Beef, It's What's for Dinner in the Patent Office: A Call for Resolving Selective Breeding as Invention

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ABSTRACT: It has long been assumed that animals cannot be patented by man unless they have been genetically engineered to make them different than what is found in nature. This rule excludes animals that are selectively bred through traditional means from patent eligibility. This assumption is now being challenged, as what many thought was an obscure theory is being tested in the patent office by cattle breeding companies. This Note argues that selectively bred animals are patent-eligible, but Congress should amend the statute to protect the livestock industry and prevent further consolidation that livestock patents would cause.

[*] J.D. Candidate, The University of Iowa College of Law, 2024. This Note is dedicated to my father, Nathan Mass, a cattle farmer who inspired me to research this topic. Additional thanks to J. Steele Kowalczyk, Michael Woo, Katie Foley, and the staff of the *Iowa Law Review* for their feedback that helped me crystallize this Note into what it is today.

INTRODUCTION

This Note argues that judicial interpretation of the patent-eligible subject matter requirements under 35 U.S.C. § 101 allows for the patenting of selectively bred animals. Strong public policy arguments, however, suggest that Congress should act to exclude these animals from patent protection. This Note begins by outlining how the Patent Trial and Appeal Board ("PTAB") and Federal Circuit have moved toward an explicit allowance of patent eligibility for selectively bred animals despite contrary assumptions that only genetically engineered animals meet the requirements of patent eligibility.[1] Allowing patents based upon selective breeding would exacerbate problems in the livestock industry by promoting greater consolidation.[2] To solve this problem, Congress should amend Title 35 to exclude selectively bred animals from the realm of patent-eligible subject matter.[3]

Companies specializing in animal genetics, inspired by the successful utilization of utility patents to protect plant genetics, are attempting to push the envelope of patent eligibility. Historically, animals were categorically excluded from patent eligibility because they were products of nature rather than of human invention.[4] But in 1980, the Supreme Court held that animals were patent-eligible if they were somehow changed by man to be different from how they existed in their natural state.[5] Legal scholars have generally interpreted this decision to mean that animals modified by genetic engineering are patent-eligible, but animals whose genes were selected through traditional breeding techniques are not.[6] Yet this assumption

1. *See infra* Part I.

2. *See infra* Part II.

3. *See infra* Part III.

4. *See, e.g.*, *Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123, 125.

5. *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that animals are not categorically patent ineligible—rather animals that have made substantively different than those found in nature, like a bacteria modified to eat oil, are inventions eligible for patent).

6. For example, see the confusion over the patent office's notice allowing eligibility over "nonnaturally occurring non-human multicellular living organisms, including animals" and the plaintiffs' and court's focus on "genetically altered animals." Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 928, 932 (Fed. Cir. 1991); *see also* Keith Schneider, *New Animal Forms Will Be Patented*, N.Y. TIMES (Apr. 17, 1987), https://www.nytimes.com/1987/04/17/us/new-animal-

overstates the case law. Neither the PTAB nor the Federal Circuit has held that only genetically modified animals are patent-eligible, and the patent office has granted patents based upon selective breeding.[7] Rather, the case law allows for the possibility of other non-naturally occurring animals fitting within patent eligibility. Now, livestock genetics companies like ABS Global are filing and arguing patent eligibility for their animals and genetics.[8]

If selectively bred animals are patent-eligible, then we should expect that large animal genetics companies will begin to patent their elite genetics because patents offer superior protection to the existing contract-based remedies that are currently prevalent in the animal husbandry market.[9] Due to the economic infeasibility of small breeders paying high costs associated with patent prosecution, large livestock genetic firms can use patent protection as a sword to disrupt the current market balances and disadvantage small farmers.[10]

While recent movement to patent eligibility for selectively bred animals seems legally correct, the courts may be able to limit many of the practical problems of patenting selectively bred animals through proper interpretation barring claims for progeny.[11] If the courts do not step in (or cannot address the problem adequately), Congress can and should amend the patent eligibility criteria codified in 35 U.S.C. § 101.[12] In the past when Congress has faced strong policy reasons for excluding patent protection from categories of inventions, it has passed statutes to exclude these categories from eligibility.[13] Similarly, Congress should exclude inventions based merely upon selective breeding and solidify what many assumed to be the case as black letter law. Alternatively, Congress could create a new, specially tailored system to protect animal genetics akin to what exists for protection of plant traits to address the specific public policy concerns that arise from utility patents for selectively bred animals.[14]

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forms-will-be-patented.html (on file with the *Iowa Law Review*) ("'This [acceptance of animal patents] won't affect our policy that products found in nature, such as farm animals produced by natural breeding, are not considered patentable,' said Mr. Van Horn of the Patent Office."); Paul Blunt, Note, *Selective Breeding and the Patenting of Living Organisms*, 48 SYRACUSE L. REV. 1365, 1366 n.2 (1998) ("Though there is no explicit judicial holding directly on point, the consensus is that the holdings in *Chakrabarty* and *Ex parte Allen* were limited to genetically engineered animals.") (citing SARAH E. TAYLOR, CONG. RSCH. SERV., IB87222, PATENTING LIFE 5–6 (1988); Diana A. Mark, *All Animals Are Equal, but Some Are Better than Others: Patenting Transgenic Animals*, 7 J. CONTEMP. HEALTH L. & POL'Y 245, 253 n.56 (1991)).

7. *See infra* Section I.B.

8. *See, e.g.*, U.S. Patent No. 10,975,351; U.S. Patent No. 10,982,187.

9. *See infra* Part II.

10. *See Animal Legal Def. Fund*, 932 F.2d at 931–32 (describing the concerns of farmers and related groups over livestock patentability).

11. *See infra* Section III.A.

12. *See infra* Section III.B.

13. *See infra* Section III.B.1.

14. *See infra* Section III.B.2.

I. PUSHING THE BOUNDARIES OF ELIGIBILITY

Historically, patents were not considered to cover animals because living creatures were seen as products of nature rather than inventions produced by human ingenuity, but this understanding of § 101 changed when the Supreme Court decided *Diamond v. Chakrabarty* in 1980.[15] Following this decision, genetically engineered animals were clearly patent-eligible, and selectively bred animals received at least one patent though there was no clear ruling from the PTAB or a court.[16] Most recently, a cattle genetics company tried a new approach and successfully patented two of its animals by claiming their cells.[17] These patents were disclaimed before the PTAB could rule on their validity,[18] but they suggest a new and likely successful mechanism for achieving animal patents. Animal patents along these lines, because of the superior legal right guaranteed, have the potential to disrupt existing mechanisms in the industry for protecting the investments of livestock breeders.[19]

A. THE HISTORY OF ANIMAL PATENTS IN THE UNITED STATES

Congress has the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[20] Congress has exercised this power to give patent eligibility to inventions that are a "process, machine, manufacture, or composition of matter."[21] While the term "composition of matter" includes much of what can be invented and discovered, it does not include naturally occurring physical phenomena.[22] Because animals are naturally occurring physical phenomena, scholars and attorneys generally viewed animals and animal genetics to be excluded from patent protection.

Patent prosecutors began to challenge the assumption that nonplant lifeforms were not patent-eligible, culminating in the Supreme Court case of *Diamond v. Chakrabarty*.[23] In *Chakrabarty*, an inventor applied for a patent on a bacterium that had been genetically modified to consume oil.[24] The Court

15. *See infra* Section I.A.

16. *See infra* Section I.B.

17. *See infra* Section I.C.

18. *See generally* Petitioner's Request for Rehearing, Select Sires Inc. v. ABS Glob., Inc., No. PGR2022-00019 (P.T.A.B. July 28, 2022), https://s3-us-west-1.amazonaws.com/ptab-filings%2FPGR2022-00019%2F11 [https://perma.cc/8JHJ-PMBN] (requesting a rehearing despite the patents being disclaimed).

19. *See infra* Section I.D.

20. U.S. CONST. art. I, § 8, cl. 8.

21. 35 U.S.C. § 101 (2018).

22. *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); *see also Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123, 127 (holding that a product of nature is not patent-eligible).

23. *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that human-made, genetically engineered bacterium is patent-eligible).

24. *Id.* at 305.

held that the "new bacterium [had] markedly different characteristics from any found in nature," and so it was patent-eligible.[25]

The dominoes quickly began to fall within the patent office after *Chakrabarty*. Soon, the Board of Patent Appeals and Interferences, an administrative board within the U.S. Patent and Trademark Office ("USPTO"), applied the rule and overturned an examiner's rejection of a patent for manipulated oysters in *Ex parte Allen*.[26] Following *Allen*, the USPTO issued a notice that it "now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101."[27] Within the next year, the office granted its first animal patent to Harvard University for a genetically modified mouse.[28] The law had changed, but the edges remained undefined.

Patent applicants and their lawyers have probed the edges of *Chakrabarty*'s holding over time, and the courts have started to fence in the realm of animal patent eligibility. The 2014 case *In re Roslin*, better known as the Dolly the Sheep case, gave the Federal Circuit its latest opportunity to fence in the doctrine.[29] After *Roslin*'s application of *Chakrabarty*, the test for animal patents is whether a claimed animal has "markedly different characteristics from any [farm animals] found in nature."[30] Dolly was a genetic clone of a preexisting sheep, and therefore she was not markedly different from her precursor and could not be patent-eligible.[31] While the process and technology behind cloning is patent-eligible, the cloned animals themselves remain outside the fence.

In another area, Congress has fenced in the undefined edges of the markedly different characteristics test. The America Invents Act forbids the patentability of any "claim directed to or encompassing a human organism."[32] As such, the USPTO rejects any application for transgenic animals that do not carve out coverage over human animals.[33] Aside from these notable exceptions though, few limits have been imposed upon animal patents, and the markedly

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25. *Id.* at 310.

26. *Ex parte* Allen, No. 86-1790, 1987 WL 123816, at *2 (B.P.A.I. Apr. 3, 1987) ("[T]he claimed polyploid oysters are non-naturally occurring manufactures or compositions of matter . . . .").

27. Animals – Patentability, 1077 OFF. GAZ. PAT. & TRADEMARK OFF. OG 24, OG 24 (Apr. 21, 1987).

28. Daniel J. Kevles, *Of Mice & Money: The Story of the World's First Animal Patent*, DAEDALUS, Spring 2002, at 78, 78.

29. *See In re* Roslin Inst. (Edinburgh), 750 F.3d 1333, 1337 (Fed. Cir. 2014).

30. *Id.* (quoting *Chakrabarty*, 447 U.S. at 310).

31. *Id.* at 1339.

32. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284, 340 (2011).

33. This prohibition may not be as impregnable as the bare statutory language may seem. Dennis Crouch, *Patents Encompassing a Human Organism*, PATENTLYO (Dec. 2, 2012), https://patentlyo.com/patent/2012/12/ex-parte-kamrava.html [https://perma.cc/S8WQ-R5DL] (criticizing the PTAB's use of § 33(A) as a grounds for ineligibility because it claimed a "catheter . . . further comprising an embryo in the distal portion" (quoting *Ex parte* Kamrava, No. 2010-010201, 2012 WL 6108089, at *6 (P.T.A.B. Nov. 26, 2012))).

different characteristics standard remains an open range. As expressed by Justice Burger, patent eligibility applies broadly to "anything under the sun that is made by man."[34]

So far, there has been no widespread use of gene editing on higher order livestock animals, such as cattle. New technologies like CRISPR, however, have the potential to allow for much easier and more efficient modification of animal genomes beyond mice and fruit flies.[35] Research is already underway to apply CRISPR gene editing to livestock, such as poultry, sheep, goats, and cattle.[36] As such research comes to its fulfillment, we may soon see an explosion of patents for transgenic, that is, genetically modified, livestock as we enter the CRISPR age. Notably, the Food and Drug Administration's Center for Veterinary Medicine has expressed that it is preparing for the regulatory challenges it sees coming from CRISPR-edited livestock.[37]

B. SELECTIVE BREEDING AS PRODUCING MARKEDLY DIFFERENT CHARACTERISTICS

Beyond the patentability of transgenic animals, it is questionable whether animals selectively bred for specific traits may be different enough from those found in nature to satisfy patent eligibility requirements. Selective breeding is defined as "the process of modifying the characteristics of living things especially to enhance one or more desirable traits by selection in breeding controlled by humans."[38] It is the process by which animal breeders, such as farmers and ranchers, have developed their herds and improved the quality of the animals they've raised for thousands of years.[39] Most have seen the

34. *Chakrabarty*, 447 U.S. at 309 (quoting S. REP. NO. 1979, at 4 (1952)).

35. *See* CONG. RSCH. SERV., IN10610, CRISPR: A REVOLUTIONARY TOOL FOR EDITING THE CODE OF LIFE? (2016).

36. *See* Collins N. Khwatenge & Samuel N. Nahashon, *Recent Advances in the Application of CRISPR/Cas9 Gene Editing System in Poultry Species*, FRONTIERS GENETICS, Feb. 19, 2021, at 1, 2; Peter Kalds et al., *Sheep and Goat Genome Engineering: From Random Transgenesis to the CRISPR Era*, FRONTIERS GENETICS, Sept. 3, 2019, at 1, 2.

For cattle, the American Angus Association recently took no action on a first-of-its-kind request to allow an Intentional Genomic Alteration ("IGA") in registered Angus cattle. Letter from the Am. Angus Ass'n Bd. of Dirs. to the Am. Angus Ass'n Membership (June 9, 2023), https://www.angus.org/pub/LetterfromthePresident_June2023.pdf [https://perma.cc/GK53-7QKH]. The slick shear gene allows cattle to blow their winter coats in the summer and therefore manage heat better. *Id.* The gene edit would therefore ensure that the edited bovine would have that gene turned "on." *See id.*

37. *See* Laura R. Epstein, Stella S. Lee, Mayumi F. Miller & Heather A. Lombardi, *CRISPR, Animals, and FDA Oversight: Building a Path to Success*, PNAS, Apr. 30, 2021, at 1, 3.

38. *Selective Breeding*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/selective%20breeding [https://perma.cc/NG8E-QS2E].

39. *Selective Breeding*, ENCYCLOPEDIA.COM (May 17, 2018), https://www.encyclopedia.com/plants-and-animals/agriculture-and-horticulture/agriculture-animals/selective-breeding [https://perma.cc/99LC-7CN9].

process of selective breeding as outside the patent eligibility expansions embraced by *Chakrabarty* and *Ex parte Allen* (the modified oysters case).[40]

However, patent applicants have begun to challenge this assumption. In 1997, the USPTO granted U.S. Patent No. 5,602,302 (hereinafter "the '302 patent") to Hiroki Mikami for "[b]ronchial hypersensitive guinea pigs prepared by . . . identifying guinea pigs with bronchial hypersensitivities, and . . . brother-sister mating or selectively mating" them to generate the population of the claimed guinea pigs.[41] The patent received no litigation or further review after allowance to solidify precedent.[42] But upon issue, patents are given a presumption of validity,[43] which means the assumption against patentability would have flipped for these guinea pigs had the Mikami patent been challenged.

In 1999, Frank Ditto applied for a patent on a breed of cat "called [a] Pixie-Bob, a cross between bobcats and domestic cats."[44] The examiner rejected the application on multiple grounds, including lack of patent eligibility as nonstatutory subject matter since the cat was a product of nature.[45] The PTAB then affirmed these rejections.[46] In finding that the breed was a product of nature, the Examiner relied upon the fact that the mating of bobcats and housecats was known to occur in the wild.[47] On review, the Federal Circuit affirmed the rejection on other grounds but did not reach the rejection under § 101.[48] As a result of this case, we see that the PTAB has not categorically ruled out selective breeding as an invention and seems open to the idea if it produces an animal with markedly different characteristics than those found in nature. Here, the Board found that it did not.[49] Further, while

40. Blunt, *supra* note 6, at 1366 n.2 ("Though there is no explicit judicial holding directly on point, the consensus is that the holdings in *Chakrabarty* and *Ex parte Allen* were limited to genetically engineered animals.").

41. U.S. Patent No. 5,602,302 (filed Dec. 30, 1993).

42. *See US-5602302-A – Models for Asthma Guinea Pig*, UNIFIED PATS., https://portal.unifiedpatents.com/patents/patent/US-5602302-A [https://perma.cc/4PLY-Q43C] (lacking any listing for litigation or PTAB proceedings).

43. 35 U.S.C. § 282 ("A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.").

44. *In re* Ditto, 499 F. App'x 1, 2 (Fed. Cir. 2012) (nonprecedential).

45. *Id.* at 3. In addition to the patent eligibility rejection under 35 U.S.C. § 101, the examiner rejected the application for lacking novelty under 35 U.S.C. § 102. *See id.*

46. *Id.* at 4.

47. *Id.* at 3.

48. *Id.* at 4.

49. *Id.* at 3–4.

the Federal Circuit reviews legal conclusions of the PTAB de novo,[50] it seems eager to avoid this issue where possible by deciding cases before it on other grounds.

Additionally, the Ditto application for the Pixie-Bob broadened the product-by-process format of claim language used in the guinea pig patent. Ditto's application claimed as his invention "a domestic cat breed produced by [breeding]."[51] Rather than claiming specific guinea pigs with specific traits, such as bronchial hypersensitive guinea pigs, he claimed an entire breed of animal.[52] The USPTO Solicitor distinguished Ditto's claim from the previous guinea pig claims of the '302 patent because unlike that patent, the Ditto application failed to "recite a specific desired trait and . . . a specific method of breeding used to obtain that trait" that would make the animals different from those found in nature.[53] That the USPTO's lawyer found the problem with the application to be one of adequate disclosure rather than subject matter eligibility suggests USPTO approval for this type of patent. However, the Federal Circuit never reached this argument. If a court were to adopt this reasoning, the success of an animal patent based on selective breeding may depend upon having a product by process claim satisfactorily detailed with what trait has been selected and bred.

The USPTO's Manual for Patent Examination and Procedure ("MPEP") instructs Examiners how to analyze the markedly different characteristics test in its interpretation of judicial holdings.[54] First, the Examiner must choose the counterpart.[55] When the claimed invention is derived from a naturally occurring thing, like an animal, the counterpart is the closest naturally occurring thing.[56] For an animal like Dolly the Sheep, the MPEP suggests that the counterpart should likely be another sheep of the same breed.[57] Second, the Examiner should identify the appropriate characteristics to compare.[58] The appropriate characteristics for comparison may be explicitly recited in the claim.[59] If they are not, the characteristics are those "apparent from the

50. *In re* Bd. of Trs. of the Leland Stanford Junior Univ., 989 F.3d 1367, 1372 (Fed. Cir. 2021) (detailing standards of review used for cases on appeal from the PTAB under the Administrative Procedure Act, 5 U.S.C. § 706(2)).

51. *In re Ditto*, 499 F. App'x at 1.

52. *Compare* '302 Patent (claiming specific guinea pigs with bronchial hypersensitivity or hyposensitivity), *with* U.S. Patent Application No. 09/276,137 (claiming a whole animal breed).

53. Dennis Crouch, *Patenting Animals Produced Through Selective Breeding*, PATENTLYO (Dec. 7, 2012), https://patentlyo.com/patent/2012/12/patenting-animals-produced-through-selective-breeding.html [https://perma.cc/M24X-6T99] (quoting Brief for Appellee at 22, *In re* Ditto, 499 F. App'x 1 (Fed. Cir. 2012) (No. 2012-1182), 2012 WL 5353004, at *23).

54. MPEP § 2106.04(c) (9th ed. Rev. 07.2022, Feb. 2023).

55. *Id.*

56. *Id.*

57. *See id.*

58. *Id.*

59. *See id.*

broadest reasonable interpretation" of the claim.[60] Finally, the Examiner should determine whether the claimed and counterpart's characteristics are markedly different.[61] If at least one of the characteristics is different because of the inventor's claimed disclosed efforts, then the claimed invention will "generally be considered a markedly different characteristic."[62]

This analysis is helpful in assessing why the Mikami patent for bronchial hypersensitive guinea pigs may have succeeded while Ditto's application for the Pixie-Bob failed. For the hypersensitive guinea pigs, the closest naturally occurring counterpart was another guinea pig. The characteristic to compare was the bronchial sensitivity to air pollutants. Because the claimed guinea pigs were hypersensitive, while natural guinea pigs were not—there was a marked difference. Although the Federal Circuit did not reach a markedly different characteristics analysis for Ditto, it seems that his Pixie-Bobs would have failed. The closest naturally occurring counterpart was not a bobcat or a housecat, but a crossbreed of the two as documented to have occurred in nature. Without specifically claimed characteristics to compare, the Examiner had to interpret characteristics from the broadest possible interpretation of the claim, which could have been almost any of the listed features of the breed. And because the claimed Pixie-bob was not in any material way different from a naturally occurring bobcat-house-cat crossbreed, there were no marked differences.

C. CLAIMING ANIMALS BY THEIR CELLS

Most recently, ABS Global, a cattle genetics company,[63] was granted two patents (one for a bull and one for a cow) based upon selective breeding.[64] ABS pursued a theory that by selectively breeding their cattle they had effectively created a new bull and a new cow that were different from those found in nature, satisfying the requirements of *Chakrabarty* and *Ex parte Allen*.[65] After an interview with ABS regarding § 101, the examiner gave notice of allowance and the patent office issued patents 10,975,351 B2 (hereinafter

60. *Id.*

61. *Id.*

62. *Id.* These changes must be claimed, otherwise they are merely incidental to the actual invention. *Id.* (citing *In re* Roslin Inst. (Edinburgh), 750 F.3d 1333, 1337 (Fed. Cir. 2014)). Thus, to be markedly different is to be different in a way that is substantively claimed by the patent and not inherent to the natural product. *Id.*

63. *See About*, ABS GLOB., www.absglobal.com/about [https://perma.cc/UZH7-9EQT].

64. *A.I. Stakeholders Petition U.S. Patent and Trademark Office*, SELECT SIRES (Feb. 1, 2022), https://www.selectsires.com/article/ss-blog/2022/01/31/a.i.-stakeholders-petition-u.s.-patent-and-trademark-office [https://perma.cc/449Q-2PAA].

65. *See* Pat. Owner's Opposition to Petitioner's Request for Rehearing at 8, Select Sires Inc. v. ABS Glob., Inc., No. PGR2022-00019 (P.T.A.B. Aug. 17, 2022), https://s3-us-west-1.amazonaws.com/ptab-filings%2FPGR2022-00019%2F12 [https://perma.cc/PYY4-8TCK].

"the '351 patent") and 10,982,187 B2 (hereinafter "the '187 patent").[66] The grant of patent rights in these two cases, as well as the argument put forward by the USPTO in *Ditto*, suggest that the patent office approves of claims based upon selective breeding.

However, the question remains complicated and lacks firm precedent from the PTAB or the Federal Circuit. Shortly after USPTO issued the '351 and '187 patents, Select Sires and other competitors petitioned the PTAB for a postgrant review of the two patents.[67] Before the PTAB instituted a postgrant review, ABS Global disclaimed its rights to both patents.[68] Select Sires requested a rehearing based upon ABS's filing of another application based upon the same theory.[69] The PTAB rejected this request because the disclaimer mooted the question of interpreting the patents' validity.[70]

Though the '351 and '187 patents are no longer, the legal issues they raised are far from moot. The patent office has published another application from ABS for the cells of a bull claimed along the same theory.[71] If this application proceeds to grant without an amendment that significantly limits the claims, like the '351 and '187 patents did, there will certainly be new litigation over its subject matter eligibility in the future. Therefore, the question of selective breeding remains unresolved but open for new precedent from the PTAB or Federal Circuit.

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66. Exhibit 1003 at 6, 134, Select Sires Inc. v. ABS Glob., Inc., No. PGR2022-00019 (P.T.A.B. Jan. 13, 2022), https://s3-us-west-1.amazonaws.com/ptab-filings/PGR2022-00019/1003 [https://perma.cc/9KW3-N79F]; Exhibit 1004 at 21, 133, Select Sires Inc. v. ABS Glob., Inc., No. PGR2022-00019 (P.T.A.B. Jan. 13, 2022), https://s3-us-west-1.amazonaws.com/ptab-filings/PGR2022-00019/1004 [https://perma.cc/ML2X-FSJ6].

67. Petition for Post Grant Rev. at 3, Select Sires Inc. v. ABS Glob., Inc., No. PGR2022-00020 (P.T.A.B. Jan. 13, 2022), https://s3-us-west-1.amazonaws.com/ptab-filings%2FPGR2022-00020%2F1 [https://perma.cc/BM99-YQ37].

68. Select Sires Inc. v. ABS Glob., Inc., Nos. PGR2022-00019, PGR2022-00020, at 2 (P.T.A.B. June 28, 2022), https://s3-us-west-1.amazonaws.com/ptab-filings%2FPGR2022-00020%2F10 [https://perma.cc/JPH3-ME74]. The reason for disclaiming the patents was not provided. *Id.*

69. *See generally* Petitioner's Request for Rehearing, *supra* note 18 (highlighting patent claims asserted by ABS as compared to Patent '351); Pat. Owner's Opposition to Petitioner's Request for Rehearing, *supra* note 65 (arguing that Select Sires's estoppel argument "would extend far beyond the two specific selectively-bred animals disclaimed in the Challenged Patents").

70. The PTAB said:

> We are not persuaded by Petitioner's argument that Patent Owner's pursuit of similar claims in a different patent family with a different selectively bred animal warrants entry of adverse judgment against Patent Owner here . . . [T]he claims in the '658 application are still under examination and can be amended during prosecution. Thus, any claim that ultimately issues in the '658 application may look very different than the claims of the published application.

Select Sires Inc. v. ABS Glob., Inc., Nos. PGR2022-00019, PGR2022-00020, at 5–6 (P.T.A.B. Oct. 25, 2022), https://s3-us-west-1.amazonaws.com/ptab-filings%2FPGR2022-00019%2F13 [https://perma.cc/4UL4-5HNM] (denying request for rehearing).

71. U.S. Patent Application No. 17/323,658 (filed May 18, 2021).

The claim language for the '351 and '187 patents takes an approach different from those of the guinea pig and Pixie-Bob patents. Unlike the other patents that claimed animals resulting from the process of breeding, the '351 patent claims a particular cattle cell.[72] The patent further claims a duplicate of the cell produced through "somatic cell nuclear transfer,"[73] also known as cloning, and the cells of the animal's offspring.[74] On top of all this from the patent's independent claims, its dependent claims are directed toward embryos, cell cultures and tissue, cows, heifers, bulls, semen, ovum (egg cells), and meat comprised of these cells.[75] The '187 patent and ABS's outstanding new application comprise of very similar language.[76]

Claiming an animal via its cells gives a more specific and narrower patent claim than claiming an animal through a product by process claim as detailed in the Mikami patent and Ditto application. Depositing a sample of biological material is common for biotechnology patents and is often necessary to satisfy the written description requirements of 35 U.S.C. § 112.[77] Rather than claiming a type of animal, the '351 and '187 patents claim an individual animal whose cells were deposited and its most closely related brethren (clones and first-generation offspring).[78] More limited language can make it easier to obtain a patent and harder for a patent to be challenged.[79]

However, claiming cells makes a broader claim set in other ways. Unlike the Mikami patent, the '351 and '187 patents also claim (in dependent claims) compositions of cells in forms other than what we normally think of as the animal itself.[80] These include embodiments such as reproductive cells, embryos, and meat. Additionally, claiming all cells with the same genetic information (germplasm) allows a patent to encompass more broadly the clones of the original animal, which also are composed of cells sharing the same DNA.[81] Finally, the '351 and '187 patents both include an independent

72. U.S. Patent No. 10,975,351 claim 1 (filed June 17, 2019) ("A *Bos taurus* cell comprising JE8400031460745 27 germplasm, a representative sample of JE8400031460745 27 germplasm having been deposited under ATCC accession number PTA-126146.").

73. '351 Patent claim 7.

74. '351 Patent claim 11. The '187 Patent similarly claims this. '187 Patent claim 6.

75. *See* '351 Patent claims 2–6, 8–10, 12–30.

76. *See* '187 Patent; '658 Patent Application.

77. *See* MPEP § 2403 (9th ed. Rev. 07.2022, Feb. 2023).

78. *See* '351 Patent claims 1, 7, 11; '187 Patent claims 1, 6, 12.

79. Michael K. Henry, *Claim Strategies for Patent Applications: Can Your Patent Claims Ever Be Too Narrow?*, HENRY PAT. L. FIRM (Dec. 7, 2017), https://henry.law/blog/can-your-patent-claims-ever-be-too-narrow [https://perma.cc/T5H2-F9VX] ("Narrower claims are easier to obtain and more resilient to challenges.").

80. *See* '351 Patent claims 2, 4–6, 8, 10, 12–13, 22–28, 30 (claiming embryos, ovum (also known as egg cells), sperm or semen, and meat); '187 Patent claims 2, 4–5, 8, 10, 13–20 (claiming embryos, and sperm or semen).

81. *See, e.g.*, '351 Patent claim 7.

claim over all first generation offspring of their respective animals.[82] It remains unclear how these offspring would meet the adequate disclosure requirement of 35 U.S.C. § 112 as their DNA would differ from that deposited for the patent due to half of it being inherited randomly from the offspring's other parent.

D. EXISTING METHODS FOR PROTECTING GENETICS IN THE LIVESTOCK INDUSTRY

Within livestock industries, like the cattle industry, traditional intellectual property protections such as patent rights have not been used to protect the investments of breeders in developing animals with high-quality genetics.[83] The lack of patents was based largely upon the assumption that traditional selective breeding methods were not patent-eligible.[84] As a result, livestock breeders have turned to contract law to recoup the costs of genetic development.[85]

Such shrink-wrap agreements are communicated to the buyer during the sale in a way that they can reject by refusing to bid or purchase an animal.[86] Contractual language is often communicated to buyers in sale catalogs.[87] These additional terms are usually communicated from the auction block either in addition to or superseding the terms in the sale catalog.[88]

One example of contractual protection occurs when a breeder sells a bull while retaining a semen revenue interest, which is a percentage of the revenue from the sale of any semen later collected from that bull.[89] This semen is a valuable frozen commodity that is sold to beef producers to breed, or

82. '351 Patent claim 11; '187 Patent claim 6.

83. *See* E. R. Ogden & K. Weigel, *Can You Shrinkwrap a Cow? Protections Available for the Intellectual Property of the Animal Breeding Industry*, 38 ANIMAL GENETICS 647, 647 (2007).

84. *See id.* at 649.

85. *See id.* at 650.

86. *Id.*

87. *See infra* notes 89–90, 92, 95.

88. *See, e.g.*, SITZ ANGUS, SITZ ANGUS 50TH ANNUAL FALL BULL SALE 3 (2015), https://issuu.com/livestockdirect/docs/4b083de4 [https://perma.cc/V6TP-P8A7] ("Announcements from the block will take precedence over information in this sale book."); AM. ANGUS ASS'N, BREEDER'S REFERENCE GUIDE 65 (2023), https://www.angus.org/Pub/suggested_sale_terms.pdf?v=1 [https://perma.cc/WYE2-NNRE] ("If there is any inconsistency in the terms of any sales materials, including sale books, supplement sheets or day-of-sale announcements, (i) the day-of-sale announcement will control over both the supplement sheet and the sale book, and (ii) the supplement sheet will control over the sale book."). The Suggested Terms and Conditions of the American Angus Association are often incorporated into the sales of Angus breeders, such as in the Sitz Angus catalog.

89. *See, e.g.*, SITZ ANGUS, *supra* note 88, at 3 ("Sitz Angus Ranch is retaining one-third revenue sharing semen interest in every bull selling in this sale. Full possession and full salvage value sells on all bulls."); CARDINAL CATTLE CO., THE PROGRAM BULL SALE 2 (2022), https://issuu.com/primetimeagri/docs/cardinalprogrambulls22-web [https://perma.cc/N9T2-CQQE] ("Unless otherwise stated here or from the auction stand, Cardinal Cattle Company retains a one-quarter semen interest in each bull selling.").

artificially inseminate, their heifers and cows without the physical presence of a bull.[90] Similarly, breeders selling cows may retain an interest in a flush of donor eggs from the cow.[91] Flushing fertilized embryos and eggs from a donor cow with desirable genetics allows a farmer to produce multiple calves with the donor's genetics at the same time by transferring the donor's embryo to the womb of a recipient cow that will carry the pregnancy.[92]

Residual rights for the use of cloning technology within the cattle industry is growing, especially in the realm of show calves, which are primarily sold for showing in livestock competitions.[93] When selling a high-quality show animal, breeders often retain the "cell rights" to the animal.[94] This means that, although they have sold the physical animal, they retain the right to harvest a cell sample (usually hair or blood sample) from the animal to produce a clone.

While one might maintain an interest in genetic material or some of the reproductive cells of an animal (sperm, eggs, and embryos), it remains the general rule that breeders do not retain an ownership interest in any progeny via these contractual provisions.[95] However, it is notable that ABS Global has begun to retain these ownership interests in progeny for some of their animals through the terms of service of their semen sale website.[96] These terms are

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90. *See* Glenn Selk, *Artificial Insemination for Beef Cattle*, OKLA. STATE UNIV. EXTENSION (Mar. 2017), https://extension.okstate.edu/fact-sheets/artificial-insemination-for-beef-cattle.html [https://perma.cc/WUW5-PBA5].

91. *See, e.g.*, SULLIVAN RANCH, POWER IN THE BLOOD 3 (2010), https://issuu.com/primetimeagri/docs/dsul [https://perma.cc/D3JP-C3ZT] ("Sullivan Ranch also reserves one flush of eight or more grade 1 or 2 embryos at our expense on all females selling.").

92. *See Bovine Embryo Transfer Helps ISU Veterinarians Improve Herd Genetics*, IOWA ST. UNIV. COLL. OF VETERINARY MED. (Sept. 2017), https://vetmed.iastate.edu/story/embryo-transfer [https://perma.cc/84JU-8LM2]; Abby Wendle, *America's Elite Cows Don't Give Birth — Their Surrogates Do*, NPR (May 29, 2015, 2:56 PM), https://www.npr.org/sections/thesalt/2015/05/29/410569221/americas-elite-cows-dont-give-birth-their-surrogates-do [https://perma.cc/9BKT-X7DY].

93. Livestock cloning remains an expensive option that tends to make economic sense only for animals with the most "elite" genetics. *See* Cassidy Woolsey, *Producers Share Their Experiences with Cloning*, PROGRESSIVE CATTLE (Jan. 24, 2015), https://www.agproud.com/articles/48542-producers-share-their-experiences-with-cloning [https://perma.cc/A2BG-7M9T]. However, the cost may be satisfied by the premium in value given to animals who have won a title on the show circuit. For example, the 2010 champion of the Iowa State Fair 4-H Steer Show was a clone of the 2008 champion. *Cloned Steer This Year's 4-H Grand Champion at Iowa State Fair*, TRI-STATE LIVESTOCK NEWS (Sept. 2, 2010), https://www.tsln.com/news/cloned-steer-this-years-4-h-grand-champion-at-iowa-state-fair [https://perma.cc/D5YB-PPER].

94. *See, e.g.*, E-mail from Smith Cattle Co. to Mass Farms (Sept. 18, 2022) (on file with author) ("Smith Cattle Company reserves the right to take the cell line to any animal purchased through this sale. If the cell line is wanted by the new owner or anyone involved with the calf leaving the farm, they must have the breeder's consent and permission to do so."); SULLIVAN RANCH, *supra* note 91, at 2 ("Sullivan Ranch retains at our expense the opportunity to obtain a DNA cell line for cloning purposes on all cattle selling in this sale.").

95. *See* sources cited *supra* notes 88–89, 91, 94 (lacking contractual language restricting rights of buyers over the offspring of their purchase).

96. The Terms of Service provide:

> DAIRY PROGENY: You agree to use dairy Progeny from Germplasm strictly as set

not typical for breeding animals. The unique nature of these lines for crossbred terminal animals makes giving away these rights of little importance to purchasers.

II. SELECTIVELY BRED ANIMALS ARE PATENT-ELIGIBLE, AND THAT'S A PROBLEM

It is tempting to merely follow the conventional wisdom that selectively bred animals are only products of nature and thus not patent-eligible—but such line drawing faces real legal challenges in the face of the broad language and construction of 35 U.S.C. § 101.

An apt analogy to selectively bred animals is their selectively bred counterparts in the plant kingdom. Historically, plant genetics companies have had the opportunity to protect their genetics through plant patents administered by USPTO for asexual plants like flowers[97] or plant variety protection administered by the USDA for sexually reproducing plants like those that produce seeds.[98] Plant Variety Protection includes an exemption that allows farmers to save seeds from the previous year to replant their crops.[99] The status quo changed in 2001 when the Supreme Court found that plant breeders could also protect their seeds through utility patents, which do not have an exemption from infringement for replanting crops.[100]

Other countries have grappled with the question of selective breeding as the basis for patents recently, as well. The Enlarged Board of Appeal of the European Patent Office recently faced the question of whether selectively

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> forth in this section. You grant ABS the exclusive and irrevocable right and option to test and purchase any such Progeny or make and acquire Genetic Materials from such Progeny, for so long as the Progeny is owned by you, under the procedures and prices listed on the ABS Icon Website ("Option"). . . .
>
> BEEF PROGENY: NuEra Germplasm (brand names NuEra® or InFocus®) may only be used to create a terminal crossbred Progeny (beef x dairy cross or beef x beef cross) that is [t]ransferred into the Beef Supply Chain. . . . Progeny from all other beef Germplasm may be used or sold for any purpose, including to create breeding stock or terminal animals.

Terms and Conditions, ABS GLOB., https://store.absglobal.com/terms-and-conditions [https://perma.cc/WZK5-VRB5].

97. *See* 35 U.S.C. §§ 161–63.

98. *See Plant and Plant Variety Protection*, U.S. PAT. & TRADEMARK OFF. (Aug. 25, 2021, 7:51 AM), https://www.uspto.gov/ip-policy/patent-policy/international-convention-protection-new-varieties-plants-upov [https://perma.cc/5P7H-C46L]. Following the 2018 Farm Bill, the Plant Variety Protection Act was amended to also allow for protection of asexually reproducing plants. 7 U.S.C. § 2402(a).

99. 7 U.S.C. § 2543.

100. *See generally* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001) (holding that human-modified plant genes for certain traits are eligible for utility patent protection, which, unlike plant patents and plant variety protections, do not exempt replanting of seeds from infringement); Bowman v. Monsanto Co., 569 U.S. 278 (2013) (holding that patent exhaustion doctrine does not allow a farmer to save and replant seed).

bred plants and animals were patent-eligible.[101] The European Patent Conventions ("EPC") states that "European patents shall not be granted in respect of . . . plant or animal varieties or essentially biological processes for the production of plants or animals" except microbiological processes and products.[102] The Board held that the EPC does not allow for "product claims and product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively *obtained by means of an essentially biological process* or if the claimed process features define an essentially biological process."[103] This means that to be patentable, plants and animals require "a technical process exceeding mere crossing and selection," which excludes selective breeding.[104] Europe has thus drawn the line where many commentators expected the line to be in the United States: Genetically modified animals are patent-eligible; selectively bred animals are not.

While it is tempting to suggest that U.S. courts should merely draw the judicial line here as well, Europe's patent system rests on a very different basis than the U.S. patent system. In the United States, Congress wrote a broad grant of utility patent eligibility to encompass all sorts of inventions that they knew they could not anticipate.[105] Because of this exceptionally broad grant, it seems likely that livestock are unique products of human invention. Many livestock animals have been selectively bred to the point where they bear

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101. *See generally* Opinion of the Enlarged Board of Appeal Dated 14 May 2020 G 3/19, 2020 O.J. EPO (A119).

102. Convention on the Grant of European Patents (European Patent Convention) art. 53, Oct. 5, 1973, 1065 U.N.T.S. 199.

103. Opinion of the Enlarged Board of Appeal Dated 14 May 2020 G 3/19, *supra* note 101, at 5 (emphasis added).

104. Axel Berger & Kerstin Galler, *Regarding the Patentability of Plants and Animals in Europe—The G 3/19 Decision ("Pepper") of the European Patent Office*, BARDEHLE PAGENBERG (July 27, 2020), https://www.bardehle.com/en/ip-news-knowledge/ip-news/news-detail/regarding-the-patentability-of-plants-and-animals-in-europe-the-g-3-19-decision-pepper-of-the-european-patent-office [https://perma.cc/2AY6-83XP].

105. The Supreme Court has said:

> In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope. The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." . . . Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man."

Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) (first quoting Act of Feb. 21, 1793, § 1, 1 Stat. 319; and then quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

characteristics wholly different than their wild counterparts.[106] Additionally, plant breeders are regularly granted utility patents for their plants derived from selective breeding.[107] There is little in the way of compelling legal difference between utility-patent-eligible, selectively bred plants and selectively bred animals as categories.[108] Accordingly, courts will likely find that selective breeding is an acceptable method of invention that is eligible for utility patent protection as long as the other requirements of utility, novelty, and nonobviousness are met.

Granting patent rights in animal breeding gives new and powerful bargaining power to the patentholder. While independent family farmers currently hold the power to purchase semen, embryos, or studding services from several companies or from the multitude of other independent farmers to carefully craft the genetic makeup of their herds, patents granting government-endorsed monopolies would restrict the rate at which competitors can sell animals with the same traits in the market. If a breeder today generates an animal with some superior trait, they may benefit by selling the animal's genetics to other farmers for breeding. But the original breeder will lose control as each year brings more descendants bearing the trait into the market. On the other hand, if the original breeder holds a patent on that trait or the animal itself, they can control any replication for up to twenty years and can guarantee financial benefit through the right to sue any farmer that breeds the animal or claimed offspring without a license for infringement. This ability greatly increases their bargaining power and control of the market.

This increased bargaining power becomes problematic if the patented trait is so valuable that it becomes difficult for farmers to compete unless they can breed animals that display it. For instance, beef producers receive a premium on every head that scores highly on the U.S. Department of Agriculture ("USDA") marbling score for intramuscular fat.[109] This marbling

106. *See, e.g.*, David S. Mader, Note, *Wilbur's Conundrum: Property in the DNA of Selectively Bred Animals*, 86 TEX. L. REV. 191, 208 (2007) ("Given the extensive human involvement in the selective breeding process, it is no stretch at all to suggest that, but for human intervention, any particular Thoroughbred horse would not exist. Each such horse is, in that sense, man's handiwork.").

107. *See, e.g.*, Catherine Anne Barrett, Note, *A Rose by Any Other Statute Would Smell As Sweet: Patent Protection of Ornamental Plants*, 4 KY. J. EQUINE, AGRIC., & NAT. RES. 501, 509 (2012) (discussing the selectively bred seed corn at issue in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 127–28 (2001)).

108. *Id.* at 510 (noting that the first "[s]cientific selective breeding" techniques for plants were "directly borrowed from cattle breeding techniques" and that "[i]f naturally-bred plants are considered to be made by man, then animal varieties are clearly within the subject matter of patents as well").

109. James Nason, *Angus 2019: Wider Premiums for Higher Marbling Cattle Predicted*, BEEF CENT. (May 24, 2019), https://www.beefcentral.com/news/angus-2019-wider-premiums-for-high-marbling-cattle-predicted [https://perma.cc/9AE9-U4FH] (quoting beef consultant Dick Whale, saying, "a prime carcase has been worth $550 per carcase above a one-marble score [select] carcase").

makes the meat more tender, juicier, and more flavorful.[110] If a breeder is able to patent a trait that guarantees a much higher rate of calves that score highly based upon marbling, then other breeders may find themselves unable to compete in a market where their animal's descendants consistently score lower on marbling and do not receive marbling premiums.

A similar story has already played out in the crop industry. Patenting of seeds contributed to the consolidation of seed companies into the hands of a few large conglomerates in the 1970s and early 1980s.[111] In 2001, the Supreme Court's ruling in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* allowed seed companies to prevent farmers from utilizing their traditional practice of setting aside a portion of each year's crops to plant the next year's.[112] Farmers faced a choice—continue to set aside unpatented but worse-performing seeds, or buy new, patented seeds every year. By 2015, the sale of seeds and agriculture chemicals was controlled by six companies, but after a round of mergers that finalized in 2018, they had consolidated even further into only four conglomerates.[113] Such conglomeration can be bad for farmers because it leaves them with fewer providers who are competing for their business, higher prices, and less choice. The seed market continues to face scrutiny today, as the U.S. Secretary for Agriculture has stated that he and the White House intend to investigate the industry's consolidation and look for ways to increase competition.[114]

Perhaps even more concerning for small farmers is the prospect of what could happen if genetics companies decide to license their patents only to large, vertically integrated livestock operations. Most small farmers have

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110. *See* D.B. GRIFFIN & J.W. SAVELL, TEX. A&M UNIV., UNDERSTANDING USDA BEEF QUALITY GRADES 1 (Oct. 2018), https://meat.tamu.edu/files/2018/10/Understanding-USDA-beef-quality-grades.pdf [https://perma.cc/F43F-P5TE].

111. *Patents and the Constitution: Transgenic Animals: Hearing Before the Subcomm. on Cts., C.L. & the Admin. of Just. of the H. Comm. on the Judiciary*, 100th Cong. 77 (1987) [hereinafter *Transgenic Animals Hearing*] (statement of Jack Doyle, Dir., Agric. Res. Project, Env't Pol'y Inst.).

112. *See J.E.M. Ag Supply, Inc.*, 534 U.S. at 145–46.

113. *See* James M. MacDonald, *Mergers in Seeds and Agricultural Chemicals: What Happened?*, U.S. DEP'T AGRIC. ECON. RSCH. SERV. (Feb. 15, 2019), https://www.ers.usda.gov/amber-waves/2019/february/mergers-in-seeds-and-agricultural-chemicals-what-happened [https://perma.cc/6TE7-966U].

114. Donnelle Eller & Brianne Pfannenstiel, *Tom Vilsack, in Iowa Visit, Says Biden Administration Will Look at Consolidation in Seed Industry*, DES MOINES REG. (Oct. 20, 2021, 7:19 PM), https://www.desmoinesregister.com/story/money/agriculture/2021/10/20/tom-vilsack-seed-industry-consolidation-joe-biden-administration-deere/6111624001 [https://perma.cc/UZ9P-DJTH]; *see also Biden-Harris Administration Announces Major Actions to Spur Competition, Protect Producers and Reduce Costs*, U.S. DEP'T AGRIC. (Sept. 26, 2022), https://www.usda.gov/media/press-releases/2022/09/26/biden-harris-administration-announces-major-actions-spur [https://perma.cc/8VNU-63F9] ("'Highly concentrated local markets in livestock and poultry have increasingly left farmers, ranchers, growers and producers vulnerable to a range of practices that unjustly exclude them from economic opportunities and undermine a transparent, competitive, and open market—which harms producers' ability to deliver the quality, affordable food working families depend upon . . . .'" (quoting Tom Vilsack, Agriculture Secretary)).

operated at one level in the market, producing an animal and then selling it on an open market.[115] Today, large corporations increasingly operate on multiple levels of the market. They breed and raise the animal, feed and finish the animal, slaughter and process the animal, and distribute the resulting meat to the stores that will sell it to the consumer.[116] Some livestock markets are more vertically integrated than others. The poultry market has been vertically integrated since the 1980s.[117] Hog production has moved in that direction.[118] The cattle industry has become vertically integrated in some areas such as cattle feeding and packing, but resistant in others, such as cow-calf operations, because of the large amount of land necessary for that portion of the business.[119]

Consolidation can lead to negative outcomes for livestock farmers and ranchers and the rural areas that they call home. Small farms already face a multitude of challenges and are on a sharp decline.[120] The loss of small farms has led to a hollowing out of rural and small-town America. Since the 1990s, the socioeconomic health of rural communities has looked bleak.[121] The *Wall Street Journal* found that:

> In terms of poverty, college attainment, teenage births, divorce, death rates from heart disease and cancer, reliance on federal disability insurance and male labor-force participation, rural counties now rank the worst among the four major U.S. population groupings (the others are big cities, suburbs and medium or small metro areas).[122]

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115. JOEY HARWOOD, RICHARD HEIFNER, KEITH COBLE, JANET PERRY & AGAPI SOMWARU, ECON. RSCH. SERV., U.S. DEP'T AGRIC., AGRIC. ECON. REP. NO. 774, MANAGING RISK IN FARMING: CONCEPTS, RESEARCH, AND ANALYSIS 17 (1999), https://www.ers.usda.gov/webdocs/publications/40946/51082_aer774.pdf?v=0 [https://perma.cc/B3FF-F6EV].

116. *Id.* at 17–18.

117. *See Transgenic Animals Hearing*, *supra* note 111, at 39 (statement of Dr. Thomas Wagner, Edison Animal Biotechnology Ctr., Ohio Univ.) ("[A]bout 90 percent of the chickens are raised by four or five different companies."); CLEMENT E. WARD, OKLA. COOP. EXTENSION SERV., OKLA. STATE UNIV., WF-552, VERTICAL INTEGRATION COMPARISON: BEEF, PORK, AND POULTRY 2, https://riskmgt.uwagec.org/MarketRisk/VerticalIntegrationComparisonBeefPork&Poultry.pdf [https://perma.cc/3KM8-HJWH].

118. WARD, *supra* note 117, at 5.

119. *Id.* at 2–3.

120. James M. MacDonald & Robert A. Hoppe, *Large Family Farms Continue to Dominate U.S. Agricultural Production*, U.S. DEP'T AGRIC. ECON. RSCH. SERV. (Mar. 6, 2017), https://www.ers.usda.gov/amber-waves/2017/march/large-family-farms-continue-to-dominate-us-agricultural-production [https://perma.cc/LNT5-VZNL] ("Small family and nonfamily farms accounted for 46 percent of production in 1991, but by 2015, that share had fallen under 25 percent.").

121. Janet Adamy & Paul Overberg, *Rural America Is the New 'Inner City*,*'* WALL ST. J. (May 26, 2017, 2:04 PM), https://www.wsj.com/articles/rural-america-is-the-new-inner-city-1495817008 (on file with the *Iowa Law Review*).

122. *Id.*

Almost forty-five hundred rural school districts had to close their doors between 2011 and 2015.[123] More market consolidation in farming likely means fewer employers and fewer successful businesses in rural areas.

Patent protection over selectively bred animals will likely contribute to these negative outcomes of consolidation because the costs of patent prosecution make it prohibitive for those without deep pockets. The reality of the livestock industry is that independent family farmers cannot afford to hire patent counsel to draft and file $15,000 applications for every animal in their herd.[124] The USDA categorizes small family farms (which make up ninety-eight percent of U.S. farms) as making less than $350,000 in annual gross cash farm income.[125] Cattle genetics firms like ABS Global and Semex may see value in cultivating previously untapped revenue from the thousands of semen straws they sell every year, but small family farmers simply will not have the capital to invest in patent prosecution and litigation for the genetics of the bulls and cows that they breed in their herds. Even more concerning is that if patent holders exclusively license their superior genetics to large, vertically integrated corporations for high dollar amounts, they could squeeze smaller producers out of the market.[126] As such, allowing patents on selectively bred animals will unevenly benefit the playing field, helping those who already have size and market power on their side and therefore disadvantaging small, traditional livestock operations.

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123. Alana Semuels, *'They're Trying to Wipe Us Off the Map.' Small American Farmers Are Nearing Extinction*, TIME (Nov. 27, 2019, 1:16 PM), https://time.com/5736789/small-american-farmers-debt-crisis-extinction [https://perma.cc/AG6A-U8QM].

124. James Yang, *What Is the Average Patent Cost?*, OC PAT. LAW. (June 5, 2022), https://ocpatentlawyer.com/how-much-does-the-average-patent-cost [https://perma.cc/F8ZW-2CVT] ("The average cost of a patent is between $15,500 to $28,000.").

125. *Farming and Farm Income*, U.S. DEP'T AGRIC. ECON. RSCH. SERV. (Mar. 14, 2023), https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/farming-and-farm-income [https://perma.cc/8RLQ-UTQZ].

126. Similar concerns were raised about the initial patent eligibility of animals in the 1980s. *See Transgenic Animals Hearing*, *supra* note 111, at 180, 189 (statement of Robert P. Merges, Julius Silver Fellow in Law, Science & Technology, Columbia L. Sch.); *id.* at 521–23 (statement of Iver P. Cooper, Patent Counsel, Ass'n Biotechnology Cos.) (expressing that farmers will likely not be targets of litigation, their suppliers will be). *Contra id.* at 26–27 (questioning answered by Rene D. Tegtmeyer, Assistant Comm'r for Pats.) (expressing that patent exhaustion doctrine will likely protect farmers). *Id.* at 39 (statement of Dr. Thomas Wagner, Edison Animal Biotechnology Ctr., Ohio Univ.) ("If the patenting of animals in not allowed, it is very clear that those people that produce them will do exclusive licenses with vertical integrators, and we will see a concentration of agriculture in the way the chickens have been concentrated."). This hearing operated largely on the assumption that only genetically modified and not selectively bred animals would be patent-eligible. *Id.* at 131 (statement of the Chairman that "the sole issue is the patentability of genetically altered animal life forms"). *Contra id.* at 353 (statement of Nicholas Seay, Patent Attorney) ("The allowance of patent protection for animals will apply to conventionally bred as well as genetically engineered animals."). Allowing for the patenting of selectively bred animals should heighten these concerns as it would broaden the field of potentially patent-eligible livestock.

III. HOW TO LIMIT THE HARMS OF PATENTING SELECTIVELY BRED ANIMALS

When faced with the challenges posed by the patentability of selectively bred animals, there are judicial holdings that could limit the negative effects of the policy. Legislative action, however, may be necessary to truly confront these challenges.

A. JUDICIALLY PROHIBIT CLAIMING FUTURE OFFSPRING

To limit the impact of selectively bred animals as patent-eligible subject matter, the courts may find that only the selectively bred animals, but not their yet unborn progeny can be claimed. This ruling would find support in the legal requirements of nonobviousness and written description as well as address most of the problems caused by animal patents. In the two ABS patents discussed earlier, both included an independent claim over the first-generation progeny of the animals claimed.[127] Claiming unborn animals raises multiple problems for fulfilling the requirements of patentability.

First, offspring of a claimed animal face nonobviousness problems. To be nonobvious, previous analogous art must not have been obvious for one of ordinary skill in the art to combine and create the new, claimed invention.[128] The Supreme Court has further stated that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious . . . ."[129] The '351 patent (for a cow named Lyric) claims any calves of that cow. When a farmer looks to breed a cow, he is necessarily looking to take advantage of her genetics and match them with the genetics of a suitable bull to improve upon the genetics of the bloodline that manifest in the resulting calf.

Suppose that a farmer sees that Lyric has a history of producing good-quality calves, but she also tends to bear calves with high birth weights (which lead to calving issues and a higher likelihood that the calf will not survive birth).[130] The farmer may seek to remedy this by breeding her to a bull with a history of siring calves with a low birth weight, hoping to, in the end, have a new heifer for his herd that will produce quality calves like its dam[131] but with lower birth weight.[132] This new heifer should fail the nonobviousness test

127. '351 Patent claim 11; '187 Patent claim 6.

128. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007).

129. *Id.* at 417.

130. "Calving difficulty (dystocia) can increase calf losses, cow mortality, and veterinary and labor costs, as well as delay return to estrus and lower conception rates. . . . Birth weight of the calf was the trait most highly correlated with calving difficulty, followed by sex of calf." William O. Herring, *Calving Difficulty in Beef Cattle: BIF Fact Sheet*, UNIV. MO. EXTENSION (Mar. 2022), https://extension.missouri.edu/publications/g2035 [https://perma.cc/8LDD-GJYJ].

131. In livestock breeding, the dam is the "mother" of an animal, while the sire is the "father" of the animal.

132. Careful bull selection is necessary here. Sires that give low birth weights also tend to give low weaning and yearling weights, which is not ideal when the goal is to breed for a market animal

given by the Court. The farmer (in patent parlance, the inventor) sought to create a new product (the heifer) by taking a technique from one device (the low-birth-weight genetics from the bull) and applying them to another existing device (the cow that produces otherwise high-quality calves). Therefore, claiming the progeny of an animal in a patent is nothing more than an attempt to claim obvious improvements upon the animal. These claims, therefore, should be rejected as unpatentable.[133]

Second, yet-unborn offspring do not meet the written description requirement for a patent. To meet the written description requirement of 35 U.S.C. § 112, an inventor must meet both an enablement requirement and a written description requirement.[134] Here, claiming all progeny of an animal faces a problem with the written description requirement. The written description of the invention must be adequate "to allow 'a person of skill in the art to recognize that the patentee invented what is claimed.'"[135] The goal of this requirement is to give proper notice about what a patent covers to other inventors in the field and prevent the owner of the patent from later construing his invention more broadly than what the written description describes.[136]

Where a patent claims a whole category (in patent terms, a genus) of invention with different members (in patent terms, species), the patentee must show that they invented the whole genus rather than just an individual species.[137] When the written description is fulfilled by a deposit (filing a physical sample) because written words on their own are not enough to recognize what is claimed, the deposits must be representative of the whole genus.[138] In other words, "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when . . . ordinary artisans could not predict the operability in the invention of any species other than the one disclosed."[139]

Here, ABS filed cell samples for the individual animal being patented. It did not file any other cell samples to prove that it had established an entire new genus. Indeed, any offspring on the claimed animal will, necessarily, only share half of its genetic makeup with its patented parent.[140] As such, it is

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that quickly gains weight and muscle mass for slaughter. Sires that give low birth weight but high postcalving growth do exist in the artificial insemination market. Herring, *supra* note 130.

133. Claims are ineligible for a patent where only an obvious improvement on the prior art to a "person having ordinary skill in the art." 35 U.S.C. § 103.

134. *In re* Curtis, 354 F.3d 1347, 1357 (Fed. Cir. 2004).

135. Tobinick v. Olmarker, 753 F.3d 1220, 1225 (Fed. Cir. 2014) (quoting Synthes USA, LLC v. Spinal Kinetics, Inc., 734 F.3d 1332, 1341 (Fed. Cir. 2013)).

136. Pandrol USA, LP v. Airboss Ry. Prods., Inc., 424 F.3d 1161, 1165 (Fed. Cir. 2005).

137. Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 966–67 (Fed. Cir. 2002).

138. *Id.* at 967–68.

139. *In re Curtis*, 354 F.3d at 1358.

140. *See Where Does Our Genome Come From?*, GENOMICS EDUC. PROGRAMME, https://www.genomicseducation.hee.nhs.uk/education/core-concepts/where-does-our-genome-come-from [https://perma.cc/TMC7-TBPN] (explaining basic human genomics, which are analogous to cattle).

difficult to say what the other half of the calf's genetic makeup will look like. And even if we did know what animal the calf's other parent would be, siblings can display different traits from each other based upon which genes they inherited from each parent. Of course, the option of filing cells to complete the written description requirement is not an option when the cells have yet to be created. With all of this in mind, it is difficult to see how a patentee could describe the operability of any of the calves with sufficient specificity.

Many of the policy problems related to patenting livestock disappear when one cannot claim the descendants of their claimed animal. Controlling the intellectual property rights over a specific animal and its cells, having the right to prevent its reproduction through cloning or future artificial reproduction of reproductive cells, is valuable.[141] However, its value is relatively limited compared to the power to exercise independent control over the descendants of an invented animal.[142] Without control of descendants, much of the current animal-market balance between farmers, breeders, and genetics researchers would remain in place because there would be little incentive to patent animals whose value lies primarily in progeny rather than cloning.

B. CONGRESS CAN CRAFT A BETTER SYSTEM FOR PATENTABLE ANIMALS

Though selectively bred animals seem to be firmly grounded from a judicial perspective, Congress has the power to intervene and make new law based upon its policy judgment. Congress could explicitly exclude claims directed toward selectively bred animal organisms from eligibility.[143] Alternatively, Congress could enact a system similar to the Plant Variety Protection Act that explicitly allows farmers to selectively breed animals as an exemption from patent infringement suits by the patent owner.[144] Either way, Congress has a distinct opportunity to implement a legislative solution here due to the policy concerns that patented livestock could lead to greater consolidation in farming and therefore negatively impact rural America. Additionally, Congress, unlike the courts, can act quickly to settle the imminent policy question of whether the government should grant legal monopolies on selectively bred livestock.

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141. The value in such patents may especially increase when claiming individual cell lines. If scientists are able to develop embryonic stem cells collected from an animal to generate into sperm and egg cells, the value in these patented cells could be huge for genetic and other research. *See* Kelly Servick, *First Cow Embryonic Stem Cells Could Lead to Healthier, More Productive Livestock*, SCI. (Feb. 5, 2018), https://www.science.org/content/article/first-cow-embryonic-stem-cells-could-lead-healthier-more-productive-livestock [https://perma.cc/Z2UY-EG44].

142. *See supra* Part II.

143. *See infra* Section III.B.1.

144. *See infra* Section III.B.2.

1. Exempting Selectively Bred Animals from Patent Eligibility

The most straightforward legislative solution to the problems proposed by granting patents on selectively bred animals is to modify the law and exempt selectively bred animals from Congress's grant of eligibility. Congress has broadly given eligibility to all inventions that are a "process, machine, manufacture, or composition of matter."[145] However, Congress has, in the past, exempted types of inventions that, despite meeting the criteria of § 101, present public policy concerns.

In 1946, for instance, Congress passed a law stating that "[n]o patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor."[146] Perhaps more similarly to patented animals, Congress in 2011 codified the policy that any "claim directed to or encompassing a human organism" is ineligible for a patent.[147] These exemptions were necessary because by the strict meaning of 35 U.S.C. § 101, these would be eligible compositions of matter.

By enacting a similar statute to the two above, Congress could say explicitly that animals produced by selectively breeding without human intervention to modify their genetics are categorically not patent-eligible. Congress came very close to rejecting animal patents (including genetically modified animals) entirely in 1988.[148] Their reasoning, just like today, was concern over the consolidation of the agricultural market as small farmers get priced out by larger competitors backed by the benefit of patents on superior genetics.[149] Today, the clock has already run on many transgenic animals, as patents have already been granted for transgenic animals like the Harvard

145. 35 U.S.C. § 101.

146. 42 U.S.C. § 2181.

147. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011). This legislation codified longstanding policy regarding the patenting of human animals. *See* MPEP § 2105 (9th ed. Rev. 07.2022, Feb. 2023). This policy dates back to shortly after *Ex parte Allen* as the USPTO determined that awarding patent rights on human beings would constitute a violation of the Thirteenth Amendment by granting a property right in the life of another person. *See* Animals – Patentability, *supra* note 27, at OG 24.

148. *See* Keith Schneider, *House Panel Rebuffs Staff on Animal Patents*, N.Y. TIMES (Mar. 31, 1988), https://www.nytimes.com/1988/03/31/us/house-panel-rebuffs-staff-on-animal-patents.html? (on file with the *Iowa Law Review*) ("Separate proposals are under consideration in the House and Senate that would prevent the Patent Office from issuing the first animal patent until Congress can consider the implications more thoroughly. The legislation pending in the House, sponsored by Representative Charlie Rose, Democrat of North Carolina, has 80 Democratic and Republican co-sponsors . . . .").

149. *See* Keith Schneider, *Witnesses Clash on Animal Patents*, N.Y. TIMES (June 12, 1987), https://www.nytimes.com/1987/06/12/us/witnesses-clash-on-animal-patents.html (on file with the *Iowa Law Review*) ("[F]arm industry analysts, like Mr. Doyle, predicted that the patent decision would have profound economic consequences for several sectors of the agricultural economy.").

Mouse.[150] To roll back these patents now would require compensation for the patentholders.[151] Additionally, pulling back these restrictions in the United States may put researchers here at a disadvantage to those in other countries who, following our lead, allowed for the patenting of genetically modified animals.[152]

2. Enacting a Farmer's Exemption

As the largest problems with the patenting of selectively bred animals are the effect it will have on consolidation of farming, one possible solution is to exempt farmers' traditional breeding and livestock raising activities from the definition of patent infringement. The Supreme Court has held that self-replicating inventions[153] still meet the definition of patent infringement.[154] Congress, knowing that utility patents give this incredibly broad protection, explicitly carved out exceptions for farmers when drafting the plant variety protection statute.[155] This exemption allows farmers to save and replant seeds.[156] This practice remained common until seed companies began to use utility patents rather than plant variety protection to avoid this exemption.[157]

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150. *See, e.g.*, Kevles, *supra* note 28, at 78.

151. *See* U.S. CONST. amend. V. When banning nuclear weapon patents, Congress retroactively invalidated any that had been issued by including language that "[a]ny patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor." 42 U.S.C. § 2181.

152. The European Patent Office, following its decision in "Opinion of the Enlarged Board of Appeal Dated 14 May 2020 G 3/19, 2020 O.J. EPO (A119)" allows for the patenting of genetically modified but not selectively bred animals.

153. Self-replicating inventions would include selectively bred animals because they mate and make a "copy" of the "claimed invention"—their offspring. This may only apply insofar as progeny that are not genetic duplicates can be claimed by a patent.

154. Bowman v. Monsanto Co., 569 U.S. 278, 284–85 (2013) ("[T]he exhaustion doctrine does not enable Bowman to make *additional* patented soybeans without Monsanto's permission (either express or implied)."). Similarly for animals, selectively breeding a cow with semen from a patented bull may be held to be infringement unless licensed because the farmer sought to duplicate the genetics of the patented bull in the resulting calf. If that seems too close, consider, what if the semen is from a first generation of the patented bull—one quarter of the genome in the new calf then may be a replicate of patented material. Is that infringement? This can be repeated ad infinitum to lead to some absurd conclusions if progeny of selectively bred animals are proper to claim.

155. 7 U.S.C. § 2543 ("[I]t shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section.").

156. *See id.*

157. Because it lacks a farmer exemption, "[a] plant protected with a utility patent cannot be propagated sexually, whether as part of a breeding plan or simply seeds saved from one season to the next." Barrett, *supra* note 107, at 504. As such, seed companies largely switched to filing utility patents rather than plant variety protection. AGRIC. MKTG. SERV., U.S. DEP'T AGRIC., MORE AND BETTER CHOICES FOR FARMERS: PROMOTING FAIR COMPETITION AND INNOVATION IN SEEDS AND OTHER AGRICULTURAL INPUTS 20 (2023), https://www.ams.usda.gov/sites/default/files/me

For such patents today, a so-called farmer exemption would allow farmers to continue with their traditional selective breeding practices on the farm while allowing for the continued operation of utility patents in the area. In the congressional hearings from the 1980s, it was noted that such an exemption would benefit farmers by protecting them from the unfair bargaining advantage held by a patent owner.[158] The same holds equally true today for selectively bred animals. While a farmer's exemption may not solve all the problems raised in other sections of this Note,[159] it may be a compromise worth making to benefit the wellbeing of our family farms.

CONCLUSION

Patent-eligible subject matter requirements under 35 U.S.C. § 101 allow for the patenting of selectively bred animals. Livestock genetics corporations will continue to push the envelope on this issue, and we may soon see litigation in their favor. Such a result will cause additional challenges in the livestock industry because selective breeding patents may promote the same consolidation that now exists within the market for crop seeds.[160] The courts should act to limit some of the worst outcomes by prohibiting claims directed toward as-yet unborn progeny of patented animals as nonobvious and insufficiently described in writing. If judicial action is not enough, Congress should act to exclude selectively bred animals from patent protection by statute.[161]

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dia/SeedsReport.pdf [https://perma.cc/HW7X-2PJS] ("Across all crops, IP composition generally shifted from mostly PVP certificates in the 1990s to a higher percentage of utility patents in 2020."); *see* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001).

Aside from plant variety protection, plant patents have a similar exemption that allows the owner of the plant to produce "seeds . . . from a patented plant without infringement, whether you cross-pollinate the plant with another variety or self-pollinate the plant." Barrett, *supra* note 107, at 503.

158. *Transgenic Animals Hearing*, *supra* note 111, at 189 (statement of Robert P. Merges, Julius Silver Fellow in Law, Science & Technology, Columbia L. Sch.) ("[A] statutory Farmer's exemption would prevent patentees from using the threat of infringement to extract major concessions from farmers when negotiating license agreements . . . . [Without the exemption,] the farmer would not be able to challenge [a license] . . . as a violation of the antitrust laws, for fear that if the license agreement were declared invalid, he would no longer be protected [from infringement].").

159. *See supra* Part II.

160. *See supra* Part II.

161. *See supra* Section III.B.