of Mrs. Lacks's first and last names.

7. While it was not known for decades to medical researchers outside Johns Hopkins that HeLa cells were Mrs. Lacks's cells, upon information and belief, it was well understood within the scientific community that the cell line was the product of non-therapeutic medical experimentation on Black patients by physicians at Johns Hopkins.

8. Medical researchers used HeLa cells to develop a huge number of scientific and medical innovations, including the polio vaccine, gene-mapping, in vitro fertilization, and many more. The HeLa cell line is one of the most important and widely used cell lines in human history. But Henrietta Lacks was never told why her tissue was taken and never gave permission for her cells to be used as they have been.

9. Ultragenyx is a pharmaceutical company focused on treatments for what the pharmaceutical industry euphemistically calls orphan diseases. Orphan diseases are diseases that only affect a small population of people. The FDA provides a wide array of benefits to pharmaceutical companies that bring orphan drugs to market—including longer exclusivity periods and research and development tax credits. In theory, these benefits are designed to

incentivize companies to research treatments that would not otherwise be commercially viable. In practice, predatory companies within this space identify drugs that can be brought to market with little research, that can then be sold at extortionate prices to desperate people.

10. A substantial portion of Ultragenyx's product development work is focused on gene therapy. Gene therapy requires manufacturing adeno-associated virus (AAV) vectors. Vectors act as vehicles that transport genetic cargo into cells, and once inside can release and enable the production of therapeutic proteins. But AAV vectors are enormously challenging to manufacture at scale. Such vectors must be grown within cells—which is no easy feat.

11. Ultragenyx has strategically positioned AAV-based gene therapy as a central pillar within its business model. But its purported competitive advantage is the theft of Mrs. Lacks's cells. Ultragenyx's answer to the challenge of how to grow AAV vectors is to commercialize for profit Mrs. Lacks's stolen cells to produce AAV vectors at a massive scale—and moreover, to be able to produce a range of different AAV vectors using the same production platform. This technique treats Mrs. Lacks's stolen cells like a dairy farm treats cows—it milks them for AAV vectors to sell as chattel. Ultragenyx has been able to massively increase its yields of AAV vector production through this technique. But by treating Mrs. Lacks's body as a mere manufacturing tool without consent, Ultragenyx denies her and her family basic dignity.

12. Ultragenyx proudly announces the centrality of Mrs. Lacks's cells to its business model. As Sam Wadsworth, Chief Scientific Officer for Ultragenyx, explained in an interview: "[t]he HeLa platform is the most advanced platform that we have. It is a highly engineered system for manufacturing AAV gene therapy vectors using HeLa cells. The elements of the platform are finely tuned to work in concert to produce AAV vectors at the scale and quality required for our products." "We like to think of this as letting biology do the work."

13. Ultragenyx's mass cultivation of Mrs. Lacks's cells is despite the fact the company is well aware—and has been at all relevant times—of the wrongful origins of the Hela cell line. Ultragenyx has even acknowledged on its own company's website that the Hela cell line was "collected" without Mrs. Lacks's "knowledge" in "Baltimore, Maryland."

14. In other words, Ultragenyx began developing and mass-producing a HeLa producer cell line to create AAV vectors, necessary for its gene therapy. Ultragenyx uses Mrs. Lacks's genetic material to commercially manufacture AAV vectors, reaping huge profits that would never have been possible without Henrietta Lacks's cells. Ultragenyx knew these cells were stolen. But Ultragenyx never sought or received permission from the Estate of Henrietta Lacks to use a human being's cells as if they were nothing more than a machine or a dairy cow.

15. Ultragenyx's choice to continue utilizing HeLa cells despite the cell lines' origin and the concrete harms it inflicts on the Lacks family can only be understood as a choice to embrace a legacy of racial injustice embedded in the US research and medical systems. Like anyone else, Black people have the right to control their bodies. Yet, Ultragenyx treats Henrietta Lacks's living cells as mere chattel to be manipulated without regard to the profound detrimental impact on the Lacks family.

16. Plaintiff brings a single cause of action—for unjust enrichment—against Ultragenyx for their choice to profit from the unlawful conduct of Johns Hopkins' physicians. Under settled law, as articulated in the *Restatement of Restitution, Third,* "a defendant who is enriched by misconduct and who acts with knowledge of the underlying wrong to the claimant" is a conscious wrongdoer liable for its profits. *Restatement (Third) of Restitution and Unjust Enrichment* § 51(3) (2011). Put simply, because it made the conscious choice to profit from the assault of Henrietta Lacks, Ultragenyx's ill-gotten gains rightfully belong to Mrs. Lacks's Estate.

PARTIES

17. Henrietta Lacks was a natural person, resident of Baltimore County, Maryland, and citizen of the state of Maryland. The executor and personal representative of Mrs. Lacks's Estate is Ron L. Lacks, Mrs. Lacks's grandson. Mrs. Lacks is a natural person, resident of Baltimore County, Maryland, and citizen of the state of Maryland.

18. Ultragenyx Pharmaceutical Inc. is a Delaware corporation headquartered in Novato, California. As used in this complaint, "Ultragenyx" refers both to Ultragenyx Pharmaceutical Inc. and to its subsidiaries, affiliates, agents, and other entities within its control that have owned, manufactured, distributed, monitored, or sold HeLa cells or related products.

19. Ultragenyx focuses on the market for drugs to treat orphan diseases. While it presents itself as an innovative research-focused company creating new treatments to help vulnerable people, in practice, it works to exploit vulnerable people with rare diseases through price gouging made possible through the preferential exclusivity rights afforded to orphan drugs—often in contexts where there is no serious argument such price gouging is needed to fund research.

20. Dojolvi, one of Ultragenyx's flagship drugs, provides an example. The active ingredient in Dojolvi is triheptanoin, a type of fat easily derived from natural oils and widely used in Europe as an additive to butter. Doctors identified triheptanoin's benefits for people with long-chain fatty acid oxidation disorders (LC-FAOD), an orphan disease, about a decade ago and began a series of studies to evaluate whether triheptanoin as a form of dietary supplement—which are typically far cheaper than FDA approved drugs—could be an effective treatment for this illness. But when those early studies were resoundingly successful, Ultragenyx swooped in and obtained FDA approval as a drug for what it termed "pharmaceutical grade" triheptanoin, Dojolvi. Ultragenyx now prices Dojolvi at $4,875 a vial, which translates to an average net price of

$138,000 per patient per year. This creates massive financial burdens for those with LC-FAOD. As a mother of two year old child with LC-FAOD observed in a public comment on a regulatory filing, "Dojolvi out of pocket is unaffordable…. I feel like by not having access to Dojolvi we are playing Russian Roulette with her life."

21. Ultragenyx engages in similar price gouging for every other drug it sells. For example, Crysvita is intended to treat children as young as six months for X-linked hypophosphatemia, a hereditary skeletal disease. Ultragenyx priced the drug at $160,000 per year for children and $200,000 per year for adults after rebates and discounts. Crysvita generated more than $1.3 billion in net sales in the first four years on the market.

22. For Mepsevii, an enzyme replacement therapy, Ultragenyx indicated the medication will cost an average of $375,000 per patient per year after discounts, with peak sales around $75 million. Mespevii is intended for treatment for children as young as five months old. Ultragenyx received Rare Pediatric Disease Priority Review Vouchers (PRV) for Mespsevii from the FDA to encourage the development of treatment for rare pediatric diseases. Ultragenyx subsequently sold this voucher for $130 million to Novartis Pharmaceuticals.

23. Ultragenyx's stock trades on the NASDAQ Global Select Market. Its estimated net proceeds at its initial public offering in 2014 were $126.4 million. It has a market capitalization in the billions. In 2022, it reported total revenues of $363 million and a year-end cash balance of approximately $896.7 million.

JURISDICTION AND VENUE

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332, based upon diversity of citizenship in that Plaintiff is not from the same state as the Defendant, and the amount in controversy exceeds $75,000.

25. This Court has specific personal jurisdiction over Ultragenyx because (1) Ultragenyx has purposefully availed itself of this forum, (2) plaintiffs' claims arise out of those activities directed at this forum, and (3) the exercise of personal jurisdiction would be constitutionally reasonable.

26. Ultragenyx has purposefully availed itself of this forum. Ultragenyx recruits patients and conducts clinical trials at the National Institutes of Health Clinical Center in Bethesda, Maryland. Ultragenyx partners with other biopharmaceutical companies that are headquartered in Maryland, such as Regenxbio to further its HeLa cell line production. Ultragenyx has also sponsored disease state marketing events at John Hopkins Hospital in Baltimore, Maryland.

27. Ultragenyx has a long-standing licensing partnership with Regenxbio, a Maryland corporation with a 132,000-square-foot, $65 million dollar gene therapy manufacturing facility in Rockville, Maryland. Since 2013 Regenxbio has granted Ultragenyx four exclusive worldwide licenses to advance Ultragenyx's treatment and gene therapy for rare diseases. Under these various licenses, Ultragenyx pays Regenxbio upfront payments, annual maintenance fees, milestone payments, and royalty payments on net sales from licensed products. Ultragenyx is required to develop licensed products in accordance with certain milestones. For example, in 2020 Regenxbio granted Ultragenyx an exclusive, worldwide license, with rights to sublicense, to Regenxbio's NAV AAV8 and AAV9 vectors for the development and commercialization of gene therapy treatments. More recently, in 2021, Ultragenyx and Regenxbio extended a license agreement to develop products to treat Wilson's disease. Ultragenyx's gene therapy UX701 for Wilson's disease is developed on its HeLa PCL platform.

28. Ultragenyx conducts extensive research at John Hopkins Hospital, in Baltimore Maryland. Since 2018, Ultragenyx has paid doctors at John Hopkins over $1.1 million in

consulting and research funding. Most recently, in November 2021, Ultragenyx paid John Hopkins University $116,382.39 for a research study. Ultragenyx also pays other doctors located in Maryland for various research. These payments include payments related to Ultragenyx's efforts to commercialize HeLa cells.

29. Ultragenyx also has a number of employees, including marketing personnel, who are based out of Maryland, and who market the company's products to Maryland physicians.

30. Ultragenyx has further purposefully availed itself to this forum by commercializing for profit HeLa cells despite its knowledge that the cells were obtained in Baltimore County, Maryland, through the deeply unethical and unlawful conduct described in this complaint. As described elsewhere in the complaint, Ultragenyx was aware not only that the HeLa cell line was a product of wrongful conduct by Mrs. Lacks's doctors at Johns Hopkins, but it was also aware—and has acknowledged publicly on the company's website—that such conduct occurred in "Baltimore, Maryland."

31. The injuries at issue here from Ultragenyx's wrongful conduct occurred in Maryland, where the Estate is situated, and where Mrs. Lacks's surviving family resides.

32. Venue is proper under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District.

FACTS

33. In 1951, the chair of gynecology at Johns Hopkins—Dr. Richard Wesley TeLinde—faced widespread criticism for his practice of frequently removing the cervix, uterus, and substantial portions of the vagina of patients with carcinoma in situ, a condition not believed to be deadly at the time.

34. TeLinde believed that by showing that carcinoma in situ behaved similarly to other forms of cervical cancer that were known to be deadly in the laboratory, he would be able to prove his aggressive surgical techniques were justified, and thus repair his tarnished reputation. TeLinde thus proposed to Dr. George Gey, then head of tissue research at Johns Hopkins, that TeLinde would provide samples of cervical cancer, taken from his patients without their knowledge or consent to Gey, if Gey would use those samples in his research and attempt to cultivate those cells in a form that could survive in a laboratory.

35. TeLinde's offer meshed well with Gey's research interests. Virtually all human cell samples at the time died quickly in laboratory conditions. Gey wanted to attempt to cultivate a cell line that would be able to survive indefinitely in a lab—an immortal cell line. Gey had little understanding of why human cells died in laboratory conditions. He tried repeating the process of creating human cell samples that could survive in laboratory conditions over and over again—a process that required more and more samples. TeLinde's proposal of an endless supply of samples thus suited Gey perfectly, and he agreed to the deal.

36. To get Gey samples, TeLinde directed the physicians under his supervision to take tissue samples from Black patients in Johns Hopkins' segregated wards who were suffering from cervical cancer. While treating Black women in racially segregated wards, the white physicians under TeLinde's supervision would cut away tissue samples from their patients' cervixes without their patients' knowledge or consent. As one physician acting under TeLinde's supervision callously observed, "Hopkins, with its large indigent [B]lack population, had no dearth of clinical material."

37. This horrifying dehumanization of Black patients and abuse of trust sadly had all too much precedent in then-recent medical history. At the same time as TeLinde and Gey

concocted their scheme, the U.S. Public Health Service, working with the Tuskegee Institute in Macon, Alabama, denied hundreds of Black men widely available treatment for syphilis to enable them to study how the disease progressed when untreated. By the time this abusive study was disclosed to the public in July 1972, 28 participants had died from syphilis, 100 more had passed away from related complications, at least 40 spouses had been diagnosed with it, and the disease had been passed to 19 children at birth.

38. The list of abuses is long. Another example is the medical practice known as the "Mississippi Appendectomy" beginning in the 1920s. The Mississippi Appendectomy was the systematic forced sterilization of poor Black women without the women's knowledge or consent. Physicians performed the hysterectomies under the pretense of appendectomies in order to prevent poor Black women from reproducing and to give young, inexperienced physicians the opportunity to practice the hysterectomy procedure. These sterilizations reflected a blatant disregard for basic human rights.

39. Similarly, during the Second World War, the United States tested mustard gas and other chemical agents on Black men, and then threatened the soldiers who complained with prison time to keep them quiet. Too often, the history of medical experimentation in the United States has been the history of medical racism.

40. In January 1951, Henrietta Lacks was diagnosed with cervical cancer at Johns Hopkins.

41. Henrietta Lacks's treating physician—acting under TeLinde's supervision—recommended an aggressive course of treatment: inserting rods of radium, a radioactive substance, into her body. This treatment approach required that Mrs. Lacks be placed under general

anesthesia—providing an opportunity for a surgeon working for TeLinde to collect the tissue samples from Mrs. Lacks. This procedure was also certain to render Mrs. Lacks infertile.

42. Henrietta Lacks was not informed that Johns Hopkins planned to take samples of her cervix. She did not consent to this surgical procedure or any such sampling. Taking a tissue sample is not medically necessary to conduct radium treatment, nor was it common practice in radium treatment at the time. Mrs. Lacks was also not told that the radium treatment she would be subjected to would render her infertile.

43. On February 5, 1951, while Henrietta Lacks was unconscious, a surgeon working under TeLinde's supervision cut two circular samples of tissue, each about three-quarters of an inch across, from her cervix. These samples were then given to Gey for experimentation.

44. Gey then attempted, once again, to create a cell line that could survive in laboratory conditions. Gey's efforts in cultivating the HeLa cell line were not meaningfully different than his prior, failed efforts. Unknown to Gey, however—and for reasons that the scientific community would not come to understand until decades later—Mrs. Lacks's cells had unique properties that meant they were able to survive in laboratory conditions. Gey was finally able to create the immortal cell line he had craved.

45. As Gey worked to cultivate the stolen cells, Henrietta Lacks died of cervical cancer on October 4, 1951. She was buried in an unmarked grave.

46. Indeed, around the same time that Henrietta Lacks passed away, Gey appeared on television, holding a vial of Mrs. Lacks's cells, to present his purported contribution to the fight against cancer. Gey introduced to the world the first successfully grown "immortal" human cell line.

47. Scientists all over the world were given HeLa cells for free to conduct their own studies. Because HeLa cells were the first human cells that could survive indefinitely in laboratory conditions, scientists were able to use them for medical research that might well not have been possible without them. In the decades that followed, the HeLa cell line became an essential resource for medical research in labs worldwide. HeLa cell tissue was used to test the first polio vaccine, to understand the effects of radiation on human cells, to develop treatment for sickle cell anemia, and in countless scientific papers.

48. Despite the widespread use of HeLa cells, for decades, the facts surrounding the origin of the HeLa cell line were unknown. Gey and Johns Hopkins went to great lengths to keep the origins of the HeLa cell line secret. As a result, for decades, the global scientific and medical communities were unaware that the HeLa cell line was the product of the assault of Henrietta Lacks. Indeed, for many years, even Henrietta Lacks's real name was not known to the public—Gey claimed the cells came from a person named Helen Lane, so as to conceal the cells' true origin.

49. Nonetheless, even before it was generally known that HeLa cells were Mrs. Lacks's cells, upon information and belief, the scientific community knew that physicians at Johns Hopkins performed unconsented-to non-therapeutic medical experimentation on its Black patients and turned a blind eye to Johns Hopkins' unlawful and tortious conduct and complete breach of trust and confidence to its patients.

50. In recent years, the origins of the HeLa cell line have become widely known in the scientific community. They have received mention in more than 2,700 academic articles discussing issues of patient consent and medical ethics.

51. Ultragenyx has publicly admitted that it is aware of the fact HeLa cells were taken from Henrietta Lacks without her consent. The company hosts an informational page on its

corporate website promoting its HeLa PLC platform that states that when Ms. Lacks "received treatment at then-segregated Johns Hopkins Hospital … tissue samples were collected and replicated without her knowledge" and that her immortal cells have "helped scientists achieve numerous medical breakthroughs." Ultragenyx has been aware of the unjust and unethical HeLa cell line origin since the development of its manufacturing platform.

52. Ultragenyx is not bona fide purchasers for value. With knowledge of the horrific misconduct by physicians at Johns Hopkins, Ultrageneyx knew its possession, cultivation, and sale of HeLa cells was, is, and will continue to be unjust. Upon information and belief, at no time did Ultragenyx give fair or sufficient consideration for Mrs. Lacks's cells.

53. Despite their awareness of the origins of the HeLa cell line, Ultragenyx made a decision to use Henrietta Lacks's genetic material for their own profit. Ultragenyx began developing and mass-producing HeLa cells for commercial research and therapeutic use, reaping huge profits that would never have been possible without Henrietta Lacks's cells. Ultragenyx never sought or received permission from the Estate of Henrietta Lacks to do so.

54. Ultragenyx has touted that its development of the HeLa PCL has resulted in high product yield and quality in a cost-effective way.

55. Following the announcement of promising top-line data from Ultragenyx's gene therapy trial utilizing the HeLa PCL platform, Ultragenyx's share price surged of 27% within a single day. Subsequently, in February 2021, following the FDA's clearance of Ultragenyx's application for UX701, an investigational gene therapy, the stock price rose about 20% within a span of 10 days.

56. Ultragenyx trademarked its HeLa PLC Platform as Pinnacle PLC in February 2022.

57. In June 2023, Ultragenyx opened a 110,000-square-foot state-of-the-art manufacturing facility with complete end-to-end gene therapy capabilities to further advance its large-scale commercialization of the HeLa PCL platform in Bedford, Massachusetts. The facility enables Ultragenyx to develop and produce gene therapy treatments at a greater scale leveraging the HeLa PCL platform capable of 2,000-liter commercial-scale manufacturing.

58. Outside the development and production of its branded gene therapies, Ultragenyx's proprietary HeLa PCL platform has proven successful in other ways. Ultragenyx has monetized its proprietary platform by establishing lucrative partnerships with multiple pharmaceutical companies that develop and manufacture gene therapies. For example, Ultragenyx licensed its HeLa PCL platform to Daiichi Sankyo Company for $200 million. In October 2020, Ultragenyx also entered into a license agreement worth $40 million with Solid Biosciences, Inc, to further develop and commercialize gene therapies utilizing Ultragenyx's HeLa 3.0 PLC platform for the creation of product candidates.

60. In other words, Ultragenyx actively engages in endeavors aimed at profiting from the sale of products and services derived from Mrs. Lacks's cellular material, develops cellular products incorporating HeLa cells, and seeks intellectual property rights on these products, staking a claim to the genetic material of Mrs. Lacks. Ultragenyx has appropriated Mrs. Lacks's genetic material solely for their pecuniary gain, all without obtaining payment, permission, or any form of approval from the Lacks Estate or family.

61. In recent years, Ultragenyx has reaped substantial financial gains through the utilization of the HeLa cell line. At the same time, regrettably, Mrs. Lacks's Estate and her family have been unjustly deprived of any form of compensation by Ultragenxy. These lucrative commercial endeavors were pursued despite the widespread publicity surrounding the origins of

the HeLa cell line. Ultragenyx was fully aware that the HeLa cells were wrongfully obtained from Mrs. Lacks, yet they consciously opted to exploit her body for their own financial benefit.

62. Because of Ultragenyx's actions, Henrietta Lacks's children and grandchildren have been forced to live with the reality that the living tissue of their mother or grandmother is exploited for research purposes and profited from by powerful organizations against her and her family's will. This robs the family of one of the most basic comforts any grieving person can ask for—the knowledge that a loved one's body has been treated with dignity.

63. Beyond this harm, the far-reaching dispersion of Henrietta Lacks's tissue has engendered a disquieting reality: the widespread availability of Mrs. Lacks's genetic information—and, as a consequence, some of the most private information about Mrs. Lacks and her family has been exposed to the general public.

64. In particular, Ultragenyx has received tremendous profits from the gene therapies it manufactures for other companies using HeLa cells, and is working towards developing its own gene therapies using HeLa cells. It has also profited directly from partnerships and sales related to its HeLa manufacturing platform. Ultragenyx acquired Dimension Therapeutics to obtain AAV-based gene therapy manufacturing technology. It has since made AAV-based gene therapy a primary focus in its business model—which requires the mass-production of HeLa cells. The effect of this is to make Mrs. Lacks complicit in the abuse of vulnerable people by Ultragenyx.

65. In October 2020, Ultragenyx entered into a strategic Collaboration and License Agreement with Solid Biosciences, Inc. for an exclusive license for any pharmaceutical product that expresses Solid's proprietary microdystrophin construct from AAV8 utilizing Ultragenyx's HeLa PCL platform.

66. After Ultragenyx announced positive top-line data out of its HeLa PCL platform gene therapy trial, Ultragenyx's share price rose 27% in one day. The stock price rose about 20% in 10 days after the FDA cleared Ultragenyx's application for UX701, investigational gene therapy in February 2021.

67. Ultragenyx joined a prestigious partnership with twelve other pharmaceutical companies to streamline gene therapy treatment in the United States, specifically focused on AAV vector development and production on a large commercial scale. The partnership has received $39.5 million in federal funding. On information and belief, Ultragenyx's HeLa PLC platform will be fundamental to the work of this partnership.

68. To this day, Ultragenyx mass-produces HeLa cells to research, develop, and manufacture gene therapies. It has received FDA approval of Investigational New Drug applications for the following:

(a) DTX 401 AAV8 gene therapy

(b) DTX301 AAV8 gene therapy

(c) UX701 AAV9 gene therapy

(d) UX111 AVV9 gene therapy

69. Ultragenyx's efforts to commercialize HeLa cells are not limited to the gene therapies it has disclosed to the FDA thus far. Ultragenyx has improved and modified its HeLa PCL platform to increase its yield and production of HeLa cells. Ultragenyx is currently conducting two additional preclinical studies for investigational gene therapies utilizing its improved platform.

70. In other words, Ultragenyx's business is to commercialize Henrietta Lacks's cells—her living bodily tissue—without the consent of or providing compensation to Ms. Lacks's

Estate. All the while, Ultragenyx understands—indeed, acknowledges on its own website—that this genetic material was stolen from Ms. Lacks. Ultragenyx's business is nothing more than a perpetuation of this theft.

71. This perpetuation is particularly troubling because of Ultragenyx's clear intent to use Mrs. Lacks's genetic material to further its predatory business model. There is no reason to think that Ultragenyx will price any treatment it develops from HeLa cells and sells under its own name any differently than the other orphan drugs it sells—any such treatment will almost certainly be sold on extortionate terms to people who have little choice but to buy. Those people will face, like the mother of the two-year-old quoted earlier who was unable to afford Dojolvi, a choice between "playing Russian Roulette with [their] li[ves]" and suffering financial ruin.

72. Mrs. Lacks's family should not be forced to watch as a company like Ultragenyx uses her living cells to extort vulnerable people. Mrs. Lacks had no choice about whether her genetic material would be used to further this extortion scheme. And absent action by the judicial system, Mrs. Lacks's family will have no means to stop their mother's and grandmother's cells from being used in this fashion.

COUNT I

For Unjust Enrichment

73. Plaintiff incorporates ¶¶1-72 by reference.

74. Ultragenyx was, is and will continue to be unjustly enriched because it received and continues to receive a benefit from Henrietta Lacks every time it acquires, cultivates, sells, and receives payment for newly-replicated HeLa cells, understood it receives a benefit from Mrs. Lacks every time it acquires, cultivates, sells, and receives payment for newly-replicated HeLa cells, and does so in circumstances in which acceptance or retention of the benefit was, is, and will continue to be inequitable without payment or permission.

75. Ultragenyx's cultivation (and continued cultivation), sale of, and receipt of payment for HeLa cell research was, is, and will continue to be inequitable without payment or permission because Mrs. Lacks's cells were obtained through breach of a relation of trust and confidence. HeLa cells are Mrs. Lacks's cells, taken by physicians in whom she had placed her trust without her consent or knowledge and for no therapeutic purpose. Nor is there any indication that Ultragenyx intends to stop its unjust cultivation and sale of HeLa cells.

76. Ultragenyx's cultivation (and continued cultivation), sale of, and receipt of payment for HeLa cells was, is, and will continue to be inequitable without payment or permission because Mrs. Lacks's cells were obtained through the unlawful conduct described above.

77. Ultragenyx's cultivation (and continued cultivation), sale of, and receipt of payment for HeLa cells in perpetuity was, is, and will continue to be inequitable without payment or permission because of the totality of circumstances surrounding the acquisition, cultivation, and sale of HeLa cells.

78. Upon information and belief, Ultragenyx is not a bona fide purchaser for value. Not only did Ultragenyx know that HeLa cells were wrongfully obtained by physicians at Johns Hopkins through unconsented-to non-therapeutic medical experimentation, it also never paid fair or sufficient consideration for its HeLa cells.

79. Ultragenyx's acted with knowledge of the underlying wrong to Henrietta Lacks or despite a known risk that the conduct in question violated the rights of Mrs. Lacks. Ultragenyx is thus liable for its net profits achieved as the fruits of its unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court, after trial on the merits, grant the following relief and judgment:

A. Order Ultragenyx to disgorge the full amount of its net profits obtained by commercializing the HeLa cell line to the Estate of Henrietta Lacks;

B. Permanently enjoin Ultragenyx from using the HeLa cell line without the permission of the Estate of Henrietta Lacks;

C. Impose a constructive trust in favor of the Estate of Henrietta Lacks on all HeLa cells possessed by Ultragenyx and its acquisitions, all related intellectual property, and all proceeds related to use thereof;

D. Award Plaintiff reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

E. Award such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: August 10th 2023,

/s/ Kim Parker
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