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Welcome to the World of Tomorrow: An Exploration of Cell-Based Meats and How the FDA and USDA May Protect Intellectual Property Rights

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WELCOME TO THE WORLD OF TOMORROW: AN EXPLORATION OF CELL-BASED MEATS AND HOW THE FDA AND USDA MAY PROTECT INTELLECTUAL PROPERTY RIGHTS

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As the accumulation of greenhouse gases continues to cause the Earth to warm,[1] as the population continues to grow at an exponential rate causing food shortage concerns,[2] and as pollution of the Earth's waterways continues to cause growing concerns of clean water shortages,[3] scientists continue to find new ways to address these issues. After years of stem cell research, scientists have started to address these issues by creating lab-grown meats, also known as cell-based meats.[4]

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1 *Climate Change: How Do We Know?*, NASA, https://climate.nasa.gov/evidence/ (last visited Apr. 10, 2020).

2 Joseph Hincks, *The World Is Headed for a Food Security Crisis. Here's How We Can Avert It*, TIME (Mar. 28, 2018), http://time.com/5216532/global-food-security-richard-deverell/.

3 Stephen Leahy, *From Not Enough to Too Much, the World's Water Crisis Explained*, NAT'L GEOGRAPHIC (Mar. 22, 2018), https://news.nationalgeographic.com/2018/03/world-water-day-water-crisis-explained/.

4 Mark J. Post, *An Alternative Animal Protein Source: Cultured Beef*, ANNALS N.Y. ACAD. SCI., Nov. 2014, at 29, 30.

Cell-based meats are meats grown using muscle tissues and stem cells in laboratory conditions.[5] Eventually, those stem cells grow into muscle fibers that resemble and taste like the meats they are derived from.[6] It is generally accepted that these types of meats are called cell-based meats, but they also go by names such as clean meat, artificial meat, cultured meat, or cultured tissue.[7]

Despite sounding like science fiction, the idea of growing meat in a laboratory setting has held a special place in the public imagination. In 1931, Winston Churchill wrote, "We shall escape the absurdity of growing a whole chicken in order to eat the breast or wing, by growing these parts separately under a suitable medium."[8] Cultivation of muscle tissue was shown to be successful as early as 1971 by Russell Ross.[9] Ross reported that, "Smooth muscle derived from the inner media and intima of immature guinea pig aorta were grown for up to 8 weeks in cell culture[s]."[10]

Cell-based meats are soon coming to grocery stores all around the country.[11] As cell-based meats get closer to coming to market, there will be serious questions raised as to how to protect intellectual property ("IP") rights related to cell lines,[12] how to protect IP rights related to growth processes,[13] and which government agency will regulate this area of the market.[14]

Part I of this Comment will discuss the general background of stem cells and

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5 G. Owen Schaefer, *Lab-Grown Meat*, SCI. AM. (Sept. 14, 2018), https://www.scientificamerican.com/article/lab-grown-meat/.

6 *Id.*

7 Sarah Zhang, *The Farcical Battle over What to Call Lab-Grown Meat*, THE ATLANTIC (July 13, 2018), https://www.theatlantic.com/science/archive/2018/07/lab-grown-meat/565049/; Jamie Mah, *Plant and Cell Based Meat, Explained*, MEDIUM (Feb. 7, 2019), https://medium.com/track-and-food/plant-and-cell-based-meat-explained-6c09dedad041.

8 Paul Shapiro, *Commentary: Science Fiction No More, Can Lab-Grown Meat Feed—and Save—the World?*, REUTERS (Feb. 26, 2018), https://www.reuters.com/article/us-shapiro-meat-commentary/commentary-science-fiction-no-more-can-lab-grown-meat-feed-and-save-the-world-idUSKCN1GA25H.

9 *See generally* Russell Ross, *The Smooth Muscle Cell: II. Growth of Smooth Muscle in Culture and Formation of Elastic Fibers*, 50 J. CELL BIOLOGY 172, 172 (1971).

10 *Id.*

11 Jade Scipioni, *Lab-Grown Meat Coming to Supermarket Shelves Soon?*, FOX BUS. (May 1, 2017), https://www.foxbusiness.com/features/lab-grown-meat-coming-to-supermarket-shelves-soon.

12 Josephine Johnston, *Intellectual Property and Biomedicine*, HASTINGS CTR., https://www.thehastingscenter.org/briefingbook/intellectual-property-and-biomedicine/ (last visited Apr. 10, 2020).

13 Chandra Nath Saha & Sanjib Bhattacharya, *Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry*, 2 J. ADVANCED PHARMACEUTICAL TECH. & RES. 88, 89 (2011).

14 Kelsey Piper, *The Lab-Grown Meat Industry Just Got the Regulatory Oversight It's Been Begging For*, VOX (Mar. 9, 2019, 8:00 AM), https://www.vox.com/future-perfect/2019/3/9/18255806/fda-usda-lab-grown-meat-cell-based-vegan-vegetarian.

how cell-based meats are grown. Next, Part II will discuss the implications of lab-grown meats in the world, including environmental impacts, social impacts, and the effects on animal-rights movements. Part III will discuss how some of the states that rely on traditional agriculture have responded to cell-based meats coming to market. Then, Part IV will continue with an explanation of the prior law of IP rights, cell rights, and expected Food and Drug Administration ("FDA") and United States Department of Agriculture ("USDA") joint regulation of cell-based meats. This part will also include a primer on the Hatch-Waxman laws. Part V will discuss some of the loopholes created by the Hatch-Waxman Act that will need to be addressed if new legislation is enacted to deal with cell-based meats. Part VI will compare the FDA and USDA laws and explain how the growing processes of lab-grown meats may find IP protections the same way generic drugs have found protections through Hatch-Waxman. Finally, Part VII will summarize the arguments: the FDA should be given full regulatory authority in order to avoid undue delays in the patent process.

This Comment explores how cell-based meats will be regulated by the FDA and the USDA, the current IP protections over the cells and growing processes, and how Congress can provide IP protections over the individual cell lines and the growing processes based on current IP frameworks in the generic drug world.

The main focus of this Comment will be how Congress could use the Hatch-Waxman Act[15] as a framework to create new IP protections for cell-based meats to give some additional IP protections to the companies producing cell-based meats. The FDA[16] will share regulatory responsibility with the USDA based on initial conversations between the White House, FDA, and the USDA.[17] Specifically, the FDA will regulate the food safety side of the industry.[18] The advantage of having the FDA involved in the regulation of cell-based meats is that the FDA already has a history of providing additional IP protections for drugs through the Hatch-Waxman Act.[19] Thus, Congress should consider

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15 *See* 21 U.S.C. § 355 (2012).

16 *USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry*, U.S. FOOD & DRUG ADMIN. (Mar. 7, 2019), https://www.fda.gov/news-events/press-announcements/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food-products-cell-lines-livestock-and.

17 Wyatt Bechtel, *Joint Letter Sent to President Trump on Lab-Grown Meat Regulations*, DROVERS (Aug. 23, 2018), https://www.drovers.com/article/joint-letter-sent-president-trump-lab-grown-meat-regulations.

18 *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell (last updated Mar. 7, 2019) [hereinafter *Formal Agreement*].

19 *See* 21 U.S.C. § 355 (2012).

passing an act similar to Hatch-Waxman in the cell-based meat arena to help implement IP protections over the cell-based meat growing processes as companies wait for approval from the FDA and the USDA. Similar to drug companies jumping into the generic drugs market after a successful showing of the brand drug, there will be an increasing number of companies trying to enter the cell-based meat market.[20] Congress will need to address the issues of competition and IP rights before it creates a backlog in the courts,[21] or a few companies create monopolies.[22] The framework of the Hatch-Waxman Act provides a practical example of how to do this moving forward.

I. BACKGROUND OF STEM CELLS AND CELL-BASED MEATS

A. The Science of Stem Cells

The science of stem cells has been studied and understood for a long time.[23] Stem cells are pervasive in all living things and among all types of cells and tissues.[24] In the simplest sense, stem cells are the cells that have yet to differentiate into specific cells or tissues.[25] These cells are influenced by the surrounding cells and have demonstrated the surprising ability to transform into other tissues and cell types.[26] Eventually, these stem cells can become muscle tissue, skin, or red blood cells.[27] Stem cells are the building blocks of the human body and how the body renews itself.[28]

There are a few different types of stem cells including embryonic,[29]

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20 Jessi Devenyns, *Cell-Based Food Maker New Age Meats Raises $2.7M in Funding*, FOOD DIVE (Jan. 13, 2020), https://www.fooddive.com/news/cell-based-food-maker-new-age-meats-raises-27m-in-funding/570267/.

21 Lawrence Hurley, *U.S. High Court Sets Record for Intellectual Property Caseload*, REUTERS (Feb. 27, 2014), https://www.reuters.com/article/us-usa-court-ip-analysis/u-s-high-court-sets-record-for-intellectual-property-caseload-idUSBREA1Q09B20140227.

22 *Cultured Meat Market Leveraging the Environment Ramifications of Animal Agriculture*, INDUSTRYARC (Aug. 26, 2019), https://www.industryarc.com/PressRelease/1749/Cultured-Meat-Market-Research.html.

23 *The Adult Stem Cell*, NAT'L INSTS. OF HEALTH, https://stemcells.nih.gov/info/2001report/chapter4.htm (last visited Apr. 10, 2020).

24 *Stem Cell Basics IV*, NAT'L INSTS. OF HEALTH, https://stemcells.nih.gov/info/basics/4.htm (last visited Apr. 10, 2020).

25 *Stem Cell Basics I*, NAT'L INSTS. OF HEALTH, https://stemcells.nih.gov/info/basics/1.htm (last visited Apr. 10, 2020).

26 David A. Prentice, *Adult Stem Cells*, 19 ISSUES L. & MED. 265, 265 (2004).

27 *Stem Cell Basics I*, *supra* note 25.

28 *Stem Cell Basics II*, NAT'L INSTS. OF HEALTH, https://stemcells.nih.gov/info/basics/1.htm (last visited Apr. 10, 2020).

29 *Stem Cell Basics III*, NAT'L INSTS. OF HEALTH, https://stemcells.nih.gov/info/basics/1.htm (last visited Apr. 10, 2020).

pluripotent, chord,[30] and hematopoietic stem cells;[31] however, the stem cells used in growing cell-based meats are the specific animal's adult stem cells.[32] Adult stem cells have certain special characteristics, such as the ability to duplicate themselves for long periods of time, which is referred to as long-term self-renewal.[33] These particular stem cells give rise to mature cell types that have specialized functions after the cell duplicates and divides.[34] The primary functions of adult stem cells are to maintain the job of a cell and to replace dead cells.[35]

When creating cell-based meats in a laboratory, scientists take certain animal cells and place those cells in a blood-like growth medium with cells similar to their future self; after some time, the result is a product that both tastes like and functions the same as the meat it was harvested from.[36] This is possible because the adult stem cells only know how to replicate the specific cells which they are programmed to become, regardless of whether they are in a living body or in a Petri dish in a lab.[37] Scientists will do this for both the smooth muscle meat cells and the fat cells of an animal to create essentially the same product available every day in grocery stores.[38]

B. Background of Cell-Based Meats

Lab-grown meats are made through a process called "cellular agriculture."[39] "Cellular agriculture is a method of agricultural production enabling the growth of meat, eggs, and leather in cell culture rather than raising and slaughtering livestock."[40] Researchers discovered this process after experimenting with animal stem cells.[41]

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30 *Id.*

31 *Stem Cell Basics II*, *supra* note 28.

32 Walter Johnson et al., *Burgers Grown in a Lab Are Heading to Your Plate. Will You Bite?*, WASH. POST (Sept. 9, 2018), https://www.washingtonpost.com/national/health-science/burgers-grown-in-a-lab-are-heading-to-your-plate-will-you-bite/2018/09/07/1d048720-b060-11e8-a20b-5f4f84429666_story.html?utm_term=.a5e08e698a86.

33 *The Adult Stem Cell*, *supra* note 23.

34 *Id.*

35 *Id.*

36 Shaefer, *supra* note 5.

37 *Stem Cell Basics II*, *supra* note 28.

38 Yaakov Nahmias, *Lab-Grown Meat Is Getting Cheap Enough for Anyone to Buy*, FAST COMPANY (May 2, 2018), https://www.fastcompany.com/40565582/lab-grown-meat-is-getting-cheap-enough-for-anyone-to-buy.

39 *Cell-Ag 101*, CAS, https://www.cellag.org/cellag101/ (last visited Apr. 10, 2020).

40 Erin Kim, *A Closer Look at Cellular Agriculture and the Processes Defining It*, AGFUNDER (July 5, 2016), https://agfundernews.com/closer-look-cellular-agriculture-and-the-processes-defining-it.html/.

41 Chase Purdy, *The Idea for Lab-Grown Meat Was Born in a Prisoner-of-War Camp*, QUARTZ (Sept. 24, 2017), https://qz.com/1077183/the-idea-for-lab-grown-meat-was-born-

One of the first reported cultivations of muscle fibers was in 1971 after researchers grew guinea pig smooth heart muscle in Petri dishes.[42] The United States National Aeronautics and Space Administration ("NASA") immediately took an interest in cell-based meats so that its astronauts could have a source of protein during prolonged space trips.[43] In 2002, NASA funded a research project focused on producing fish filets using cellular agriculture techniques.[44] These fish filets were breaded and fried before they were presented to a food panel.[45] The panel commented that the cell-based fish sticks resembled and smelled like real fish filets; however, FDA regulations prevented the panel from performing a taste test because of health concerns.[46]

After the NASA experiment, the Dutch government funded research on cultured meat from 2004 to 2009 and tasked Dr. Mark Post with leading the project.[47] Although the initial project did not result in a huge breakthrough, Dr. Post continued his research independently after the Dutch government cut funding. [48]

In 2013, as a result of his research, Dr. Post was able to create and present the first cell-based burger at a highly publicized conference in London.[49] The cell-based burger was produced by "removing the stem cells from the shoulder muscle of a cow, growing them into thin strips of muscle in tissue culture flasks, and combining about 20,000 strips to make a burger."[50] Dr. Post displayed the world's first cultured beef hamburger that "served as a proof of concept for this method, using established tissue engineering methods (the science of growing organs for human medical use) to grow the cow muscle cells that formed the beef patty."[51] As a result, "a small number of entrepreneurs are already

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in-a-prisoner-of-war-camp/.

42 Ross, *supra* note 9, at 172.

43 Paul Shapiro, *Lab-Grown Meat Is on the Way: It's Good for the Planet, and Surveys Show that Significant Numbers of People Would Be Willing to Give It a Try*, SCI. AM. (Dec. 19, 2017), https://blogs.scientificamerican.com/observations/lab-grown-meat-is-on-the-way/.

44 M.A. Benjaminson et al., *In Vitro Edible Muscle Protein Production System (MPPS): Stage 1, Fish*, 51 ACTA ASTRONAUTICA 879 (2002).

45 Maddie Stone, *Meet the Radical Scientists Who Want to Grow Our Seafood in a Lab*, GIZMODO (Feb. 9, 2016), https://gizmodo.com/meet-the-radical-scientists-who-want-to-grow-our-seafoo-1752950596.

46 Laura Cassiday, *Clean Meat*, AOCS, https://www.aocs.org/stay-informed/read-inform/featured-articles/clean-meat-february-2018 (last visited Apr. 10, 2020).

47 *Id.*

48 *Id.*

49 *Id.*

50 *Id.*

51 Kim, *supra* note 40.

embracing the science and launching startups like Memphis Meats,[52] Muufri,[53] Clara Foods,[54] Afineur,[55] Meatable,[56] and Gelzen."[57]

Dr. Post's research spawned several startups that show the promise of creating a product that can be marketed.[58] Meatable was created as a startup and has since been backed by both the University of Cambridge and Stanford University.[59] The company has secured over $3.5 million in seed money from these investors.[60] Meatable has created cell lines of certain meats that will replicate themselves indefinitely, creating a process that may tackle the scalability and cost issues that accompany cell-based meats.[61]

Memphis Meats is another cell-based meat startup that has benefited greatly from outside investing.[62] Memphis Meats was founded in 2015 by a cardiologist and a cellular scientist.[63] The startup created its first lab-grown meatball a year later and its first lab-grown poultry breast in March 2017.[64] After its recent success, Memphis Meats will try to bring its products to market by 2021.[65]

Memphis Meats has received substantial investments from both private and public sources.[66] It has received Class A investments from the likes of Bill Gates,

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52 *Home*, MEMPHIS MEATS, https://www.memphismeats.com/ (last visited Apr. 16, 2020).

53 *How It Works*, PERFECT DAY FOODS, https://www.perfectdayfoods.com/ (last visited Apr. 16, 2020).

54 *Home*, CLARA FOODS, https://www.clarafoods.com/ (last visited Apr. 16, 2020).

55 *Home*, AFINEUR, https://www.afineur.com/ (last visited Apr. 16, 2020).

56 *Home*, MEATABLE, https://www.meatable.com/ (last visited Apr. 16, 2020); *see* Catherine Lamb, *Meatable Claims to Hold the Key to Scalable Cultured Meat in a Single Cell*, SPOON (Oct. 5, 2018), https://thespoon.tech/meatable-claims-to-hold-the-key-to-scalable-cultured-meat-in-a-single-cell/.

57 *About Us*, GELTOR, http://geltor.com/ (last visited Apr. 16, 2020); Kim, *supra* note 40.

58 Kim, *supra* note 40.

59 Jessica Hasson, *Meatable to Feed the World with Breakthrough Single-Cell-Based Meat Technology*, GLOBE NEWSWIRE (Sept. 30, 2018), https://www.globenewswire.com/news-release/2018/09/30/1587407/0/en/Meatable-to-Feed-the-World-with-Breakthrough-Single-Cell-based-Meat-Technology.html.

60 *Id.*

61 *Id.*

62 *Memphis Meats Raises $161 Million for Cell-Based Meat*, RED HERRING (Jan. 24, 2020), https://www.redherring.com/top-story/memphis-meats-raises-161-million-for-cell-based-meat/.

63 *About*, MEMPHIS MEATS, https://www.memphismeats.com/about (last visited Jan. 26, 2020).

64 *Id.*

65 Jon Card, *Lab-Grown Food: "The Goal Is to Remove the Animal from Meat Production"*, GUARDIAN (July 24, 2017), https://www.theguardian.com/small-business-network/2017/jul/24/lab-grown-food-indiebio-artificial-intelligence-walmart-vegetarian.

66 Elie Dolgin, *Sizzling Interest in Lab-Grown Meat Belies Lack of Basic Research*, NATURE (Feb. 6, 2019), https://www.nature.com/articles/d41586-019-00373-w.

Cargill, and Richard Branson.[67] More recently, it received a very large investment from Tyson.[68] The company has raised over $17 million in series A funding as of the end of 2017.[69] These investors have been outspoken in their support for lab-grown meats.[70] Most of the support touted by these investors stems from the hope that this new technology will help end world hunger, be more environmentally friendly than current agricultural processes, and curve adverse livestock treatment.[71]

II. IMPLICATIONS OF CELL-BASED MEATS FOR THE WORLD

There is a lot of excitement behind new cell-based meat technology. Much of the excitement behind this technology is tied to the belief that it may solve the world food crisis.[72] This is because the labs that grow the meat do not require much space to operate.[73] Unlike farms that need space for animal grazing, milking, and slaughtering, lab-grown meats only need the lab and an area for harvesting.[74] Thus, the physical footprint of agriculture can be reduced wherever these labs are located. In addition, these labs can be placed in areas that do not traditionally support livestock.[75]

Part of the world food crisis is influenced by the soaring prices, demand, and supply of certain types of meats.[76] Producing meat from livestock is extremely inefficient.[77] To produce one pound of beef, it requires more than "38 pounds of feed and 1,799 gallons of water."[78] Farm animals are fed enough grain to end

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67 Rick Morgan, *Bill Gates and Richard Branson Are Betting Lab-Grown Meat Might Be the Food of the Future*, CNBC (Mar. 23, 2018), https://www.cnbc.com/2018/03/23/bill-gates-and-richard-branson-bet-on-lab-grown-meat-startup.html.

68 *Id.*

69 Emma Cosgrove, *Memphis Meats Adds Tyson to Investor List with Cargill, Gates, Branson, Musk, More*, AGFUNDER (Jan. 29, 2018), https://agfundernews.com/memphis-meats-raises-17m-series-cargill-gates-branson-musk.html/.

70 Gene Marks, *Lab-Grown Meat of the Future Is Here—and May Even Sustainably Fill Demand*, GUARDIAN (Nov. 29, 2018), https://www.theguardian.com/business/2018/nov/29/meat-poultry-sustainable-affordable-solution-lab-grown.

71 Morgan, *supra* note 67.

72 Jeff Bercovici, *Why This Cardiologist Is Betting That His Lab-Grown Meat Startup Can Solve the Global Food Crisis*, INC. (Oct. 24, 2017), https://www.inc.com/magazine/201711/jeff-bercovici/memphis-meats-lab-grown-meat-startup.html.

73 Marks, *supra* note 70.

74 *Id.*

75 Isha Datar, *Environmental Impacts of Cultured Meat*, NEW HARVEST (Nov. 19, 2015), https://www.new-harvest.org/environmental_impacts_of_cultured_meat.

76 Karen McColl, *Can We Feed the World?*, 336 BMJ 1336, 1336–37 (2018).

77 Morgan, *supra* note 67.

78 *Id.*; Kai Olson-Sawyer, *Meat's Large Water Footprint: Why Raising Livestock and Poultry for Meat Is So Resource-Intensive*, FOOD TANK (Dec. 2013), https://foodtank.com/

world hunger twenty times over.[79]

The total world population is forecasted to exceed nine billion people within thirty years;[80] humanity simply cannot sustain meat production for a population of that size.[81] In addition to food shortages, there will not be enough clean water to support a population of that size, let alone agricultural and horticultural needs.[82] In light of the population, food, and water issues, proponents of cell-culture meat are excited about the potential benefits because it is estimated that this technology requires "100 times less land and 5.5 times less water" than traditional meat production.[83]

Once the technology is better perfected and becomes more efficient, the time it takes to produce cell-based meats and to bring the product to table will be greatly reduced. Currently, it takes between eighteen to twenty-four months to bring a cow weighing over a thousand pounds to slaughter,[84] and between eight to twelve weeks for a chicken weighing slightly over five pounds.[85] For cell-based meats, it is estimated that in ideal conditions this process can produce fifty thousand tons of pork in just two months.[86] Again, production time of cell-based meats is likely to decrease, and yield is likely to increase once there are greater technological advances and streamlined processes in this area.[87]

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news/2013/12/why-meat-eats-resources/.

79 Morgan, *supra* note 67; Mimi Bekhechi, *Five Things Would Happen if Everyone Stopped Eating Meat*, INDEP. (Jan. 31, 2016), https://www.independent.co.uk/voices/five-things-would-happen-if-everyone-stopped-eating-meat-a6844811.html.

80 POPULATION DIV., UNITED NATIONS DEP'T OF ECON. & SOC. AFFAIRS, WORLD POPULATION PROSPECTS: THE 2017 REVISION 1 (2017), https://population.un.org/wpp/Publications/Files/WPP2017_KeyFindings.pdf.

81 Morgan, *supra* note 67; Nathan Halverson, *The World Already Would Be Out of Water if Everyone Ate Like Americans*, REVEAL NEWS (Apr. 22, 2016), https://www.revealnews.org/blog/the-world-wouldve-already-run-out-of-water-if-everyone-ate-like-americans/.

82 Halverson, *supra* note 81.

83 Morgan, *supra* note 67; *Our Meatless Future: How The $1.8T Global Meat Market Gets Disrupted*, CB INSIGHTS (Nov. 13, 2019), https://www.cbinsights.com/research/future-of-meat-industrial-farming/?utm_source=CB+Insights+Newsletter&utm_campaign=999f46e7e8-FriNL_03_16_2018&utm_medium=email&utm_term=0_9dc0513989-999f46e7e8-89466837.

84 Marybeth Feutz, *Beef Cattle Life Stages*, MY FEARLESS KITCHEN, https://www.myfearlesskitchen.com/beef-cattle-life-stages/ (last visited Apr. 16, 2020) ("[Cows fed with feedlot] are fed and taken care of until they reach around 1000–1200 pounds, which is usually around 18 months old.… Because [grass fed cows] don't receive the same amount of calories every day as their grain-fed counterparts, they are often closer to three years old before they reach their finished weight.").

85 Danelle Wolford, *How to Raise Meat Chickens: Part 1*, WEED'EM & REAP, https://www.weedemandreap.com/raise-meat-chickens-part-1/ (last visited Apr. 16, 2020).

86 Damien Gayle, *Artificial Meat Grown in a Lab Could Become a Reality This Year*, DAILY MAIL (Jan. 17, 2012), https://www.dailymail.co.uk/sciencetech/article-2087837/Test-tube-meat-reality-year-scientists-work-make-profitable.html.

87 LIZ SPECHT & CHRISTIE LAGALLY, GOOD FOOD INST., MAPPING EMERGING

Another rallying cry in support of cell-based meats is that they may reduce environmental impacts.[88] As climate change worsens, reducing greenhouse gas emissions that contribute to the problem should be a priority for developed nations because their intellectual, financial, and technological resources put them in the best position to do so.[89] The current estimate is that the world needs to cut about 40 percent of global greenhouse gas emissions by 2050 to avoid a global crisis.[90]

Livestock is a significant contributor to greenhouse gas emissions.[91] Farming livestock produces around 14.5 percent of global greenhouse gas emissions.[92] The gases produced include carbon dioxide, methane, and nitrous oxide, and the total production is around 7.1 gigatonnes of gases per year.[93] Stem cells' exponential multiplication means that the cells of only 150 cows could be needed to feed the entire world; food manufacturers currently require 1.5 billion cows to partially feed the world.[94] However, cell-based meats will not solve the climate change problem entirely. Still, cell-based meats cutting into the livestock market can only help in the battle to reduce the effects of climate change, even if it is only by a reduction in a few percentage points of emissions.[95]

Finally, animal rights activists are excited about this technology because it

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INDUSTRIES: OPPORTUNITIES IN CLEAN MEAT 1–2 (2017), https://www.gfi.org/images/uploads/2017/06/Mapping-Emerging-Industries.pdf.

88 Bahar Gholipour, *Lab-Grown Meat May Save a Lot More than Farm Animals' Lives*, NBC NEWS (Apr. 6, 2017), https://www.nbcnews.com/mach/innovation/lab-grown-meat-may-save-lot-more-farm-animals-lives-n743091.

89 *Id.*

90 Andrea Thompson, *Major Greenhouse Gas Reductions Needed by 2050: IPCC*, CLIMATE CENTRAL (Apr. 13, 2014), http://www.climatecentral.org/news/major-greenhouse-gas-reductions-needed-to-curtail-climate-change-ipcc-17300.

91 Mario Herrero, *To Reduce Greenhouse Gases from Cows and Sheep, We Need to Look at the Big Picture*, CONVERSATION (Mar. 21, 2016), http://theconversation.com/to-reduce-greenhouse-gases-from-cows-and-sheep-we-need-to-look-at-the-big-picture-56509.

92 P.J. GERBER ET AL., FOOD & AGRIC. ORG. OF THE UNITED NATIONS, TACKLING CLIMATE CHANGE THROUGH LIVESTOCK: A GLOBAL ASSESSMENT OF EMISSIONS AND MITIGATION OPPORTUNITIES 15, 107 (2013) (explaining the updated report on greenhouse gas emissions is generally consistent with the previous study indicating livestock emissions contributed to 18 percent of greenhouse gas emissions, but the two figures cannot be accurately compared given their different data inputs in calculating this amount); Herrero, *supra* note 91.

93 GERBER ET AL., *supra* note 92, at 15; Herrero, *supra* note 91.

94 Post, *supra* note 4, at 29–30 (explaining the economic efficiency of cultured beef is contingent upon reducing the production costs of developing it); Cassiday, *supra* note 46.

95 Hanna Tuomisto & M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, 45 ENVTL. SCI. & TECH. 6117, 6117 (2011); AMY L. LUERS ET AL., UNION OF CONCERNED SCIENTISTS, HOW TO AVOID DANGEROUS CLIMATE CHANGE: A TARGET FOR U.S. EMISSIONS REDUCTIONS 2 (2007), https://www.ucsusa.org/resources/target-us-emissions-reductions ("To meet this minimum target, the United States must reduce its emissions an average of 4 percent per year starting in 2010.").

ensures that no actual animals are caged in close, unsanitary conditions or abused in any manner.[96] This should ease consumer concerns about animal husbandry, thereby opening a whole new market of meat products to those who did not previously eat meat due to abuse, raising conditions, or other ethical concerns.[97]

However, opponents of this technology focus on how cell-based meats are simply theoretical; thus, any hopes that a product can tackle some of the biggest issues faced by modern humanity are purely conjectural.[98] The cost of the meat and the cost of energy to grow the meat would cancel out any environmental or efficiency argument.[99] In addition, cell-based meat arguments do not account for the fact that the rest of the cow is used to create other products.[100] The byproducts made from the cow include leather, soaps, cosmetics, pet food, fertilizer, vaccines, and prescription medicines.[101]

Even though other valid arguments related to uses of the animal carcass exist against the current state of cell-based meat technology, this technology will only continue to improve to increase the efficiency and lower the environmental impact of the process.[102] In addition, if the cell-based meat technology takes off as its proponents claim, society can expect some market corrections to the leather industry where there will still be enough cows raised for these purposes and for meat, or other forms of synthetic leather created.[103] Some companies are innovating to produce these other byproducts with just the cells from animals and without harvesting the animals.[104] For example, Modern Meadow has developed a process to use genetically engineered yeast to produce bovine collagen.[105] That collagen is then assembled into layers of leather that can be worked like traditional leather.[106]

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96 *Cellular Agriculture: The Future of Food*, CELL AGRI, https://www.cell.ag/cellular-agriculture-future-of-food/ (last visited Apr. 13, 2020); *PETA's 'In Vitro' Chicken Contest*, PETA, https://www.peta.org/features/vitro-meat-contest/ (last visited Apr. 13, 2020).

97 *See Cellular Agriculture: The Future of Food*, *supra* note 96.

98 Suzanne Jacobs, *Lab-Grown Meat Could Be the Future—If We Can Figure Out How to Make It Not Gross*, VOX (Aug. 15, 2015), https://www.vox.com/2015/8/15/9149725/laboratory-meat.

99 Cassiday, *supra* note 46.

100 *Id.*

101 *Id.*; Daniel Marti et al., *Beef and Pork Byproducts: Enhancing the U.S. Meat Industry's Bottom Line*, USDA (Sept. 1, 2011), https://www.ers.usda.gov/amber-waves/2011/september/beef-and-pork-byproducts/.

102 *See* Cassiday, *supra* note 46.

103 *Id.*

104 *Id.*

105 *Id.*; *Our Technology*, MOD. MEADOW, http://www.modernmeadow.com/our-technology/ (last visited Apr. 13, 2020).

106 Cassiday, *supra* note 46; *Our Technology*, *supra* note 105.

A. Food Safety

In addition to the environmental benefits, experts also believe that cell-based meats could be safer than traditional meats.[107] *Salmonella* and *Escherichia coli* are always a concern when preparing traditional meats for consumption because these bacteria exist in nearly all livestock meats and can be transferred to humans if the meat is not cooked properly.[108] When people ingest *Salmonella* or *E. coli*, they can experience a wide range of symptoms from mild discomfort to severe dehydration.[109] This is also known as food poisoning.[110]

Not all strains of these bacteria cause illness.[111] The human body has strains of *E. coli* within its normal biome.[112] Similarly, cattle and poultry also have certain strains of these bacteria in their respective systems that are not pathogenic to them.[113] However, the *E. coli* found in their gastrointestinal track is pathogenic to humans.[114] These specific strains of *E. coli* can contaminate food, like ground beef, during the food processing stage.[115]

It takes a few days for the bacteria to promulgate enough to cause harm to the human body.[116] This is when it is called food poisoning.[117] If enough people get sick, then the manufacturer may recall the product, which is a costly process.[118] The USDA published figures showing that, in 2018, there were 31 beef recalls amounting to 13,185,563 pounds of product lost and 34 poultry recalls amounting to 1,214,839 pounds of product lost.[119]

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107 Cassiday, *supra* note 46.

108 *Id.*; *E. coli*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/e-coli/symptoms-causes/syc-20372058 (last visited Apr. 13, 2020); *Salmonella Infection*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/salmonella/symptoms-causes/syc-20355329 (last visited Apr. 13, 2020).

109 *Food Poisoning Symptoms*, CDC, https://www.cdc.gov/foodsafety/symptoms.html (last updated Oct. 11, 2019).

110 Brandon Baker, *How to Avoid Food Poisoning from E. coli and Salmonella*, PENN TODAY (June 5, 2018), https://penntoday.upenn.edu/news/how-avoid-food-poisoning-e-coli-and-salmonella.

111 *Id.*

112 *Id.*

113 *Id.*; *What Foodborne Organisms Are Associated with Meat and Poultry?*, AM. MEAT SCI. ASS'N (Nov. 12, 2015), https://meatscience.org/TheMeatWeEat/topics/meat-safety/article/2015/11/12/what-foodborne-organisms-are-associated-with-meat-and-poultry.

114 Baker, *supra* note 110.

115 *Id.*; *How Food Gets Contaminated—The Food Production Chain*, CDC, https://www.cdc.gov/foodsafety/production-chain.html (last updated Sept. 5, 2017).

116 Baker, *supra* note 110.

117 *Id.*

118 *Id.*; Jessica White-Carson, *Understanding Food Recalls: The Recall Process Explained*, FOOD SAFETY NEWS (Aug. 12, 2013), https://www.foodsafetynews.com/2013/08/understanding-food-recalls-the-recall-process-explained/.

119 *Summary of Recall Cases in Calendar Year 2018*, USDA FSIS,

The introduction of pathogens into food will not be a problem for cell-based meat products.[120] Since cell-based meats are grown in sterile conditions, scientists can test for and prevent contamination before the product goes to market.[121] The introduction of cell-based meats to market may reduce the incidents of commercial pathogen or other emerging diseases, which are linked to livestock farming.[122] The ability to control exactly what is in the food product throughout all stages of growth will save costs by avoiding the expensive recalls and preventing illness.[123]

In addition, cell-based meats could help reduce the growing concern of superbugs that has resulted from widespread antibiotics use in livestock.[124] When an antibiotic is overused without killing off all the intended bacteria, the remaining bacteria develop genes that make the bacteria resistant to further drug treatments.[125] Bacteria also possess the ability to give these drug resistant genes to neighboring bacteria.[126] Thus, the drug resistance spreads to all the surviving bacteria.[127] Resistant bacteria are found in livestock, meat, and people worldwide.[128] Farmers or doctors must find different or new antibiotics to effectively treat illnesses caused by these drug-resistant bacteria.[129] Bacteria that are resistant to two or more antibiotics are called superbugs.[130]

Superbugs are a serious concern for the public health and medical community. About two million people get sick from superbugs annually and, of those, about

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https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-summaries (last updated June 14, 2019).

120 Cassiday, *supra* note 46.

121 *Id.*

122 Mark Post, *Cultured Meat from Stem Cells: Challenges and Prospects*, 92 MEAT SCI. 297, 297 (2012).

123 *Id.*

124 Cassiday, *supra* note 46.

125 Jodi A. Lindsay & Matthew T.G. Holden, *Understanding the Rise of the Superbug: Investigation of the Evolution and Genomic Variation of Staphylococcus aureus*, 6 FUNCTIONAL & INTEGRATIVE GENOMICS 186, 186 (2006).

126 *Id.*

127 *Id.*

128 Caroline Plante, *In the Race to Fight Antibiotic Resistance, the Livestock Industry Can Be a Game Changer*, STAT (Jan. 12, 2017), https://www.statnews.com/2017/01/12/antibiotic-resistance-livestock-industry/.

129 Laura Joszt, *Slow Uptake Among Physicians of Effective Antibiotics to Treat Superbugs*, AJMC MANAGED MKTS. NETWORK (Aug. 27, 2019), https://www.ajmc.com/focus-of-the-week/slow-uptake-among-physicians-of-effective-antibiotics-to-treat-superbugs.

130 *What's at Stake: Overuse of Modern Antibiotics Has Given Rise to "Superbugs"—Bacteria that Are Now Resistant to Numerous Antibiotics*., NRDC, https://www.nrdc.org/save-antibiotics?gclid=CjwKCAiAyeTxBRBvEiwAuM8dnbdK9UQqnNy5h-ThxsmNA7_AB-DkwotFMeixCaXwpVXleSpBbxshNxoCNasQAvD_BwE (last visited Apr. 17, 2020).

twenty-three thousand die from the pathogens.[131] Therefore, coming up with new treatments and new ways to keep bacteria out of the food chain is very important.

As with normal pathogens, cell-based meats are not susceptible to superbugs infiltrating the product.[132] For example, Memphis Meats claims that neither antibiotics nor growth hormones are required in its process because of the sterile lab conditions.[133] Therefore, there is no risk of antibiotic resistance being created in cell-based meats because there is no introduction of antibiotics into the product.[134] In addition, sterile laboratory conditions eliminate the risk of any superbug being in the food product itself.[135] Thus, the growth of cell-based meats would stop the cycle of creating food-based pathogens and eliminate the introduction of superbugs into food.[136]

The sterile conditions in which the cell-based meats are grown, cultivated, and processed reduce the risk of food-based pathogens.[137] Not only do they reduce the risk of these pathogens, but they also reduce the creation of bacteria that are resistant to multiple antibiotics.[138] The increased level of food safety will put consumers at ease and save manufacturers money that would have gone to the recall of their respective products.[139]

B. Novel Foods

Meats grown in a lab have the potential to be healthier than those that are traditionally harvested.[140] The manufacturers can alter the cell culture or a cell's genomic makeup so that cell-based meats would be fortified with beneficial vitamins and fatty acids.[141] For example, omega-3s found in fatty cold-water fish could be produced by cow cells which would increase the nutritional value of

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131 *Stop the Spread of Superbugs: Help Fight Drug-Resistant Bacteria*, NEWS IN HEALTH (Feb. 2014), https://newsinhealth.nih.gov/2014/02/stop-spread-superbugs.

132 SPECHT & LAGALLY, *supra* note 87, at 2.

133 Cassiday, *supra* note 46; Marta Zaraska, *Lab-Grown Meat Is in Your Future, and It May Be Healthier than the Real Stuff*, WASH. POST (Mar. 2, 2016), http://tinyurl.com/WP-labmeat.

134 Zaraska, *supra* note 133.

135 Cassiday, *supra* note 46; Zaraska, *supra* note 133.

136 Cassiday, *supra* note 46; Zaraska, *supra* note 133.

137 Cassiday, *supra* note 46; Zaraska, *supra* note 133.

138 Cassiday, *supra* note 46; Zaraska, *supra* note 133.

139 Cassiday, *supra* note 46.

140 *Id.*

141 *Cellular Agriculture: The Future Food*, NEW HARVEST, https://www.new-harvest.org/cellular_agriculture (last visited Apr. 17, 2020) (showing examples of how scientists have modified genes to produce other types of food and drink).

the cow product.[142] Even unhealthy saturated fats could be eliminated and replaced with more healthy polyunsaturated fats.[143] The combinations are limitless. Theoretically, different genomes from different species' cells could be "combined to produce meat blends with new flavor, texture, and nutritional profiles."[144]

Researchers such as Liz Specht, a senior scientist at the Good Food Institute, are confident that they can alter conditions so that they can produce healthier meats, stating, "Clean meat version 1.0 involves recapitulating as quickly as possible the products that consumers already know and love, but for version 2.0, the question is, could we actually tailor the composition of these cells to make them, for example, healthier?"[145] Ms. Specht notes that it is possible to simply infuse fatty acids by adding the compounds to the culture growth medium.[146] Other nutrients may be effectively infused into the cell-based meat cells in a similar fashion.[147] Another way to add nutrients and fats to the cell-based meats would be to genetically modify the cells so that they produce the specific compound desired.[148]

III. THE STATE RESPONSE TO CELL-BASED MEATS

The response to cell-based meats has already begun on the state level. State lawmakers have started to propose legislative action against cell-based meats in order to protect their farmers. Bills have either been proposed or passed in Montana,[149] Kentucky,[150] North Dakota,[151] and Missouri.[152] At least thirteen state bills proposed in 2019 have to do with labeling requirements for cell-based

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142 Zaraska, *supra* note 133.
143 Cassiday, *supra* note 46.
144 *Id.*
145 *Id.*
146 *Id.*
147 *Id.*
148 *Id.*
149 H.R. 327, 66th Leg., Reg. Sess. (Mont. 2019).
150 Don Sergent, *House Bill Takes Aim at Lab-Grown Meat*, BOWLING GREEN DAILY NEWS (Feb. 25, 2019), https://www.bgdailynews.com/news/house-bill-takes-aim-at-lab-grown-meat/article_f7738485-ddb4-5f23-b5c3-411ee485996b.html; Taylor Six, *Lab Grown or Livestock? HB311 to Require Labeling of Meats*, RICHMOND REG. (Feb. 25, 2019), https://www.richmondregister.com/news/lab-grown-or-livestock/article_58ed1f0a-86c0-5e40-b81c-7af0c25e3eeb.html.
151 Jenny Schlecht, *Bill Defining Meat in North Dakota Goes to the Governor, Other States Work on Similar Efforts*, GRAND FORKS HERALD (Mar. 4, 2019), https://www.grandforksherald.com/business/agriculture/981367-Bill-defining-meat-in-North-Dakota-goes-to-the-governor-other-states-work-on-similar-efforts.
152 Zlati Meyer, *Missouri Becomes First State to Regulate Use of the Word 'Meat'*, USA TODAY (Aug. 28, 2018), https://www.usatoday.com/story/money/2018/08/28/animal-meat-missouri-law/1114285002/.

meat products.[153] In 2019, fourteen states total passed seventeen laws against cell-based meat labels.[154]

House Bill 311 in Kentucky, which was proposed in late February 2019 and signed into law on March 21, 2019, amended the state's food labeling laws.[155] A food product is now considered misbranded if "it purports to be or is represented as meat or a meat product and it contains any cultured animal tissue produced from in vitro animal cell cultures outside of the organism from which it is derived."[156] This means that all cell-based meats would need to be explicitly labeled as such on the packaging or the relevant company would face penalties from the state for misbranding a food product.[157] This is a preemptive strike against cell-based meat companies and technology in order to protect Kentucky farmers and "real" meats.[158]

Washington State has proposed a bill, the Natural Meat Protection Act, that would criminalize the sale of cell-based meats and restrict funding for the research of new technologies.[159] The bill states that "(1) [a] person may not advertise, sell, or offer for sale a cell-cultured meat product in the state of Washington [and] (2) State funding may not be appropriated or expended to fund research or development of cell-cultured meat product."[160] Lawmakers in Washington have stated that they are concerned about the safety of the lab grown product because the food product is untested.[161] As of January 2020, the bill has not made it out of the Washington House of Representatives.[162]

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153 Greg Cima, *Lawmakers Want to Restrict the Use of the Word 'Meat'*, AM. VETERINARY MED. ASS'N (Feb. 27, 2019), https://www.avma.org/javma-news/2019-03-15/lawmakers-want-restrict-use-word-meat.

154 *E.g.*, H.R. 4245, 123rd Gen. Assemb., Reg. Sess. (S.C. 2019) (amending South Carolina's food labeling laws to make it illegal to represent clean meat as a "meat" product); H.R. 327, 66th Leg., Reg. Sess. (Mont. 2019); H.R. 311, 2019 Leg., Reg. Sess. (Ky. 2019); H.R. 1400, 2019 Leg., Reg. Sess. (N.D. 2019); S. 68, 65th Leg., Gen. Sess. (Wyo. 2019); Megan Poinski, *Cell-Based Meat Products Are Years Away, So Why Are States Making So Many Laws About Them?*, FOODDIVE (Feb. 12, 2020), https://www.fooddive.com/news/cell-based-meat-products-are-years-away-so-why-are-states-making-so-many-l/571071/.

155 Sergent, *supra* note 150; H.R. 311, 2019 Leg., Reg. Sess. (Ky. 2019); Six, *supra* note 150.

156 Sergent, *supra* note 150; Six, *supra* note 150; H.R. 311, 2019 Leg., Reg. Sess. (Ky. 2019).

157 Sergent, *supra* note 150; Six, *supra* note 150.

158 Sergent, *supra* note 150; Six, *supra* note 150.

159 H.R. 1519, 66th Leg., Reg. Sess. (Wash. 2019).

160 *Id.*

161 Nathaniel Popper, *You Call That Meat? Not So Fast, Cattle Ranchers Say*, N.Y. TIMES (Feb. 9, 2019), https://www.nytimes.com/2019/02/09/technology/meat-veggie-burgers-lab-produced.html.

162 *Bill Information*, WASH. ST. LEGISLATURE (Jan. 29, 2020), https://app.leg.wa.gov/billsummary?BillNumber=1519&Year=2019&Initiative=false.

Many farm trade organizations have been vocal against this new technology.[163] For example, Kentucky Agriculture Commissioner Ryan Quarles commented on the Kentucky bill saying, "In a couple of years, lab-grown meat will be available across America. . . . It's important that we stand up and protect our cattle farmers, and it's important that consumers know the difference between a steak that comes from a farm and a steak grown in a lab."[164] This sentiment is generally shared by farm lobbyists.

Some of these bills are being challenged in court by the American Civil Liberties Union ("ACLU") and other faux meat groups like Tofurky, which produces a tofu turkey substitute that might fall within the new labeling requirements for cell-based meats.[165] The challengers state that a new Missouri law will only confuse the average consumer and discriminate against out-of-state retailers.[166] In addition, the challenge claims that "the law plays favorites to benefit the meat industry, violates free-speech, … violates a law preventing discrimination against out-of-state companies," and is too vague to follow.[167]

Pro cell-based meat groups have responded to the states' concerns by rallying lobbyists and even sending a letter to President Trump in hopes of clarifying the regulatory and legal issues surrounding the new technology.[168] Sarah Sorscher, the regulatory affairs representative for the Center for Science in the Public Interest, challenges the idea that consumers will be confused by the labeling laws.[169] Ms. Sorscher said, "We think the issue of whether they use a term like meat is a proxy for this bigger issue, which is that the meat industry is concerned about competition from these products. . . . The bills don't seem to be directed

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163 *E.g.*, U.S. CATTLEMEN'S ASS'N, PETITION FOR THE IMPOSITION OF BEEF AND MEAT LABELING REQUIREMENTS: TO EXCLUDE PRODUCTS NOT DERIVED DIRECTLY FROM ANIMALS RAISED AND SLAUGHTERED FROM THE DEFINITION OF "BEEF" AND "MEAT" (2018), https://www.fsis.usda.gov/wps/wcm/connect/e4749f95-e79a-4ba5-883b-394c8bdc97a3/18-01-Petition-US-Cattlement-Association020918.pdf?MOD=AJPERES.

164 Sergent, *supra* note 150; Six, *supra* note 150.

165 Popper, *supra* note 161; *Lawsuit Raises the Stakes in Food Fight over the Term "Meat"*, ACLU MO. (Aug. 27, 2018), https://www.aclu-mo.org/en/news/lawsuit-raises-stakes-food-fight-over-term-meat; Complaint for Declaratory and Injunctive Relief, Tofurky v. Soman, No. 4:19-cv-00514-KGB (E.D. Ark. July 22, 2019).

166 Chris Albrecht, *Tofurky and the ACLU Go to the Meat-resses in Legal Dispute with Missouri*, SPOON (Aug. 28, 2018), https://thespoon.tech/tofurkey-and-the-aclu-go-to-the-meat-resses-in-legal-dispute-with-missouri/; Complaint for Declaratory and Injunctive Relief, *supra* note 165, at 1, 15.

167 Albrecht, *supra* note 166; Complaint for Declaratory and Injunctive Relief, *supra* note 165.

168 Letter from Memphis Meats & N. Am. Meat Inst., to Donald J. Trump, U.S. President (Aug. 23, 2018), https://static1.squarespace.com/static/5674c0c22399a3a13cbc3af2/t/5b7edcd588251b2ccdb7fa47/1535040750340/Memphis+Meats+-+North+American+Meat+Institute+letter.

169 Popper, *supra* note 161.

at solving a problem in the marketplace. It is about fighting off competition."[170] Data showing that farming is becoming less viable supports Ms. Sorscher's position.[171]

IV. THE LAW: PATENT LAW, REGULATORY LAW, AND THE HATCH-WAXMAN ACT

A. Patent Law in General

Intellectual property rights are granted to any original creation of the mind in the fields of art, literature, or science to protect the work for a predetermined period of time.[172] IP rights are given to creators or inventors in the form of copyrights, patents, trademarks, or trade secrets.[173] These forms of protection trace their roots back to England and are well ingrained in our society.[174] IP rights are essential in allowing the creator or manufacturer of a work to protect his or her energy, time, and monetary investments that were poured into its creation or process without the fear of a competitor using the creator's investments to undercut them in the marketplace.[175]

All patents must be novel, useful, and non-obvious.[176] "Novel" means that the invention has not been described in a published patent application or other publication, nor in the market, before the submitted patent application.[177] When a patent is challenged, the claim of a novel patent can extend up to one year prior to the submission of the patent application.[178]

When evaluating the term "useful," the invention to be patented needs to have a purpose.[179] There are very few patent applications that have been denied

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170 Popper, *supra* note 161.
171 Gholipour, *supra* note 88.
172 Saha & Bhattacharya, *supra* note 13, at 88.
173 *Id*.
174 *Id*.
175 *See id.*
176 *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF. (Oct. 15, 2015), https://www.uspto.gov/patents-getting-started/general-information-concerning-patents.
177 *Frequently Asked Questions on Patents*, BROWN & MICHAELS, http://www.bpmlegal.com/patqa.html (last visited Apr. 18, 2020); J. Lille Tidwell & Lance A. Liotta, *Inventions and Patents: A Practical Tutorial*, 823 METHODS MOLECULAR BIOLOGY 391, 392 (2012).
178 *Frequently Asked Questions on Patents*, *supra* note 177; *see generally* John Calvert, *The Provisional Patent Application: What You Need to Know*, U.S. PAT. & TRADEMARK OFF. (Apr. 2010), https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/provisional-patent-application-what-you-need-know.
179 *Frequently Asked Questions on Patents*, *supra* note 177; *General Information*

because the invention was not useful.[180] Almost anything that someone seeks a patent for does something that can be determined to be useful.[181]

Finally, the "not obvious" term means that the invention must be different or not obviously the same as what has come before the thing seeking to be patented.[182] The standard of judgment is from the perspective of "an ordinary person skilled in the applicable field."[183] In other words, the invention is obvious if a person, who knows the ins and outs of a certain field, "would have known to combine previously-existing inventions to result in your invention, without having seen your patent application first."[184]

The cell-based meat manufacturers will obtain patents on a number of processes and cell lines.[185] With the average patent application timeline lasting twenty-one months,[186] the manufacturers will have to plan for what they seek patents on and how they will patent their ideas.[187] When seeking patents, there are two types of patents that these meat manufacturers can obtain: utility patents and design patents.[188]

Utility patents cover machines, manufactured articles, processes, chemicals, cells lines, or any combination of these.[189] Utility patents last for at least twenty years from the initial filing or earliest priority date in a patent application to the United States Patent and Trademark Office ("USPTO").[190] However, maintaining these types of patents is not free.[191] Maintenance fees are paid

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Concerning Patents, *supra* note 176.

180 *Frequently Asked Questions on Patents*, *supra* note 177; *see generally Usefulness*, JUSTIA, https://www.justia.com/intellectual-property/patents/patentability-requirements/usefulness/ (last updated June 2019).

181 *Frequently Asked Questions on Patents*, *supra* note 177; *see generally* Michael Risch, *Reinventing Usefulness*, 2010 B.Y.U. L. REV. 1195, 1200.

182 *Frequently Asked Questions on Patents*, *supra* note 177; *General Information Concerning Patents*, *supra* note 176.

183 *Frequently Asked Questions on Patents*, *supra* note 177; Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 59 (2008).

184 *Frequently Asked Questions on Patents*, *supra* note 177; Mandel, *supra* note 183, at 59.

185 Robert Yaman, *Cell-Based Meat Patent Analysis Part 1: Memphis Meats and Just*, ROBERT YAMAN (Sept. 2, 2018), https://www.robertyaman.com/blog/clean-meat-patent-analysis-part-1.

186 *How Long Does It Take to Get a Patent?*, ERICKSON L. GROUP, PC, http://www.ericksonlawgroup.com/law/patents/patentfaq/how-long-does-it-take-to-get-a-patent/ (last visited Apr. 18, 2020); *see generally December 2019 Patents Data, at a Glance*, U.S. PAT. & TRADEMARK OFF. (Dec. 2019), https://www.uspto.gov/dashboards/patents/main.dashxml (demonstrating the average patent application timeline in December 2019).

187 *See generally How Long Does It Take to Get a Patent?*, *supra* note 186.

188 *See generally General Information Concerning Patents*, *supra* note 176.

189 *Id.*

190 *Id.*

191 *See Maintain Your Patent*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/

throughout the life of a utility patent.[192] If the fees are not paid, the patent will expire earlier than the twenty-year term.[193]

Design patents are granted to the holder when the aesthetic configuration of the patented object is novel, useful, and not obvious.[194] A design patent does not cover the function or construction of the invention like its utility patent counterpart.[195] As of 2015, they are valid for a period of fifteen years from the date of issue.[196] Unlike utility patents, there are no maintenance fees required to maintain the validity of design patents.[197]

After a patent expires, the invention is freely available to all.[198] Therefore, it is incredibly important for the holder to use the duration of the patent as efficiently as they can or they risk losing potential profits from being the sole provider of the product or licensing the subject of the patent to others.[199]

A manufacturer or inventor cannot seek a patent on the following: processes that are purely mental;[200] mathematical algorithms or formulas that do not have a real-world effect, although, "a formula or algorithm may be claimed as part of a method";[201] arrangements of printed words;[202] naturally occurring things that have not been changed;[203] and the underlying principle to a device or method

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patents-maintaining-patent/maintain-your-patent (last visited Apr. 18, 2020).

192 *See id.*

193 *Patent Maintenance Fees: Everything You Need to Know*, UPCOUNSEL, https://www.upcounsel.com/patent-maintenance-fees (last visited Apr. 18, 2020); *Maintain Your Patent*, *supra* note 191.

194 *General Information Concerning Patents*, *supra* note 176.

195 *Id.*

196 *Patent Term Calculator*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patent/laws-and-regulations/patent-term-calculator (last visited Apr. 18, 2020).

197 Joe Stone, *What Is a Lifespan of a Patent?*, CHRON, https://smallbusiness.chron.com/lifespan-patent-55972.html (last visited Apr. 18, 2020); *Maintain Your Patent*, *supra* note 191.

198 *General Information Concerning Patents*, *supra* note 176; Beverly Bird, *What Happens to a Patent When It Expires?*, LEGAL ZOOM, https://info.legalzoom.com/happens-patent-expires-20317.html (last visited Apr. 19, 2020).

199 *General Information Concerning Patents*, *supra* note 176; Bird, *supra* note 198.

200 *What Does a Patent Do: Everything You Need to Know*, UPCOUNSEL, https://www.upcounsel.com/what-does-a-patent-do (last visited Apr. 19, 2020); *see generally* Pamela Samuelson, Benson *Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025, 1034–37 (1990).

201 *How to Read an Office Action*, BROWN & MICHAELS, http://www.bpmlegal.com/howtooa3.html (last visited Apr. 19, 2020); *see generally* Samuelson, *supra* note 200, at 1034–37.

202 *How to Read an Office Action*, *supra* note 201; *see generally* Samuelson, *supra* note 200, at 1034–37.

203 *How to Read an Office Action*, *supra* note 201; *see generally* Samuelson, *supra* note 200, at 1034–37.

which, based on new scientific principles, cannot be patented.[204] Manufacturers of cell-based meats will have to walk a fine line in order to prove that cell-based meats do not merely involve a formula or a naturally occurring thing, but rather involve an object or process that can be patented so that they can keep their products protected.[205]

The patents sought for cell-based meat products could be both utility and design patents.[206] The utility patents will be for the manufacturing processes of the cell-based meats, the machines used in the process, the cell lines, and the chemicals used throughout the process.[207] Even though there is not much use for design patents in this field, there will be applications tied to how the finished meat products look.[208] Eventually, the manufacturers will want to design the meat to look like T-bone steaks or real chicken breast;[209] therefore, the manufacturers will want to have patents on those specific designs.[210]

It is generally understood that the stronger the protections available, the better these creations of the mind can be protected.[211] Specifically, strong patent laws for biotechnology creations create more incentives for research and more opportunities for securing funding, which can lead to earlier discoveries.[212] In addition, stronger biotechnology patent laws create greater public awareness of the invention because patents are disclosed to the public; this further drives the funding and incentives to create new technologies.[213]

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204 *What Does a Patent Do*, *supra* note 200; Andrew A. Schwartz, *The Patent Office Meets the Poison Pill: Why Legal Methods Cannot Be Patented*, 20 HARV. J.L. & TECH. 333, 354 (2007).

205 Yaman, *supra* note 185.

206 *Utility Patent vs. Design Patent: Everything You Must Know*, UPCOUNSEL, https://www.upcounsel.com/utility-patent-vs-design-patent (last visited Apr. 19, 2020) (explaining the difference between the two types of patents); Lawrence O. Gostin & Benjamin E. Berkman, *Pandemic Influenza: Ethics, Law, and the Public's Health*, 59 ADMIN. L. REV. 121, 134 (2007).

207 *Utility Patent vs. Design Patent: Everything You Must Know*, *supra* note 206; Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect*, 11 VA. J.L. & TECH. 1, 39 (2006).

208 *Utility Patent vs. Design Patent: Everything You Must Know*, *supra* note 206; Bijal Vakil, *Design Patents: A Growing Trend in the Hardware*, WHITE & CASE (July 29, 2019), https://www.whitecase.com/publications/article/design-patents-growing-trend-hardware-space.

209 Clara Rodríguez Fernández, *Beyond the Lab-Grown Burger: 'Cellular Agriculture' Is Taking over the Food Industry*, LABIOTECH (Apr. 9, 2019), https://labiotech.eu/features/cellular-agriculture-food-industry/ (explaining that some startups have taken on the challenge of designing cell-based meats to look like the traditional counterpart).

210 Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 93–94 (2010).

211 *The Economic Case for a Strong Patent System*, SAVE THE AM. INVENTOR (Nov. 12, 2013), https://www.savetheinventor.com/blog/economic-case-strong-patent-system.

212 Johnston, *supra* note 12.

213 *Id.*

However, strong patent laws are not without a number of disadvantages as well.[214] For example, biomedical research and methods may be restricted broadly by creating a fee that researchers must first pay.[215] Another disadvantage is that the patent incentives are wiped out if the market is not profitable.[216] A disadvantage that is also noticeable is the cost of health care may be driven up if patent holders charge excessive prices for the use of their respective inventions.[217]

A strong patent system will drive a certain industry to create more and will boost the economy of that industry.[218] However, this may cause a product to become unobtainable by the low-income population.[219] A weaker protection system allows for many players to compete in the same industry, which makes a product more widely available and affordable.[220] Thus, regulators must walk a fine line in order to promote the economy of an industry, while also ensuring products are not out of reach for some of the population due to high prices.[221]

A recent example of how strong patent laws can cause problems in biomedical research occurred with the BRCA2 gene.[222] The BRCA2 gene is a well-known gene that, when mutated, will eventually cause breast cancer.[223] Even though it was very sought after, only one company, Myriad Genetics, held the rights to

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214 *Advantages and Disadvantages of Patents*, UPCOUNSEL, https://www.upcounsel.com/advantages-and-disadvantages-of-patents (last visited Apr. 19, 2020); Robert E. Thomas, *Vanquishing Copyright Pirates and Patent Trolls: The Divergent Evolution of Copyright and Patent Laws*, 43 AM. BUS. L.J. 689, 703 (2006).

215 Emily A Largent & Holly Fernandez Lynch, *Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward*, 17 YALE J. HEALTH POL'Y L. & ETHICS 61, 102 (2017).

216 *Id.* at 75.

217 *Id.* at 87.

218 *The Patent System: Economic Benefits of the Patent System*, AUSTRALIAN L. REFORM COMMISSION, https://www.alrc.gov.au/publications/2-patent-system/economic-benefits-patent-system (last updated Aug. 2, 2010); Michael J. Malinowski & Maureen A. O'Rourke, *A False Start - The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 214 (1996).

219 Gaston Kroub, *The Cost of a Cure: Patent Rights and Drug Prices*, ABOVE THE L. (June 6, 2017), https://abovethelaw.com/2017/06/the-cost-of-a-cure-patent-rights-and-drug-prices/; Marie F. Kuczmarski, *Beverage Consumption Patterns of a Low-Income Population*, NCBI (Oct. 20, 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957908/.

220 Kroub, *supra* note 219; Lital Helman & Gideon Parchomovsky, *The Best Available Technology Standard*, 111 COLUM. L. REV. 1194, 1210 (2011).

221 R. SHERMER & CO., INTELLECTUAL PROPERTY: CHALLENGES FACED DURING DIVESTITURES FROM THE MONITOR/TRUSTEE'S PERSPECTIVE 1, 7, http://rshermer.com/images/Intellectual_Property_v2.0.pdf.

222 E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S39, S43–S44 (2010).

223 *Id.*

the gene due to extremely strong IP protections.[224] Anyone who wanted to research breast cancer and the BRCA2 gene had to either obtain permission from this company or use their services.[225] This led to scarcely any research being done on breast cancer, outside of Myriad Genetics, because the company was charging an obscene amount to allow others to use the gene in their research.[226] This monopoly alone hindered an entire area of cancer research across the nation.[227]

Eventually, a lawsuit was brought against Myriad Genetics by the Association of Molecular Pathology.[228] The suit by the Association of Molecular Pathology alleged that Myriad Genetics' patents were invalid.[229] Specifically, the association alleged that the naturally occurring products of nature, such as specific isolated genes, were unpatentable and that the diagnostic and screening tests were just basic procedures of science that did not yield any real-world transformations.[230] United States law defines patent eligible to include "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[231] However, if the property falls under an excluded category, such as a "naturally occurring article," as defined in case law, then it is not patent eligible.[232]

Association for Molecular Pathology v. United States Patent and Trademark Office[233] led to important cases, such as *Genetic Technicians v. Bristol-Myers Squibb Co.*, which defined intellectual property rights for genes and other biotechnologies.[234] In *Association for Molecular Pathology*, the court held that any naturally occurring gene may not be eligible for patent rights;[235] however, if the gene were to be modified in some way from how it occurs naturally, then there may be IP rights given to the creator.[236] Therefore, if a gene matches molecule for molecule what one could find naturally occurring in the wild, then

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224 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 587 (2013); Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost*., 43 HOUS. L. REV. 1373, 1418 (2007).

225 *Ass'n for Molecular Pathology*, 569 U.S. at 584–85.

226 Gold & Carbone, *supra* note 222, at S39, S43–S44.

227 *Id.*

228 *Ass'n for Molecular Pathology*, 569 U.S. at 576.

229 *Id.* at 596.

230 *Id.* at 595.

231 35 U.S.C. § 101 (2012).

232 *Ass'n for Molecular Pathology*, 569 U.S. at 580; Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012).

233 *Ass'n for Molecular Pathology*, 569 U.S. at 581, 587.

234 Genetic Techs. Ltd. v. Bristol-Myers Squibb Co., 72 F. Supp. 3d 521, 531, 536 (D. Del. 2014) (citing Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 576 (2013)).

235 *Ass'n for Molecular Pathology*, 569 U.S. at 580.

236 *Id.* at 590–91.

one cannot stake a claim to it.[237] The scientists had to actually change something in the DNA code in order to establish a patent claim.[238]

The rule related to gene patenting has been transferred not just to sequences of DNA, but also to patenting entire cell lines.[239] Essentially, one may patent a cell line if he or she can show that it satisfies the initial definition of a patent—novel, useful, and non-obvious—and that the cell line was created artificially.[240] Currently, there are over two thousand patented cell lines.[241] In *Sherley v. Sebelius*, two scientists questioned various stem cell lines after President Obama expanded the ability of researchers to use different lines of stem cells.[242]

More often, the courts will see suits over the patented process of creating and maintaining a cell line. For example, the United States Court of Appeals for the Federal Circuit in *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*[243] oversaw a challenge to a patented method of extracting stem cells from the umbilical cord, cryogenically freezing those cells, and then later thawing those stem cells for use.[244] These living cells can be difficult to work with and keep alive, so finding techniques to preserve, feed, and keep the cells viable for experimentation becomes more important than protecting the cell line itself.[245] If the cells cannot be kept alive, what is the point in patenting the line in the first place? A large focus of all scientists, whether in a specific industry or at a university, is on the process of how to work with their cell lines.[246]

This concept is extremely important for cell-based meat because the stem cells that will eventually become the meat or fat will need to be kept alive and viable to become the product.[247] Also, the same stem cells may be edited for faster growth or to produce vitamins, and the scientists will want to protect their

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237 *Id.* at 577, 594.

238 *Id.* at 587.

239 Jon F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 COMMUNITY GENETICS 203, 206 (2005).

240 *Id.* at 204–06.

241 *Cellosaurus Search Result*, CELLOSAURUS, https://web.expasy.org/cgi-bin/cellosaurus/search?input=patent (last visited Apr. 19, 2020) (showing a search result of 2,307 patents on cell lines).

242 Sherley v. Sebelius, 776 F. Supp. 2d 1, 4, 7 (D.D.C. 2011).

243 Pharmastem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342, 1346 (Fed. Cir. 2007).

244 *Id.* at 1366 (discussing a patent issue around a certain strain of stem cells).

245 *Id.* at 1347.

246 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 581–82 (2013); *Pharmastem Therapeutics*, 491 F.3d at 1348; Genetic Techs. Ltd. v. Bristol-Myers Squibb Co., 72 F. Supp. 3d 521, 532, 534–35 (2014); Gold & Carbone, *supra* note 222, at S43–S44; Merz & Cho, *supra* note 239, at 204–05.

247 Ginger Hultin, *Lab-Grown Meat: Exploring Potential Benefits and Challenges of Cellular Agriculture*, FOOD & NUTRITION (Feb. 27, 2017), https://foodandnutrition.org/march-april-2017/lab-grown-meat-exploring-potential-benefits-challenges-cellular-agriculture/.

specific lines of cell-based meat.[248] Overall, the scientists will want to protect the specific processes by which they create products.[249]

In addition, the cell-based meat lines, when naturally in their host animal, have all the nutrients and support systems of that animal to thrive.[250] These consist of things such as vitamins and nutrients, a constant flow of oxygen, and a medium to grow in.[251] Therefore, the scientists will have to replicate this environment to keep the cells happy and thriving.[252] This will also take specific processes that they will want to patent and protect.[253]

B. Regulatory Oversight

There has been much dispute as to which regulatory agency will oversee cell-based meat production.[254] As of late October 2018, the FDA and the USDA have decided to share this responsibility.[255] The FDA will have regulatory oversight over good manufacturing practices, the quality of the food, labeling, and every other major food regulation that would apply under the Food, Drug, and Cosmetic Act ("FDCA").[256] Under this agreement, the USDA will have regulatory authority over harvesting and marketing.[257]

The FDA will have regulatory oversight over the food product of cell-based meats.[258] This authority comes from 21 U.S.C. § 321 within the FDCA.[259] Under FDA law, there is no debate over whether cell-based meat is considered food.[260] The term "food" means: "any articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article."[261] Even as circular as this definition is, there is no doubt that cell-based meats are

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248 *Id.*

249 *See* Gold & Carbone, *supra* note 222, at S39.

250 Neil Stephens et al., *Bringing Cultured Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture*, 78 TRENDS IN FOOD SCI. & TECH. 155, 160 (2018).

251 *Id.* at 159.

252 *Id.* at 158–59.

253 *Id.* at 158.

254 John Dillard, *Who Will Regulate Lab-Grown Meat?*, DROVERS (Dec. 11, 2018), https://www.drovers.com/article/john-dillard-who-will-regulate-lab-grown-meat.

255 Sam Bloch, *Dispatch from D.C.: USDA and FDA Agree to Jointly Regulate Cell-Cultured Meat. And Yes, It's Meat*, NEW FOOD ECON. (Oct. 25, 2018), https://newfoodeconomy.org/usda-fda-lab-grown-cell-cultured-joint-regulation/.

256 *See id.*; *see also* Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301–399i (2012).

257 Bloch, *supra* note 255.

258 *Id.*

259 *See* 21 U.S.C. § 321 (2012).

260 Bloch, *supra* note 255.

261 21 U.S.C. § 321(f) (2012).

to be used for food.[262]

A company looking to get their cell-based meat approved for consumption will have to address any additives it puts in its product.[263] The term "food additive" under the FDCA means:

> Any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use).[264]

An additive in this process could be the recombinant DNA, the growth medium of the cells, or the other nutrients the cells need to become meat proteins.[265] Each of these could easily be understood as a substance which becomes a component of the food.[266] For example, the company may want to manufacture cell-based beef that has extra vitamin A, C, and D to provide for a better-balanced diet.[267] The company can do this either by adding extra vitamins to the growth medium or by adding recombinant DNA to the cells so that the cells produce the vitamins themselves.[268] In order to use this process, the manufacturers will need to get approval from the FDA under the food additive provisions because both of the additives become a component of the food.[269]

Another approval that companies may need from the FDA is processed food approval.[270] The term "processed food" means: "any food other than a raw agricultural commodity and [this] includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling."[271] This is not an exhaustive list and what is considered "processed"

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262 Bloch, *supra* note 255.

263 *See* 21 U.S.C. § 321(s) (2012).

264 *Id.*

265 VALENTIN WASCHULIN & LIZ SPECHT, GOOD FOOD INST., CELLULAR AGRICULTURE: AN EXTENSION OF COMMON PRODUCTION METHODS FOR FOOD 1, 16–17 (2018), https://www.gfi.org/images/uploads/2018/03/Cellular-Agriculture-for-Animal-Protein.pdf.

266 *See generally* 21 U.S.C. § 321(s) (2012) (defining what constitutes a food component).

267 Muhammad Sajid Arshad et al., *Tissue Engineering Approaches to Develop Cultured Meat from Cells: A Mini Review*, 3 COGENT FOOD & AGRIC. 1, 3 (2017).

268 Stephens et al., *supra* note 250, at 202; *Determining the Regulatory Status of a Food Ingredient*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/ingredientspackaging labeling/foodadditivesingredients/ucm228269.htm (last visited Apr. 19, 2020).

269 Stephens et al., *supra* note 250, at 202; *Determining the Regulatory Status of a Food Ingredient*, *supra* note 268.

270 *See* 21 U.S.C. § 321(gg) (2012).

271 *Id.*

is up for interpretation by the FDA.[272] Here, there could be a debate over whether or not cell-based meats are considered "raw agricultural commodities."[273] A raw agricultural commodity is defined as, "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing."[274] They may be considered raw agricultural commodities because the manufacturers grow the raw cells up from the primary material, much like plants are grown from seeds.[275] However, because these meats are going through many different processes like packaging, freezing, and antibacterial or antifungal treatments, it would be easy for the FDA to find that these are "processed foods."[276] Under the FDCA, a processed food is any food that is processed for consumption.[277]

C. Hatch-Waxman Primer

The FDA is unique as a regulatory agency because it has the legal framework available to handle any safety and IP challenges to cell-based meat.[278] When it comes to patent rights, the FDA has a special statute called the Hatch-Waxman Act, codified at 21 U.S.C. § 355; it modified the FDCA and was formally known as the Drug Price Competition and Patent Term Restoration Act.[279] Hatch-Waxman was a bipartisan effort undertaken by a Republican Senator from Utah and a Democratic Representative from California.[280] The act was enacted with a few goals in mind; specifically, as the FDA stated, "[The] main goal . . . in this area is to promote innovation, while also promoting rapid access to low-cost, safe and effective generic drugs."[281] It represents a bargain between the pioneer drug and the generic drug industries.[282]

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272 *Id.*; *see* 21 U.S.C. § 341 (2012) (granting the Secretary authority to define reasonable standards of identity and quality); 21 C.F.R. § 110.80 (2019) (defining the criteria for food production).

273 21 U.S.C. § 321(r) (2012).

274 *Id.*

275 21 C.F.R. § 1.227 (2019).

276 *See* 21 C.F.R. § 1.227(2) (2019).

277 21 U.S.C. § 321(gg) (2012).

278 RENU LAL, CDER SMALL BUS. & INDUS. ASSISTANCE, U.S. FOOD & DRUG ADMIN., PATENTS AND EXCLUSIVITY 1 (2015), https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307.pdf.

279 *See* 21 U.S.C. § 355 (2012); *Hatch-Waxman Letters*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters (last visited Apr. 20, 2020).

280 Erik Neumann, *How Sen. Orrin Hatch Changed America's Health Care*, HEALTH LEADERS (Jan. 2, 2019), https://www.healthleadersmedia.com/strategy/how-sen-orrin-hatch-changed-americas-health-care.

281 Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 436 (2011).

282 PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 1000 (4th

Moreover, Congress wanted to help companies get their generic drugs to market faster and to overrule *Roche Products, Inc. v. Bolar*.[283] In *Roche Products, Inc.*, the United States Court of Appeals for the Federal Circuit held that even testing a generic drug to prepare it for FDA approval while the brand drug's patent was still in effect was patent infringement under 35 U.S.C. § 271.[284] This meant that companies that wanted to create a generic drug had to wait until the corresponding brand drug's patent had expired before they could start trials or testing for purposes of the FDA's New Drug Approval ("NDA") process.[285]

Prior to the enactment of Hatch-Waxman, FDA officials developed a policy for the approval of abbreviated NDAs in 1962.[286] The policy change required that, before introduction into interstate commerce, evidence that all new drugs be "safe and effective for their intended use and recognized by the FDA as such."[287] The "safe and effective" requirement must be proven by an "adequate and well-controlled" clinical study.[288] This FDA approval with the safe and effective designation constituted part of the NDA process.[289]

Generic drug approval depends on when the FDA approves the brand drug's NDA.[290] A generic drug applicant could apply for approval with a "paper NDA."[291] An NDA applicant using a paper NDA relies upon data from "published scientific literature" to demonstrate effectiveness of the generic product, as well as the brand drug approved application.[292] However, testing can take years to complete, and an exuberant amount of money must be spent to get FDA approval of these NDAs.[293] In the past, this caused extensive delays in getting to market, which cost manufacturers money.[294] Generic drug

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ed. 2014).

283 *Id.*; *see* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).

284 *Roche Prods., Inc.*, 733 F.2d at 863.

285 *Id.* at 864; Kelly, *supra* note 281, at 424 (stating that the Hatch-Waxman Act revised portions of the patent laws and overturned *Roche Products*, which considered filing an ANDA too early as patent infringement).

286 Erika Lietzan, *ANDAs Before Hatch-Waxman*, OBJECTIVE INTENT (Aug. 19, 2017), https://objectiveintent.blog/2017/08/19/andas-before-hatch-waxman/; *The Hatch-Waxman Act: A Primer*, EVERYCRSREPORT.COM (Sept. 28, 2016), https://www.everycrsreport.com/reports/R44643.html#_Toc463343270.

287 S*ee* 21 U.S.C. § 355(d) (2012).

288 S*ee id.*

289 *The Hatch-Waxman Act: A Primer*, *supra* note 286; 21 U.S.C. § 355 (2012).

290 *The Hatch-Waxman Act: A Primer*, *supra* note 286.

291 *Id.*; 21 U.S.C. § 355.

292 *The Hatch-Waxman Act: A Primer*, *supra* note 286; 21 U.S.C. § 355.

293 *The Hatch-Waxman Act: A Primer*, *supra* note 286; 21 U.S.C. § 355.

294 *The Hatch-Waxman Act: A Primer*, *supra* note 286; 21 U.S.C. § 355.

manufacturers were dissatisfied with their disadvantage in the marketplace.[295]

If generic manufacturers did not want to pursue a paper NDA, then these manufacturers had to submit a full NDA.[296] Therefore, many brand drugs would go without a generic counterpart because of the risks of patent infringement, financial loss, and generic drug manufacturers being outcompeted by other generic drug manufacturers.[297] These risks and this fear of generic drug manufacturers created an artificial extension to the exclusivity period for the brand name drug manufacturers that was taken advantage of but was not intended by IP laws.[298]

Pioneer manufacturers, meanwhile, were frustrated that the patent life of a product was consumed by a lengthy regulatory process.[299] The pioneer manufacturers could not legally market their respective drugs without FDA approval, which increased the overall market frustration.[300] Both the pioneer brand manufacturers and the generic drug manufacturers turned to Congress for help.[301]

Under the 1984 Hatch-Waxman Act,[302] the FDA may approve a generic drug version's abbreviated NDA ("ANDA") after: "(1) all relevant product and use patents have expired for the pioneer drug and (2) all relevant periods of market exclusivity for the pioneer drug have also expired."[303] If these conditions are met, then a generic drug may be submitted for approval if the generic version is the same as the pioneer drug in all material respects.[304] In these cases, all a generic manufacturer must do to receive the FDA's approval is submit the ANDA, no "further consideration about the safety and effectiveness of the generic [drug]" is required.[305] This is because if the generic drug is the same as the pioneer drug which already showed safety and efficacy through the NDA, then there is no need to demonstrate safety and effectiveness again.[306]

If, however, the generic drug does differ from its pioneer counterpart (such as by having a different active ingredient, dosage strength, or form), then the

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295 *The Hatch-Waxman Act: A Primer*, *supra* note 286; 21 U.S.C. § 355.
296 *The Hatch-Waxman Act: A Primer*, *supra* note 286; 21 U.S.C. § 355.
297 *The Hatch-Waxman Act: A Primer*, *supra* note 286.
298 *Id.*; 21 U.S.C. § 355.
299 HUTT ET AL., *supra* note 282, at 1001.
300 *Id.*
301 *The Hatch-Waxman Act: A Primer*, *supra* note 286; 21 U.S.C. § 355.
302 21 U.S.C. § 355.
303 HUTT ET AL., *supra* note 282, at 1001; 21 U.S.C. § 355.
304 HUTT ET AL., *supra* note 282, at 1001.
305 *Id.*
306 *Id.*; *FDA Ensures Equivalence of Generic Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/resources-you-drugs/fda-ensures-equivalence-generic-drugs (last visited Apr. 20, 2020).

generic drug applicant must submit a "suitability petition" to the FDA.[307] The petition needs to demonstrate that the difference between the drug and the pioneer drug is not enough to preclude ANDA approval and that no additional studies are needed to show safety and efficacy.[308] This compromise allows a generic drug company to use the innovator's data in its submission, substantially cutting costs to generic drug manufacturers.[309]

In return for allowing generic manufacturers to use the pioneer drug data to support the ANDAs, the pioneer manufacturers receive patent-term extensions and market exclusivity.[310] The terms of a patent may be extended to compensate a patent owner when a FDA-regulated review has caused a delay in using that patent in the marketplace after it has been issued.[311] The length of the extension depends on how long the regulatory review periods last.[312] For example, the regulatory review periods for a new drug include the testing phase and the agency approval phase.[313] A drug manufacturer will submit the required Investigational New Drug ("IND") application before pre-clinical testing is performed to determine if the drug is reasonably safe for humans;[314] the period between when the IND and the NDA are filed is the testing phase.[315]

The period between filing the NDA and the FDA's approval is considered the approval phase.[316] The testing phase of a drug approval can last up to nine years,[317] and the average approval phase normally lasts less than two years.[318] The patent term extension is calculated by first reducing the extension by any time that the applicant did not act with due diligence during the approval phase, which is based on a finding by the FDA.[319] After the calculated time, if any, has been subtracted for a lack of due diligence, "one-half of the time

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307 HUTT ET AL., *supra* note 282, at 1001; *FDA Ensures Equivalence of Generic Drugs*, *supra* note 306.

308 HUTT ET AL., *supra* note 282, at 1001; U.S. FOOD & DRUG ADMIN., MANUAL OF POLICY AND PROCEDURES: ANDA SUITABILITY PETITIONS 1 (2018), https://www.fda.gov/media/86656/download.

309 HUTT ET AL., *supra* note 282, at 1001.

310 *Id.*

311 S*ee* 35 U.S.C. § 156(a)(4) (2012).

312 *See id.* § 156(c).

313 S*ee id.* § 156(g)(1)(B)(i)–(ii).

314 21 C.F.R. § 312.1(a) (2004); *Investigational New Drug (IND) Application*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application (last visited Apr. 20, 2020).

315 *See* 35 U.S.C. § 156(g)(1)(B)(i) (2012).

316 *See id.* § 156(g)(1)(B)(ii).

317 Dennis S. Fernandez et al., *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry*, IN IPHANDBOOK OF BEST PRACTICES 965–66 (2007).

318 *Id.*

319 35 U.S.C. § 156(c)(1) (2012).

remaining in the testing phase would be added to the time remaining in the approval phase"[320] and that time is given as an extension to the patent.[321]

V. CAUTIONS FOR USING THE HATCH-WAXMAN ACT AS A MODEL

The Hatch-Waxman Act has solved several issues when it comes to providing more generic drugs as a low-cost alternative to the average consumer.[322] However, the Hatch-Waxman Act contains a few loop-holes and workarounds that brand companies can abuse to make profits and delay the introduction of the generic version of a drug.[323] Brand drug companies will engage in actions such as reverse payments, citizen petitions, and product hopping in order to find loop-holes or circumvent the Hatch-Waxman Act.[324] By recognizing the ways in which these companies have taken advantage of this act, Congress and regulatory agencies can incorporate better language into legislation and formulate rules that prevent brand cell-based meat companies from delaying competitors from entering the market and holding a monopoly.[325]

A. Reverse Payments

The first and most common way brand companies circumvent the Hatch-Waxman Act is through reverse settlement payments or simply reverse payments.[326] Reverse payments are used to pay off generic drug filers seeking to enter a specific drug space.[327] Once generic drugs enter the market, they quickly take up a large portion of the market, cutting into brand companies' profits.[328] To continue making profits on their drugs, brand companies will pay

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320 *See id.* § 156(c)(2); *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program (last updated Feb. 4, 2020).

321 *See* 35 U.S.C. § 156(c)(2).

322 Danielle Perini & Katherine Vogel Anderson, *How Generic Drugs Are Made*, U.S. PHARMACIST (June 21, 2013), https://www.uspharmacist.com/article/how-generic-drugs-are-made.

323 Kieran Meagher, *Abuse of the Hatch-Waxman Act: Mylan's Ability to Monopolize Reflects Weakness*, 11 BROOK. J. CORP. FIN. & COM. L. 589, 590 (2017).

324 *Id.*

325 *See id.* at 614.

326 *Id.* at 596–97; Steven Adamson, *Pharmaceutical Patent Wars, Reverse-Payment Settlements, and Their Anticompetitive Effects for Consumers*, 30 LOY. CONSUMER L. REV. 241, 252 (2018).

327 Meagher, *supra* note 323, at 589, 596–97.

328 *Id.* at 596 (stating that once generics enter the market, they can occupy up to 44 percent of the given area).

generic filers to delay entering the market.[329] The brand companies can legally do this by suing the generic manufacturers for patent infringement, regardless of the validity of the suits, and then settling quickly with the generic manufacturers.[330] In fact, reverse payment settlements actually "cost American consumers anywhere between $0.6 billion and $7.5 billion each year, or $3.5 billion each year on average."[331]

The concern for the future cell-based meat market will be that major brand producers will want to engage in a similar practice.[332] Not only would this be bad for consumers, but this would be bad for free-market principles that guide the economy.[333] By preventing competitors from entering into the market through reverse settlement payments, a cheaper, "generic" alternative will be kept from the common consumer.[334]

Allowing reverse payments would also create a pseudo-monopoly.[335] A monopoly over this budding industry would stifle ingenuity and growth. In an industry that needs more innovation to become viable, this could be a death sentence.[336]

Therefore, Congress, the FDA, and the USDA need to ensure they include language that would prevent reverse payments.[337] Whether this is through an organic act that would give the FDA and USDA supervisory power, or by granting antitrust agencies such as the FTC the power to review the settlements, federal authorities need to learn from how companies have circumvented Hatch-

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329 *Id.* at 597.

330 *Id.*; *see* Ramsi A. Woodcock, *Uncertainty and Reverse Payments*, 84 TENN. L. REV. 99, 112–13 (2016).

331 Alyssa L. Brown, *Modest Proposals for a Complex Problem: Patent Misuse and Incremental Changes to the Hatch-Waxman Act as Solutions to the Problem of Reverse Payment Settlements*, 41 U. BALT. L. REV. 583, 590 (2012).

332 Cathy Siegner, *Perdue Farms Is the Latest Company to Target Plant-Based Meat Alternatives*, FOOD DIVE (Sept. 10, 2018), https://www.fooddive.com/news/perdue-farms-is-the-latest-company-to-target-plant-based-meat-alternatives/531801/.

333 *See Pay for Delay*, FED. TRADE COMMISSION, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay (last visited Apr. 20, 2020).

334 *FTC Enters Global Settlement to Resolve Reverse-Payment Charges Against Teva*, FED. TRADE COMMISSION (Feb. 19, 2019), https://www.ftc.gov/news-events/press-releases/2019/02/ftc-enters-global-settlement-resolve-reverse-payment-charges.

335 Joshua D. Wright, Comm'r, Fed. Trade Comm'n, Remarks at the Antitrust Masters Course VII (Oct. 10, 2014).

336 Nicole Manuel, *How Does a Monopoly Affect Business and Consumers?*, CHRON (Jan. 25, 2019), https://smallbusiness.chron.com/monopoly-affect-business-consumers-70033.html; *see generally Hospitals & Monopoly*, OPEN MKTS., https://openmarketsinstitute.org/explainer/hospitals-and-monopolies/ (last visited Apr. 20, 2020) (explaining the impact of monopolies in the medical provision).

337 Tracey Toll, *Pharmaceutical Reverse Payment Settlement Agreements and a Proposal for Clarifying the Application of Antitrust Law Rule of Reason Analysis to These Agreements*, 15 HOUS. J. HEALTH L. & POL'Y 281, 284–85 (2015).

Waxman to prevent the same kind of actions.[338] Reverse settlements would be greatly detrimental to the industry and to consumers.

B. Citizen Petitions

A second way brand companies circumvent the Hatch-Waxman Act is through citizen petitions.[339] Congress has allowed any citizen to petition an agency;[340] citizens may petition agencies to take or refrain from taking certain administrative actions.[341] Pursuant to the Administrative Procedure Act ("APA"),[342] the FDA must give the public a right to petition an agency action.[343] Citizen petitions were intended to open a line of communication between the public and the agency so that all important information concerning the agency action is presented to the agency.[344]

Brand companies have been able to use these citizen petitions as a tactic to delay agency actions, such as delaying the approval of competing generic drugs.[345] Some savvy companies will file a 505(q) citizen petition with the FDA.[346] These citizen petitions are mostly used to delay generic drug entry.[347] When a citizen petition is filed, the FDA must respond within one hundred and fifty days after the filing date.[348] A brand company will typically file a petition a few weeks before a final decision on a generic ANDA, forcing the FDA to respond to the petition before it completes the generic drug's approval.[349] This is an effective tactic for pushing back the approval of the generic drug's ANDA.[350]

This tactic involves what is known as an " 'eleventh hour' petition because companies would file them 'on the eve of drug approval for the purpose of

338 *Id.*
339 Meagher, *supra* note 323, at 600.
340 *Id.*
341 *Id.*
342 Administrative Procedure Act, 5 U.S.C. §§ 551–559 (2012).
343 *Id.* § 553(e).
344 Scott Gottlieb, Deputy Comm'r for Med. & Sci. Affairs, Food & Drug Admin., Remarks Before Annual Generic Drug Forum (Apr. 7, 2006).
345 Meagher, *supra* note 323, at 600.
346 *Id.*
347 *Id.*
348 *Id.*; *see also* Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Pub. L. No. 112-144, 126 Stat. 993 (codified as amended at 21 U.S.C. § 355 (2012)).
349 Meagher, *supra* note 323, at 600.
350 *Id.* at 600–01; Eric Sagonowsky, *UPDATED: FDA's New Citizen Petition Rules Remove Speed Bumps for Generic, Biosim Approvals*, FIERCEPHARMA (Nov. 9, 2016), https://www.fiercepharma.com/pharma/fda-changes-citizen-petition-rules-to-avoid-undue-generic-delays.

delay.' "[351] Citizen petitions are long and complex.[352] Thus, the generic drug's approval is often delayed for the full one hundred and fifty days.[353] This tactic effectively delays the approval of generic drugs and circumvents the amended application process which Hatch-Waxman was designed to accelerate.[354]

The concern for legislation protecting cell-based meat intellectual property and encouraging competitors to enter the market is that brand companies will use citizen petitions to delay the approval of any other "generic" version of cell-based meat.[355] Being delayed up to half a year has a major effect on profits that generic companies could earn and profits that brand companies could retain.[356]

Any legislation would need to prevent or limit this stalling tactic in order to encourage fair market competition, to protect intellectual property rights, and to aid the consumer.[357]

C. Product Hopping

The final way a company may circumvent the Hatch-Waxman Act is through "product hopping."[358] Product hopping is a strategy used when a brand company's patent exclusivity is about to expire, allowing for generics to seek an ANDA to enter the market.[359]

The brand company will pull the brand drug from the market and quickly

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351 Meagher, *supra* note 323, at 600–01.

352 *Id.* at 601.

353 *Id.* at 600.

354 *Id.*

355 Elaine Watson, *Future Meat Technologies Raises $14m to Commercialize Cell Cultured Meat: 'We See a Path to Reality Here, It's Not Just Something on a Power Point Presentation,' Says S2G Ventures*, FOODNAVIGATOR-USA (Oct. 11, 2019), https://www.foodnavigator-usa.com/Article/2019/10/11/Future-Meat-Technologies-raises-14m-to-commercialize-cell-cultured-meat.

356 Sarah Zhang, *How Pharma Companies Use 'Citizen Petitions' to Keep Drug Prices High*, THE ATLANTIC (Mar. 8, 2017), https://www.theatlantic.com/health/archive/2017/03/pharma-citizen-petitions-drug-prices/518544/.

357 Ben Hargreaves, *US FDA to Crackdown on Citizen Petition 'Loophole' Hindering Generic Entry*, OUTSOURCING-PHARMA.COM (Oct. 4, 2018), https://www.outsourcing-pharma.com/Article/2018/10/04/US-FDA-to-crackdown-on-citizen-petition-loophole-hindering-generic-entry (explaining that the FDA is working on informal rulemaking to slow down or stop the abuse of citizen petitions).

358 New York *ex rel.* Schneiderman v. Actavis PLC, 787 F.3d 638, 638, 643 (2d Cir. 2015); *see generally* Phebe Hong, *Stopping the Pharmaceutical "Product Hopping"*, BILL OF HEALTH (Oct. 11, 2019), https://blog.petrieflom.law.harvard.edu/2019/10/11/stopping-the-pharmaceutical-product-hop/ (explaining that product hopping occurs when a "pharmaceutical manufacturer winds down production of an old drug formulation whose patent expiration date has passed or is approaching. The company then forces or persuades patients to switch prescriptions to the drug's new—and newly patented—formulation.").

359 Meagher, *supra* note 323, at 605.

substitute the drug for the company's own generic version.[360] This forces consumers to use the company's generic drug instead, which allows the brand company to continue its monopoly over a specific part of market.[361]

Product hopping was addressed in the case of *New York v. Actavis*.[362] In *Actavis*,[363] an antitrust action was commenced against Actavis.[364] Namenda IR was the Defendant's drug designed to treat Alzheimer's disease, but it was close to the end of its patent exclusivity period.[365] Actavis introduced a new version of the drug called Namenda XR.[366] The new version of the drug still had exclusivity through patents.[367] This would restrict other companies from introducing other generic versions of the same drug to the market for many years.[368] To avoid competition, Actavis "decided to withdraw virtually all Namenda IR from the market in order to force Alzheimer's patients who depend on Namenda IR to switch to XR before generic IR becomes available."[369] This product hopping by Actavis restricted any generic competition on its drug, and the cost of having the patients switch drugs "further ensure[d] that Defendants would maintain their effective monopoly in the relevant drug market beyond the time granted by their IR patents" and the Hatch-Waxman Act.[370]

The Court of Appeals for the Second Circuit held that "a scheme to coerce patients to switch from an old product to a new one, by withdrawing from the market with an intent to affect generic competition, violated antitrust laws."[371] Even though antitrust laws have made this tactic effectively illegal, the Hatch-Waxman Act does not prevent this tactic,[372] and because it is not prevented by Hatch-Waxman itself, the FDA will not catch drug companies using product hopping.[373] Companies can therefore product hop for years before they are sued and challenged in court.[374] As a result, brand companies will reap more rewards

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360 *Id.*

361 *Id.*

362 *Actavis PLC*, 787 F.3d at 650; *see* Justine Amy Park, Note, *Product Hopping: Antitrust Liability and A Per Se Rule*, 35 CARDOZO ARTS & ENT. L.J. 745, 745–46 (2017) (explaining the second circuit's holding in *Actavis*, which was that "product hopping," a scheme to force people to switch from an old product to a *new* one, was a violation of antitrust laws).

363 *Actavis PLC*, 787 F.3d 638.

364 *Id.* at 642.

365 *Id.* at 642, 649.

366 *Id.* at 642.

367 *Id.*

368 *Id.*

369 *Id.*

370 *Id.* at 642–43.

371 Meagher, *supra* note 323, at 605; *Actavis PLC*, 787 F.3d at 652, 654.

372 Meagher, *supra* note 323, at 606; *see* Hatch-Waxman Act, 21 U.S.C. § 355 (2012).

373 Meagher, *supra* note 323, at 606.

374 *Id.*

in profits and recognition than they will pay out in fines levied for antitrust violations.[375]

Congress will have to include anti-product hopping language in any legislation it enacts.[376] If cell-based meat brand companies could pull their products and introduce modified versions in order to keep exclusivity on their products, cell lines, or growth processes, major companies could secure monopolies over their respective areas of the market.[377] If these monopolies were to fly under the radar of federal regulators, this would keep prices higher for consumers and inhibit critical innovation.[378]

The Hatch-Waxman Act has made great headway in encouraging competition in the drug markets and cutting costs to consumers.[379] Furthermore, lessons learned about how companies have worked around the act can be used by Congress and regulatory agencies when enacting new legislation or promulgating new rules.[380] If federal authorities want to protect secondary, "generic" cell-based meat companies looking to compete in the budding market, then rules and laws should be implemented to inhibit reverse payments, citizen petitions, and product hopping. By preventing these tactics, monopolies can be prevented, costs can be cut, and innovation can be encouraged.[381]

VI. ANALYSIS OF POTENTIAL PATENT PROBLEMS RELATED TO CELL-BASED MEATS

Legislation such as the Hatch-Waxman Act solved many issues for both brand and generic drug manufacturers by creating an extended period for companies to maintain their patents on drugs while these drugs went through an FDA

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375 *Id.*

376 Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168–69, 205 (2016) (proposing ways to end product hopping in addition to antitrust laws).

377 *See* Babak Kusha, *Future Foods - A Patent Landscape Study*, KILPATRICK TOWNSEND & STOCKTON LLP (Sept. 12, 2019), https://www.gaba-network.org/Files/Events/Presentations/FutureFoodsPatentLandscape-BabakKusha.pdf; *see generally* Carrier & Shadowen, *supra* note 376, at 171–72, 174, 177–78 (explaining the consequences of product hopping in regard to drug companies, such as being able to keep exclusivity and a monopoly).

378 Carrier & Shadowen, *supra* note 376, at 182–83.

379 *Id.* at 190.

380 Philip S. Johnson, *Hatch Amendment Would Preserve Balanced Incentives for Pharmaceutical Innovation and Drug Affordability*, HEALTH AFF. BLOG (Nov. 9, 2018), https://www.healthaffairs.org/do/10.1377/hblog20181106.217086/full/ (showing that Congress is considering amendments to end the accidental loopholes created by the Hatch-Waxman Act).

381 *Id.*

approval process.[382] With the framework of Hatch-Waxman in mind, Congress could create a new amendment to the FDCA that would give a time extension to cell-based meats patents.[383]

As stated above, there will be many regulatory approval stages that cell-based meat manufacturers will have to go through before they can introduce their products into interstate commerce.[384] The FDA will oversee areas such as lab safety (including clean working areas and good manufacturing processes),[385] cell collection from animals, maintaining a clean and unadulterated cell-bank,[386] and ensuring a clean cell-growth and differentiation process for public safety.[387]

Even though the FDA has the infrastructure in place and the knowledge base to handle these inspections and approvals,[388] this new technology will not come without some hiccups. FDA inspectors will need to familiarize themselves with the terminology of the various scientific moving parts, the inspection schemes will need to be optimized for the most efficient flow of a visit, and the scientists who have never before been inspected by the FDA, let alone a federal government agency, will need to adapt and change the way in which the company stores and communicates information about its growth process.[389] All of these moving parts will create delays and increase the time it takes for lab-grown meat manufacturers to get their products to grocery store shelves.[390]

In addition to FDA approval of the processes and quality of lab-grown meats, manufacturers will also need approval from the Food Safety and Inspection

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382 21 U.S.C. § 355(j) (2012).

383 *Id.*

384 *See Development & Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/developmentapprovalprocess/default.htm (last visited Apr. 20, 2020).

385 *See generally Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/guidanceregulation/guidance documents/ucm2005190.htm (last visited Apr. 20, 2020) (providing guidelines for FDA lab conditions and safety protocols).

386 *See generally* CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., FDA PUBLIC MEETING TRANSCRIPT: FOODS PRODUCED USING ANIMAL CELL CULTURE TECHNOLOGY 26–28, 43, 86 (2018), https://www.fda.gov/media/115122/download (outlining FDA procedures for food manufactured from animal cells).

387 *See generally id.* at 95, 147 (outlining FDA procedures to ensure clean cell-growth and differentiation in food manufactured from animal cells).

388 *See Biotechnology Inspection Guide (11/91)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074181.htm (last updated Sept. 2, 2014).

389 *See generally* U.S. FOOD & DRUG ADMIN., INVESTIGATIONS OPERATIONS MANUAL: CHAPTER 5 – ESTABLISHMENT INSPECTIONS (2020), https://www.fda.gov/media/76769/ download (outlining FDA procedure for conducting inspections).

390 Lauren Stine, *FDA and USDA Create Framework for Cell-Cultured Meat Regulation, But Labeling, Social License Still Uncertain*, AGFUNDER (Mar. 11, 2019), https://agfundernews.com/fda-and-usda-create-framework-for-cell-cultured-meat-regulation-but-labeling-social-license-still-uncertain.html.

Service ("FSIS"), an agency of the USDA.[391] After the FDA's inspection and approval, there will be a transition from the FDA to the USDA for oversight at the cell harvest stage.[392] The USDA will then oversee the production and labeling of the lab-grown meats.[393] Although the USDA has the appropriate infrastructure for handling labeling and food production oversight, this infrastructure is currently organized and designed around living animals.[394] The USDA is not experienced in working in a pure laboratory setting.[395] This will provide a few extra hurdles to overcome when deciding what is going to be on a label and how the harvesting of the product will occur.[396] This will initially cause delays as there will inevitably be some trial and error to optimize the system for reporting and the collection of information.[397]

This transition of regulatory oversight is also something that the government and the FDA have experience in through coordinated frameworks.[398] There are many areas in which different government agencies share responsibilities.[399] For example, the Federal Insecticide, Fungicide, and Rodenticide Act has led to an understanding that the FDA and EPA will jointly regulate antimicrobial agents depending upon the use.[400] The most complicated uses involve antimicrobials

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391 *See Labeling/Label Approval*, U.S. DEP'T OF AGRIC., https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling (last visited Apr. 20, 2020).

392 *Formal Agreement*, *supra* note 18.

393 *Id.*

394 *See id.* (outlining what the USDA-FSIS will do under the agreement, with most of the USDA-FSIS's functions being related to "livestock").

395 *See id.* (outlining the statutory responsibilities of the USDA, none of which pertain to laboratory work); *see also* NATHANIEL HIGGINS ET AL., U.S. DEP'T OF AGRIC., ECONOMIC EXPERIMENTS FOR POLICY ANALYSIS AND PROGRAM DESIGN: A GUIDE FOR AGRICULTURAL DECISIONMAKERS 7 (2017) (noting that while the USDA will do some research experiments in a laboratory environment, field experiments are important, especially in economic and government policy research, since naturally occurring environments offer variables that cannot be replicated in laboratory conditions).

396 *See Formal Agreement*, *supra* note 18 (noting that the USDA will have to coordinate with the FDA on most decisions pertaining to labeling and harvesting the product).

397 *See id.* (formalizing in the agreement that the FDA and USDA will work together in transferring regulatory oversight to the USDA).

398 Memorandum from John P. Holdren et al. on Modernizing the Regulatory System for Biotechnology Products 2–3 (July 2, 2015).

399 *See generally* Memorandum of Understanding Among Dep't of Health & Human Servs. (Food & Drug Admin.), Dep't of Agric. (Animal and Plant Health Inspection Serv., Biotechnology Regulatory Servs.), and Envtl. Prot. Agency (Office of Chem. Safety and Pollution Prevention, Office of Pesticide Programs) (Aug. 31, 2016) (outlining EPA, FDA, and USDA shared responsibilities for implementing the Coordinated Framework for Regulation of Biotechnology); *see also* Mei Jen Hung & David H. Rosenbloomn, *Administrative Law and Culture for the U.S. Collaborative Governance State*, 2009 J. DISP. RESOL. 1, 8 (2009) (noting that for government agencies to function properly and minimize disputes, they should consider sharing power with other agencies).

400 U.S. ENVTL. PROT. AGENCY, PESTICIDE REGISTRATION MANUAL: CHAPTER 18 - OTHER

being used in or on food.[401] These include uses such as:

> [The] treatment of raw agricultural commodities in a food processing facility [with antimicrobial agents]; [the] application of an antimicrobial agent to process water in a food processing facility and control a pest in the water (e.g., pulp and paperboard use, use in cane-sugar and beet-sugar mills); [the] production of food packaging; [the] production of food contact articles other than food packaging; no intended effect on the surface of the article.[402]

Sharing the regulation of bioengineered meats is not a new concept for the FDA, as the agency has regulated genetically engineered meats for decades.[403] An example of this is AquAdvantage Salmon, more commonly referred to as GE Salmon.[404] Even though the IP rights tied to GE organisms are still being worked out in the courts,[405] the GE Salmon model could parallel how the FDA and USDA share the responsibility of regulating cell-based meats.[406]

To illustrate this point further, the executive branch's biotechnology coordinated framework policy has played a large part in the United States' bioengineered product regulation.[407] Initially integrated in June 1986 as the Coordinated Framework for Regulation of Biotechnology, three agencies—the USDA, FDA, and EPA—would share the responsibility for implementation policies regarding biotechnology and recombinant DNA ("rDNA") products.[408] Recombinant DNA are DNA sequences that have been artificially made by adding in a segment of DNA from one organism's genome to another organism's DNA sequence.[409] Recombinant DNA products can be transgenic plants,

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FEDERAL OR STATE AGENCY REQUIREMENTS (2020), https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency.

401 *Id.*

402 *See generally* 21 C.F.R. §§ 175–178 (2019) (providing sections of regulations pertaining to antimicrobials used in food or food packaging); *see also* PESTICIDE REGISTRATION MANUAL: CHAPTER 18 - OTHER FEDERAL OR STATE AGENCY REQUIREMENTS, *supra* note 400.

403 *FDA Approves 1st Genetically Engineered Product for Food*, L.A. TIMES (Mar. 24, 1990), http://articles.latimes.com/1990-03-24/news/mn-681_1_genetically-engineered-product-for-food.

404 *See* Matthew Morgan, *The AquAdvantage Salmon: Who Owns Escaped Genetically Modified Animals?*, 17 OCEAN & COASTAL L.J. 127, 137 (2011); *see also* Mark Summerfield, *Patented 'Frankenfish' Finally Granted FDA Approval*, PATENTOLOGY (Nov. 21, 2015), https://blog.patentology.com.au/2015/11/patented-frankenfish-finally-granted.html.

405 Morgan, *supra* note 404, at 138.

406 *Formal Agreement*, *supra* note 18.

407 John P. Holdren et al., *supra* note 398, at 2.

408 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302–23,304 (June 26, 1986).

409 Suliman Khan et al., *Role of Recombinant DNA Technology to Improve Life*, 2016 INT'L J. GENOMICS (SPECIAL ISSUE) 1, 2–3.

bacteria, or pesticides.[410] These products are found widely in modern society.[411]

The coordinated framework resolved jurisdictional disputes among the agencies over biotechnology products that fell within the jurisdiction of multiple agencies, and it established the basis for much of the rDNA and biotech regulation that exists today.[412] In fact, "Since announcement of the coordinated framework, federal regulators have cleared the way for hundreds of new agricultural, health care, and industrial products, including dozens of plants modified through modern biotechnology."[413] For example, a policy that came out of the coordinated framework was that the USDA would "regulate plants grown to produce food or feed," and the FDA "would have jurisdiction over the food or feed itself."[414]

However, plant issues and similar issues were not addressed in the coordinated framework.[415] The coordinated framework left certain issues open, such as how to handle transgenic plants that were modified to resist disease and ward off insect pests because such plants technically fall under the jurisdiction of all three agencies.[416] It took nearly fourteen years for the three agencies to finally come to a conclusion on how to regulate these cross-cutting issues with an update in 2000,[417] and the agencies still needed to amend and update the coordinated framework again in 2017 to further resolve disputes over regulation.[418]

Due to the decades-long disputes over jurisdictional issues that could not easily be solved, there were a number of delays in biotech and rDNA products coming to market.[419] These errors and delays tied to multi-agency regulations can be minimized if agencies clearly state and focus on their individual missions, invite discussions at earlier stages, and promptly comply with their end of the coordinated framework.[420]

In the future, a joint regulation between the FDA and the USDA over cell-

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410 *See generally id.* (describing products that utilize rDNA technology).

411 *See id.* (describing products that utilize rDNA technology).

412 COMM. ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 144 (2000).

413 *Id.*

414 *Id.*; *Formal Agreement*, *supra* note 18.

415 GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION, *supra* note 412, at 144.

416 *Id.* at 145.

417 *Id.*

418 Memorandum for Heads of Food & Drug Admin., Envtl. Prot. Agency, and Dep't of Agric. Regarding Modernizing the Regulatory System for Biotechnology Products to the Exec. Office of the President (July 2, 2015).

419 GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION, *supra* note 412, at 178–79.

420 *Id.* at 178–81.

based meats will give rise to similar jurisdictional disputes when these meat products attempt to come to market. These disputes could result in delays during the handoff of the approval process stage.[421] For example, what constitutes a good manufacturing process and what constitutes harvesting may become points of contention under current FDA and USDA definitions.[422] Thus, when a company submits its process, there may be some dispute as to whose job it is to give the approval and what exactly is approved.[423]

Meanwhile, the patent for the company's manufacturing process will continue to run while these jurisdictional issues are worked out between the FDA and the USDA. The Hatch-Waxman Act provides a good example for Congress to follow in authorizing the FDA to give cell-based meat producers an extension on their patents for both processes and cell lines while the companies are awaiting FDA approval.[424]

One way to address time loss on a patent is Congress could allow for time to be added back to each of the company's patents as an extension[425] while the cell-based meat manufacturers are awaiting FDA and USDA approval of the manufacturing process (collection stage, growth stage, and harvesting stage) and labeling requirements.[426] Time could also be reduced for a lack of action on the part of the manufacturers so that active participation of the manufacturers can be ensured; the FDA could do this as it already has experience in this area.[427]

The alternative to not having legislation that extends the length of patents on cell-based meats is relying on the general timeframe of the current patent

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421 *Id.*

422 *Facts About the Current Good Manufacturing Practices*, U.S. FOOD & DRUG ADMIN. (June 25, 2018), https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps; U.S. FOOD & DRUG ADMIN., CLASSIFICATION OF ACTIVITIES AS HARVESTING, PACKING, HOLDING, OR MANUFACTURING/PROCESSING FOR FARMS AND FACILITIES: GUIDANCE FOR INDUSTRY 8 (2016), https://www.fda.gov/media/99911/download; 21 C.F.R. § 1.227 (2019) (defining harvesting as it applies to farms and farm mixed type facilities as "activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food").

423 *See* 21 C.F.R. § 110.80 (2019); *Slaughter Inspection 101*, U.S. DEP'T OF AGRIC., https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/slaughter-inspection-101/slaughter-inspection-101 (last visited Apr. 21, 2020).

424 35 U.S.C. § 156 (2012); *2750 Patent Term Extension for Delays at Other Agencies Under 35 U.S.C. 156 [R-11.2013]*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/web/offices/pac/mpep/s2750.html (last visited Apr. 21, 2020).

425 35 U.S.C. § 156; *2750 Patent Term Extension for Delays at Other Agencies Under 35 U.S.C. 156 [R-11.2013]*, *supra* note 424.

426 *See Formal Agreement*, *supra* note 18.

427 *See generally* 35 U.S.C. § 156; *see also 2750 Patent Term Extension for Delays at Other Agencies Under 35 U.S.C. 156 [R-11.2013]*, *supra* note 424.

system.[428] As of May 2017, the average pendency of a patent application is roughly thirty-three months,[429] and right now, for drugs at least, approval takes about seven to twelve years.[430] There is no indication that the approval process for a patent tied to cell-based meats will take that long, but it is safe to assume that it will take a year or more because of the backlog in other areas of the FDA, such as drugs and devices.[431] Therefore, cell-based meat manufacturers are already looking at multiple years from the time of applying for a patent until they are able to reap the rewards and benefit from their innovations.[432]

Even when using the fastest, most generous estimate of time, the approval of the patents and approval from the FDA and USDA will still take a substantial amount of time. This could amount to at least three years of earnings that these manufacturers will have to forfeit and which investors will not be able to recover their money from.[433]

However, the shortened time, especially on the design patents, will help bring competitors into the market in a quicker way than if there were patent extensions.[434] Design patents have an average pendency anywhere from thirteen months to nineteen months.[435] If manufacturers could find a way to make design patents sufficient to protect their works, then this would increase the supply of cell-based meats brought to market.[436] The increased supply generated from

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428 Eli Lilly & Co. v. Medtronic Inc., 496 U.S. 661, 669 (1990) (addressing distortions to the normal "patent term produced by the requirement that certain products must receive premarket regulatory approval").

429 Vic Lin, *How Long Is the US Patent Application Process (How Much Time Does It Take to Get a Utility Patent)?*, PAT. TRADEMARK BLOG, http://www.patenttrademarkblog.com/how-long-us-utility-patent-application-process/ (last visited Apr. 21, 2020).

430 *See generally* Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1 An Overview of Approval Processes for Drugs*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 170, 171 (2016) ("For drugs, this process can take 10 to 15 years and cost millions of dollars.").

431 *Id.*

432 *See generally*, Dean Best, *How Can Cell-Based Food Reach Scale?*, JUST-FOOD (Oct. 23, 2019), https://www.just-food.com/analysis/how-can-cell-based-food-reach-scale_id142481.aspx (describing the risk investors take when investing in cell-based meat products).

433 *See generally id.*

434 Jeffrey Kuo, *Expedited Examination for Design Patent Applications in the USPTO*, POLSINELLI LLC (May 22, 2017), https://www.polsinelli.com/intelligence/blog-expedited-examination-for-design-patent.

435 U.S. PATENT & TRADEMARK OFFICE, FY 2018 PERFORMANCE AND ACCOUNTABILITY REPORT 56 (2018), https://www.uspto.gov/sites/default/files/documents/USPTOFY18PAR_1.pdf.

436 *See* Scott J. Allan et al., *Bioprocess Design Considerations for Cultured Meat Production with a Focus on the Expansion Bioreactor*, FRONTIERS IN SUSTAINABLE FOOD SYS. (June 12, 2019), https://doi.org/10.3389/fsufs.2019.00044.

competitors would then drive down costs.[437] The biggest concern of the cell-based meat market is the cost of the meats per pound; in 2019, it was estimated that the first meat product to market would cost about fifty dollars per pound.[438] This price is still much too high to even consider making a profit at this point.[439] However, in the same way generic drugs have driven down the price of brand drugs,[440] other cell-based meat manufacturers looking to scale up manufacturing will cause the price of cell-based meats to drop.[441]

Even though a reduced timeframe of patents on cell-based meat products by allowing the natural course of the patent to run would be beneficial to cost and efficiencies, it is hard to say if three, four, or even five years is enough of a reduction in time to see these benefits.[442] Budding science still needs to attract market investors and manufacturers to the market.[443] Without these investors and manufacturers, there would be no incentive to even consider reducing the cost or improving the efficiency of the growing process.[444]

In addition, more competitors and investors would increase the experimentation of the processes and techniques used in the growth process.[445] This experimentation would help develop better manufacturing processes and more efficient collection, growth, and harvesting processes.[446] This increased efficiency would also help drive down the cost of cell-based meat products and increase their availability to consumers.[447]

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437 Adam Hayes, *Economics Basics: Supply and Demand*, INVESTOPEDIA, https://www.investopedia.com/university/economics/economics3.asp (last visited Apr. 21, 2020) (discussing the supply and demand curve on market economics).

438 Purdy, *supra* note 41.

439 *See id.*

440 Dena Bunis, *AARP Report: Generics 18 Times Cheaper Than Brand-Name Drugs*, AARP (Apr. 8, 2019), https://www.aarp.org/politics-society/advocacy/info-2019/drug-price-report-generics.html.

441 Clara Rodríguez Fernández, *You Will Be Eating Lab-Grown Meat Soon: Here's What You Need to Know*, LABIOTECH (Dec. 12, 2018), https://labiotech.eu/features/cultured-meat-industry/.

442 *See generally* Purdy, *supra* note 41.

443 *See* Frank Morris, *Lab-Grown Meat Draws Big Investors—And Big Opposition*, NPR (Dec. 16, 2018), https://www.npr.org/2018/12/16/677157694/lab-grown-meat-draws-big-investors-and-big-opposition.

444 *See generally id.*

445 *See generally* PRICEWATERHOUSECOOPERS, GROWTH REIMAGINED: PROSPECTS IN EMERGING MARKETS DRIVE CEO CONFIDENCE 11 (2011), https://www.pwc.com/gx/en/ceo-survey/pdf/14th-annual-global-ceo-survey.pdf; *Does Competition Drive Innovation?*, EDISON AWARDS, http://www.edisonawards.com/news/competition-drive-innovation/ (last visited Apr. 22, 2020).

446 *See* Allan et al., *supra* note 436.

447 Passant Rabie, *The Truth About Lab-Grown Meat*, SCIENCELINE (Jan. 16, 2019), https://scienceline.org/2019/01/the-truth-about-lab-grown-meat/.

VII. CONCLUSION

Strong patent protections allow for innovators and manufacturers to create and produce without the fear of being undercut or have their work stolen.[448] Also, strong patent protections incentivize investments in new technologies, thereby spurring newer, faster innovations.[449] Currently, there is nothing more innovative than the science-fiction like cell-based meats.[450] As this young area of food science is starting to bud, society needs to ensure that there are sufficient patent protections and incentives available to allow this market to find its niche.[451]

Fortunately, Congress has already worked to protect areas of new and upcoming technology.[452] Congress has experimented and has come to a reasonable solution in the world of drug development.[453] Using the current drug regulatory sphere and the Hatch-Waxman Act as a framework, we can transpose that on the novel and innovative area of cell-based meats.

The FDA and USDA will share regulatory oversight over the cell-based meat products.[454] This joint regulatory oversight will come with delays due to the general approval process as well as jurisdictional questions.[455] Therefore, Congress should consider giving back time on the cell-based meat patents due to these delays.[456] This will allow for a fairer market and stronger protections for those companies manufacturing these meat products.

Because the FDA already has the legal framework in place to handle both public health and patent challenges,[457] Congress should use the patent extensions given to drug manufacturers in the Hatch-Waxman Act as a future legislative guide to give patent extensions to cell-based meat manufacturers.[458] In doing so, Congress should give the FDA the responsibility of designating the time extension as well.[459] This would allow for a smoother transition for the new act of Congress and, therefore, a more efficient process of giving the patent extensions to manufacturers seeking to enter the cell-based meat market.

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448 *The Economic Case for a Strong Patent System*, *supra* note 211.
449 *Id.*
450 *See* Shapiro, *supra* note 8.
451 *See* Saha & Bhattacharya, *supra* note 13, at 88.
452 *See* 21 U.S.C. § 355 (2012); Kelly, *supra* note 281, at 418.
453 *See generally* 21 U.S.C. § 355; Kelly, *supra* note 281, at 417.
454 *Formal Agreement*, *supra* note 18.
455 *See id.*
456 *See generally* 35 U.S.C. § 156 (2012); *see generally 2750 Patent Term Extension for Delays at Other Agencies Under 35 U.S.C. 156 [R-11.2013]*, *supra* note 424.
457 *See* 21 U.S.C. § 355.
458 *See id.*
459 *See* 35 U.S.C. § 156.