PATENTING WORKING ANIMALS

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ABSTRACT

Since ancient times, humans have harnessed animals for various tasks, evolving from hunting companions to sophisticated detectors of medical conditions and hazards. Despite the evident commercial potential, patenting these "working animals" remains an underexplored

domain, rarely attempted and often met with skepticism among patent practitioners. But such skepticism is ill-founded – there is no general prohibition against patenting living organisms, and certainly not working animals in particular. This Article unravels the complexities surrounding the protection of intellectual property related to working animals, offering pragmatic advice to developers of animal-based inventions and patent practitioners engaged in this unique field.

The most significant contribution of this Article is developing a framework identifying seven overarching categories to describe the various types of patent claims covering working animals and related training. A detailed review of patents in this space identifies patents within each category and, through a detailed analysis of these patents, this Article sheds light on the challenges associated with patenting different types of methods and tools for working animals, outlining the boundaries of patentable subject matter in each classification. Notably, patent claims for novel methods and tools related to working animals generally prove patentable, while those trying to claim the animal itself are likely *per se* unpatentable.

This study, with its in-depth analysis and nuanced categorization, not only uncovers the scarcity of patents related to working animals but also provides strategic insights for successful patenting. The findings serve as a guide for patent practitioners, empowering them to navigate the uncharted territory of animal-based patents with insight and expertise. The Article concludes by proposing congressional action that could foster innovation in this field by facilitating the process for patenting working animals by (1) amending the Patent Act to clarify the scope of patent eligible subject matter regarding animal-based inventions, and (2) creating a new type of patent, analogous to a plant patent, specifically to protect animal-based inventions.

INTRODUCTION

Humans have trained animals to perform tasks since the dawn of civilization. There is evidence that our hunter-gatherer ancestors domesticated and trained dogs to aid with hunting.[1] Over the next several thousand years, people trained animals to serve a variety of roles, such

1. *See* Maria Lahtinen et al., *Excess Protein Enabled Dog Domestication During Severe Ice Age Winters*, SCI. REPS., Jan. 7, 2021, at 3, https://doi.org/10.1038/s41598-020-78214-4; Angela R. Perri, *Prehistoric Dogs as Hunting Tools*, *in* DOGS: ARCHAEOLOGY BEYOND DOMESTICATION 7, 10, 19–23 (Brandi Bethke et al. eds., 2020) (noting at least one researcher "proposed that protodogs assisted human hunters in outcompeting Neanderthals up to 32,000 years ago . . . .").

as riding mounts, draft animals, and guard animals. More recently, animals have been trained to use their heightened senses for detection purposes—e.g., canines or other animals trained to detect a particular scent and alert their handlers accordingly. These scent detection tasks include identifying asymptomatic COVID-19, malaria, various cancers, and *C. difficile* infections; detecting firearms, explosives, and missing persons; signaling the presence of known allergens; detecting the onset of seizures and epileptic episodes; and identifying molecular indicators of narcoleptic episodes.[2] However, as people continue to develop new uses for working animals, the question arises whether such animals are protectable as intellectual property.[3]

This Article explores potential pitfalls and provides practical advice on patenting working animals and their related training techniques. The utility of these animals as life-saving tools is undeniable and provides an opportunity for significant commercialization – but training and maintaining animals to perform these precise tasks consumes significant resources. Developers naturally seek to protect their investments as intellectual property, particularly in a world that places a high monetary value on patent portfolios.[4] However, the research for this Article indicates that developers rarely file patents related to working animals.[5] While the reasons for this dearth of patents are unclear, it is likely due to a combination of many animal-training

2. *See* Matthew Avery & Makenzi Galvan, *Animal-Based Medical Diagnostics: A Regulatory Problem*, 75 FOOD & DRUG L.J. 370, 370–372, 375–376 (2020) (discussing canines used to detect COVID-19 infections, malaria infections, *C. difficile* bacterial infections, firearms, explosives, narcotics, missing persons, some temporal conditions, and allergens); *see also* Héctor Guerrero-Flores et al., *A Non-Invasive Tool for Detecting Cervical Cancer Odor by Trained Scent Dogs*, BMC CANCER, Jan. 26, 2017, https://doi.org/10.1186/s12885-016-2996-4 (describing a study wherein dogs were proven to detect cervical cancer in human samples with a success rate of >90%); *Seizure-Alert Dogs: Just the Facts, Hold the Media Hype*, EPILEPSY FOUND. (2007), https://www.epilepsy.com/stories/seizure-alert-dogs-just-facts-hold-media-hype (discussing potential for dogs to assist in seizure-alert and seizure response).

3. This Article defines "working animals" as animals that have been domesticated and trained by humans to perform certain tasks. It is beyond the scope of this Article to analyze patenting undomesticated animals or their uses.

4. *See* John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 435 (2004) (stating inventors spend more than $4.33 billion per year to obtain patents); *see also* Michael Risch, *Patent Portfolios as Securities*, 63 DUKE L.J. 89, 101 (2013) (describing a consortium of technology companies that purchased a patent portfolio for $4.5 billion).

5. *See* discussion *infra* Part III.A., III.B., and III.C.

techniques being well-known in the art or such training techniques being considered unpatentable subject matter.[6]

This Article categorizes various aspects of training and developing working animals to help identify those areas ripe for patent protection and those that may face difficulty at the United States Patent and Trademark Office (USPTO). Part I of this Article provides a brief overview of the science and history behind training working animals. Part II introduces applicable patent law in the context of working animals and related training tools. Part III identifies the various categories of animal-based innovations and analyzes existing patents in an effort to elucidate the metes and bounds of patentable subject matter in each category. Part IV then explains the practical impact of the trends found in Part III and provides insight into how developers can improve their chances of successfully patenting their animal-based inventions. Finally, Part V proposes that Congress could encourage innovation in this area by either (1) reforming patent eligibility laws more generally to clarify the scope of patentable subject matter, or (2) enacting special legislation more specifically for animal patents similar to the Plant Patent Act for plant patents.[7]

The most significant contribution of this Article is developing a framework identifying seven overarching categories to describe the various types of patent claims covering working animals and related training, which is outlined below:

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6. To obtain a patent on an invention, the invention must be eligible subject matter, novel, and non-obvious. 35 U.S.C. §§ 101–103. *See infra* Part II.A and II.B.

7. It is beyond the scope of this Article to analyze the following issues related to patenting working animals: (1) ethical issues related to the training, use or patenting of working animals; (2) patenting undomesticated animals that are selectively bred or modified, including transgenic animals; (3) certain Patent Office objections and rejections, such as indefiniteness, objections to drawings, utility, restriction requirements, and double-patenting, because these are common patenting hurdles that do not raise specific issues related to patenting working animals; (4) patentability outside the United States; (5) tools, such as toys, for recreational dog owners, and (6) design patents. For a discussion of ethical issues related to working animals, see Jailson Jose Gomes da Rocha, *Laboralidade Animal: implicações ético-jurídicas*, 45 REVISTA DE BIOETICA & DERECHO 213, 213 (2019). For a discussion of ethical issues related to patenting animals, see Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS 399 (1988). For a discussion of patenting GMO animals, see W. A. Adams, *The Myth of Ethical Neutrality: Property, Patents, Animal Rights and Animal Welfare in* Commissioner of Patents v. President and Fellows of Harvard College, 39 CAN. BUS. L.J. 181 (2003).

Method Claims

1. Training Methods Using Novel Techniques (with Existing Tools)—i.e., patenting novel training methods using existing tools (method claim with novel step during training).

2. Training Methods Using Novel Tools (with Existing Techniques)—i.e., patenting existing training methods using novel tools (method claim with known steps using novel device/composition during training).

3. Working Methods Using Novel Techniques (with Existing Tools)—e.g., patenting novel methods for using the trained animal, alone or in combination with existing tools (method claim with novel step while working).

4. Working Methods Using Novel Tools (with Existing Techniques)—e.g., patenting existing methods for using the trained animal in combination with novel tools (method claim with known steps using novel device/composition while working).

Tool Claims (i.e., Device/Composition of Matter Claims)

5. Novel Training Tools—i.e., patenting the training tool (device/composition of matter claim).

6. Novel Working Tools—i.e., patenting the tools used in combination with the trained animal (device/composition of matter claim).

Animal Claims

7. Trained Working Animals—i.e., a claim on the animal itself.

By analyzing patents within this framework, this Article finds that patent claims directed to novel methods and novel training/working tools are generally patentable, as discussed *infra*. Many training method claims recited the use of a tool to impart novelty. Further, there were fewer ineligible-subject-matter rejections than expected among the patents that the Authors reviewed. However, claims directed to trained working animals likely cover *per se* unpatentable subject matter and no patents were identified in this final category.

I. SCIENCE AND OVERVIEW OF WORKING ANIMALS

A. The Science of Working Animals

Humans employ animals to perform many important tasks and continue to find new ways to utilize them. Some animals are specifically trained to perform a task, e.g., explosive detection dogs, while

others are useful in their untrained states, such as medicinal maggots that treat chronic wounds.[8] Animals are selected as working animals based on their inherent abilities, such as their odor detection abilities, trainability, strength, and natural instincts.

1. Detection Animals

Detection animals are one of the most common types of working animals. Many animals have strong olfactory capabilities which can be used to detect particular odors. For instance, dogs have extremely sensitive olfactory receptors and are able to detect many scents that a human cannot.[9] Dogs can pick out specific scent molecules in the air, even at low concentrations.[10] In fact, dogs possess an extra olfactory organ in their nose, and the portion of their brain that analyzes scent molecules is forty times larger than that of a typical human.[11] This allows dogs and other animals with strong olfactory capabilities to be trained to detect various objects and conditions via scent.

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8. *See* Caitlin Talbot, *Wales's Trade in Leeches and Maggots*, THE ECONOMIST (Nov. 24, 2022), https://www.economist.com/britain/2022/11/24/waless-trade-in-leeches-and-maggots. Note that medicinal maggots are not domesticated and trained by humans, and thus are not considered "working animals" as defined by this Article. *See supra* note 3.

9. *See* ALEXANDRA HOROWITZ, INSIDE OF A DOG: WHAT DOGS SEE, SMELL, AND KNOW 72 (2009). To put this in perspective, a human may be able to detect a teaspoon of sugar in a cup of water; however, dogs are able to detect a teaspoon of sugar in one million gallons of water—the equivalent of two Olympic-sized pools. However, there are reports of humans that are capable of astounding olfactory feats too, including Joy Milne, a woman who is able to sniff out biochemical indicators of Parkinson's disease. *See* Alix Spiegel & Elena Renken, *Her Incredible Sense of Smell is Helping Scientists Find New Ways to Diagnose Disease*, NPR (Mar. 23, 2020, 4:45 PM), https://www.npr.org/sections/health-shots/2020/03/23/820274501/her-incredible-sense-of-smell-is-helping-scientists-find-new-ways-to-diagnose-di.

10. *See* Klaus Hackner & Joachim Pleil, *Canine Olfaction as an Alternative to Analytical Instruments for Disease Diagnosis: Understanding "Dog Personality" to Achieve Reproducible Results*, J. BREATH RES., Jan. 9, 2017, https://iop-science.iop.org/article/10.1088/1752-7163/aa5524/pdf. According to one study, the upper limit of a dog's olfactory detection of volatile organic compounds is 1.5 parts per trillion (ppt). *See* Astrid R. Concha et al., *Canine Olfactory Thresholds to Amyl Acetate in a Biomedical Detection Scenario*, FRONTIERS IN VETERINARY SCI., Jan. 22, 2022, at 1, https://pmc.ncbi.nlm.nih.gov/articles/PMC6350102/pdf/fvets-05-00345.pdf.

11. *See* Peter Tyson, *Dogs' Dazzling Sense of Smell*, PBS (Oct. 4, 2012), http://www.pbs.org/wgbh/nova/nature/dogs-sense-of-smell.html.

Detection animals identify objects like drugs or weapons based on the specific chemical vapor profiles of those objects.[12] Additionally, many physiological processes in organisms produce detectable odorants.[13] Odorants detectable by animals are likely volatile organic compounds (VOCs), such as terpenoids, alcohols, and carbonyls, which have a relatively high vapor pressure at room temperature.[14] These odorants are typically released from the breath, urine, feces, skin, tissue, and blood of humans.[15] For example, different types of cancer cells produce unique VOC signatures that may be distinctly identified by trained animals.[16] Further, certain bacterial or viral infections produce unique scent profiles in humans.[17] Thus, as scientists discover new scents associated with particular disease states, working animals can be trained to detect those conditions.

12. *See* Craig Angle et al., *Canine Detection of the Volatilome: A Review of Implications for Pathogen and Disease Detection*, FRONTIERS IN VETERINARY SCI., Jun. 24, 2016, at 1.

13. *See id.* at 3.

14. *See* Palas Mondal et al., *Exhaled Volatile Organic Compounds (VOCs): A Potential Biomarkers for Chronic Disease Diagnosis*, 4 SCI. J. BIOLOGY 5, 6–8 (2021); *see also* Edward Maa et al., *Canine Detection of Volatile Organic Compounds Unique to Human Epileptic Seizure*, EPILEPSY & BEHAV., Dec. 23, 2020, at 4, https://www.epilepsybehavior.com/action/showPdf?pii=S1525-5050%2820%2930870-2 ("Volatile organic compounds are a class of carbon-based chemical compounds with a high vapor pressure at room temperature."). Vapor pressure is a measure of the tendency of a substance to transition from a liquid or solid phase into a gas or vapor phase. Since volatile organic compounds have a high vapor pressure at room temperature, volatile organic compounds are excreted as gas from humans.

15. *See* Angle et al., *supra* note 12, at 1.

16. *See* Mondal et al., *supra* note 14, at 8; *see also* Angle et al., *supra* note 12, at 1.

17. *See* Angle et al., *supra* note 12, at 1, 3.

Presently, detection dogs have been used to detect drugs and bombs,[18] people,[19] bed bugs,[20] food allergens,[21] and even some pathogens and cancers.[22] In fact, trained dogs can detect and alert owners *before* the onset of temporal conditions that currently have no

18. *See* FED. BUREAU OF INVESTIGATION, *FBI Working Dogs*, YOUTUBE (Mar. 13, 2009) https://youtu.be/RWlif5f_bAI (explaining dogs can detect 19,000 different explosive combinations).

19. *See* Stephanie Dazio, *Police Canines Bring Special Skills to Dangerous Job*, NEWSDAY (Sep. 29, 2018), https://www.newsday.com/long-island/suffolk/longisland-police-dogs-1.21301029.

20. For example, the National Pest Management Association encourages the use of certified canine detection teams to detect bed bugs when visual inspections are inadequate. *See Best Practices for Bed Bugs*, NAT'L PEST MGMT. ASS'N, at 11, https://npmapwcdn-afabcafzhkfnebcs.z02.azurefd.net/media/rliieovg/npma-bed-bug-best-management-practices-2023_v2.pdf (last visited Oct. 28, 2024).

21. *See* Stephanie Gibeault, *Peanut Detection Dogs Save Lives*, AM. KENNEL CLUB (Aug. 8, 2022), https://www.akc.org/expert-advice/lifestyle/peanut-detection-dogs-save-lives/.

22. *See* Marije K. Bomers et al., *Using a Dog's Superior Olfactory Sensitivity to Identify Clostridium Difficile in Stools and Patients: Proof of Principle Study*, BMJ, Dec. 13, 2012, at 7, 3, 9, https://www.bmj.com/content/bmj/345/bmj.e7396.full.pdf (describing dogs used to detect the presence of *C. difficile* bacteria); Michael McCulloch et al., *Diagnostic Accuracy of Canine Scent Detection in Early- and Late-Stage Lung and Breast Cancers*, 5 INTEGRATIVE CANCER THERAPIES 30, 37 (2006) (describing dogs used to detect lung and breast cancers); Hideto Sonoda et al., *Colorectal Cancer Screening with Odour Material by Canine Scent Detection*, 60 GUT 814, 814 (2011); Gyorgy Horvath et al., *Human Ovarian Carcinomas Detected by Specific Odor*, 7 INTEGRATIVE CANCER THERAPIES 76, 79 (2008); Carolyn M. Willis et al., *Olfactory Detection of Human Bladder Cancer by Dogs: Proof of Principle Study*, BMJ, Sept. 23, 2004, at 5, https://www.bmj.com/content/bmj/329/7468/712.full.pdf; Duane Pickel et al., *Evidence for Canine Olfactory Detection of Melanoma*, 89 APPLIED ANIMAL BEHAV. SCI. 107, 107 (2004). In addition, the use of animal-based diagnostics for Parkinson's disease, hypoglycemia, and other cancers is widely reported, but there are no published studies validating such uses of animal-based diagnostics at this time. *See* Sarah Knapton, *Dogs Could Sniff Out Parkinson's Disease Years Before Symptoms Appear*, TELEGRAPH (July 9, 2017) https://www.telegraph.co.uk/science/2017/07/09/dogs-could-sniff-parkinsons-disease-years-symptoms-appear/ (describing how a team at Manchester University is conducting a proof of principle study into whether dogs can be trained to detect the scent of Parkinson's disease in humans); *see also Welcome to PADs for Parkinson's*, PADS FOR PARKINSON'S, https://www.padsforparkinsons.org (last visited Oct. 4, 2024) ("PADs has trained more than 25 dogs to successfully select Parkinson's samples from healthy human control samples with an accuracy rating of 90% or higher."); K. S. Weber et al., *Do Dogs Sense Hypoglycaemia?*, 33 DIABETIC MED. 934, 936 (2015) (a survey-based report of anecdotal evidence from diabetic patients about how their dogs react to hypoglycemic episodes); Jessica Glenza, *Dog Trained to Detect Thyroid Cancer 'with 88% Accuracy'*, GUARDIAN (Mar. 9, 2015, 5:05 PM), https://www.theguardian.com/us-news/2015/mar/09/dog-detects-thyroid-cancer-research.

diagnostic tests available, including narcoleptic and epileptic episodes, migraines, and severe allergic reactions.[23]

Animals are selected as detection animals based on their natural senses and instincts.[24] For example, detection dogs are selected not only based on their keen sense of smell, but also based on their obedience, desire to please humans, motivation to perform certain actions, sharpness, tendency to be distracted, and stamina.[25] German Shepherds and Labrador Retrievers are regarded as the best breeds for detection dogs.[26] Additionally, rodents and bees have high olfactory sensitivity and odor discrimination abilities.[27] However, other animals can also be similarly used as detection animals. For example, mice have been trained to distinguish between the scents of samples infected with avian flu versus non-infected samples.[28] Fruit flies have been shown to be able to detect certain cancer odors.[29] African giant pouched rats have been used to detect land mines in Cambodia.[30] Bees

23. *See* L. Dominguez-Ortega et al., *Narcolepsia y Olor: Resultados Preliminares*, 39 SEMERGEN -MEDICINA DE FAMILIA 348, 349 (2013); EPILEPSY FOUND., *supra* note 2; *see also* Dawn A. Marcus & Amrita Bhowmick, *Survey of Migraine Sufferers with Dogs to Evaluate for Canine Migraine-Alerting Behaviors*, 19 J. ALT. & COMPLEMENTARY MED. 501, 502 (2023); Gibeault, *supra* note 21.

24. *See* Julia Layton & Sarah Gleim, *How Search-and-Rescue Dogs Work*, HOWSTUFFWORKS (Feb. 8, 2023) https://animals.howstuffworks.com/animal-facts/sar-dog1.htm.

25. *See id.*; *see also* Lucia Lazarowski et al., *Selecting Dogs for Explosives Detection: Behavioral Characteristics*, FRONTIERS IN VETERINARY SCI., Sep. 2, 2020, at 1.

26. *See* Christopher Daniels, *What Canine Breed is the Best for Detection?*, GLOB. K9 PROT. GRP. (Feb. 10, 2019), https://www.globalk9protectiongroup.com/insights/what-canine-breed-is-the-best-for-detection.

27. *See* Yunkwang Oh et al., *Olfactory Detection of Toluene by Detection Rats for Potential Screening of Lung Cancer*, SENSORS, Apr. 23, 2021, at 7 (describing rats trained to detect lung cancer); Evangelos Kontos et al., *Bees Can Be Trained to Identify SARS-CoV-2 Infected Samples*, BIOLOGY OPEN, Apr. 15, 2022, at 1, 5 (presenting diagnostic sensitivity of ninety-two percent and specificity of eighty-six percent).

28. *See* Bruce A. Kimball et al., *Avian Influenza Infection Alters Fecal Odor in Mallards*, PLOS ONE, Oct. 16, 2013, at 1 (explaining trained mice accurately discriminated between avian flu-infected and non-infected duck feces eighty percent of the time).

29. *See* Martin Strauch et al., *More than Apples and Oranges – Detecting Cancer with a Fruit Fly's Antenna*, SCI. REPS., Jan. 6, 2014, at 1 (describing fruit flies' consistent responses to volatile organic compounds produced by cancer cells in a controlled environment).

30. *See* Laurel Wamsley & Merrit Kennedy, *After Years of Detecting Land Mines, a Heroic Rat Is Hanging Up His Sniffer*, NPR (Jun. 4, 2021, 12:18 PM), https://www.npr.org/2021/06/04/1003258540/after-years-of-detecting-land-mines-a-heroic-rat-is-hanging-up-his-sniffer (describing an African giant pouched rat trained to sniff out explosives).

have been trained to extend their proboscises-tubular organs in the presence of odorous compounds, including those associated with explosives and COVID-19.[31] A notable benefit of detection animals is that they can quickly examine a large number of samples, such as large crowds of people.[32] For example, preliminary research indicates that trained canines are able to detect COVID-19 in humans with a specificity of 99.93% and a sensitivity of 81.58%, values which are comparable to RT-PCR detection methods.[33] Considering it can take up to three days to receive RT-PCR test results, a properly-trained sniffer dog could expedite the process and save countless person-hours and resources without sacrificing accuracy.[34] As scientists discover new scent profiles associated with diseases and conditions, there could be a greater demand for working animals with olfactory abilities.[35]

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31. *See* Stephen Ornes, *Using Bees to Detect Bombs*, MIT TECH. REV. (Dec. 7, 2006), https://www.technologyreview.com/2006/12/07/227361/using-bees-to-detect-bombs ("Entomologists have long known that honeybees can be trained to detect many scents, including the olfactory footprints of deadly explosives."); *see also* Marisa Iati, *Scientists May Have Found a New Coronavirus Rapid-Testing Method: Bees*, WASH. POST (May 7, 2021, 5:40 PM), https://www.washingtonpost.com/science/2021/05/07/covid-bee-testing/; Kelly McLaughlin, *Scientists Have Taught Bees to Smell the Coronavirus. They Can Identify a Case Within Seconds*, BUS. INSIDER (May 6, 2021, 3:41 PM), https://www.businessinsider.com/scientists-taught-bees-to-smell-covid-19-infections-2021-5.

32. *See* T. Craig Angle et al., *Real-Time Detection of a Virus Using Detection Dogs*, FRONTIERS IN VETERINARY SCI., Jan. 8, 2016, at 2.

33. *See* Nele Alexandra ten Hagen et al., *Canine Real-Time Detection of SARS-CoV-2 Infections in the Context of a Mass Screening Event*, BMJ GLOB. HEALTH, Nov. 11, 2022, at 1 (discussing high diagnostic accuracy of dogs detecting SARS-CoV-2 at event with large number of people); *see also* Federica Pirrone et al., *Sniffer Dogs Performance Is Stable Over Time in Detecting COVID-19 Positive Samples and Agrees With the Rapid Antigen Test in the Field*, SCI. REPS., Mar. 5, 2023, at 1 (discussing potential for detection animals to be used in public settings such as schools or airports). Sensitivity is the ability of a test to correctly identify positive cases. Specificity measures the ability of a test to correctly identify negative cases.

34. *See* ten Hagen et al., *supra* note 33, at 6; *see also* Pirrone et al., *supra* note 33, at 1 (discussing that tested dog performance exceeded minimum performance criteria set by the World Health Organization for SARS-CoV-2 antigen-detecting rapid diagnostic tests); *see Testing for COVID-19*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/covid/testing/ (last visited Oct. 29, 2024) (discussing that PCR tests for COVID-19 may take up to three days to receive results).

35. *See* Kurt Gardinier, *Bomb-Sniffing Dogs Are in Short Supply Across the U.S.*, NPR (Nov. 29, 2022, 1:41 PM), https://www.npr.org/2022/11/28/1139388835/bomb-sniffing-dogs-shortage (discussing shortage of bomb-sniffing dogs); *see also* Greg Cima, *Hunting for Detection Dogs as Demand Spikes*, AM. VETERINARY MED. ASS'N (Oct. 9, 2019), https://www.avma.org/javma-news/2019-11-01/hunting-detection-dogs-demand-spikes (discussing unmet needs by the U.S. military and federal government for detection dogs).

2. Service Animals

In addition to scent detection, animals can be trained to perform a variety of other tasks. They can provide comfort to veterans with post-traumatic stress disorder (PTSD), limited mobility, or other mental and physical impairments.[36] Service animals can help people with impaired vision by assisting with navigation, or people with clinical anxiety or depression by providing comfort and companionship.[37] Additionally, service animals can prevent or interrupt destructive or impulsive behaviors in people with psychiatric or neurological disabilities.[38] Hearing service dogs can be trained to alert their deaf owners to phones, doorbells, or fire alarms.[39] Mobility service dogs can help those who are physically disabled by fetching important items on command.[40]

Service animals are a statutorily-defined subset of working animals that are "individually trained to do work or perform tasks for people with disabilities."[41] Due to their close relationship with humans, dogs are almost exclusively used as service animals.[42] However, the Americans with Disabilities Act also recognizes miniature horses as service animals and requires their accommodation where reasonable.[43] Although not within the technical definition of "service animal,"

36. *See* Rick A. Yount et al., *Service Dog Training Program for Treatment of Posttraumatic Stress in Service Members*, U.S ARMY MED. DEP'T J. Apr. – June 2012, at 63.

37. *See The Different Types of Service Animals & How They Can Help*, U.S. SERV. ANIMALS, https://usserviceanimals.org/blog/types-of-service-animals/ (last visited Dec. 17, 2024); *see also Guide Dog Training*, GUIDE DOGS FOR THE BLIND, https://www.guidedogs.com/about-guide-dogs-for-the-blind/dog-departments/guide-dog-training (last visited Oct. 8, 2024).

38. *See Service Animals*, ADA NAT'L NETWORK, https://adata.org/sites/adata.org/files/files/Service_Animals_final2017.pdf. (last visited Oct. 30, 2024).

39. *See How to Train Your Own Service Dog Like a Pro: Expert's Guide*, SERV. DOG REGISTRATION OF AM. (Jan. 11, 2023), https://www.servicedogregistration.org/blog/how-to-train-your-own-service-dog/.

40. *Id.*

41. *ADA Requirements: Service Animals*, U.S. DEP'T OF JUST. (Feb. 28, 2020), https://www.ada.gov/resources/service-animals-2010-requirements/.

42. *See* U.S. SERV. ANIMALS, *supra* note 37.

43. *See* 28 C.F.R. § 35.104 (2024) ("Service animal means any dog that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability. Other species of animals, whether wild or domestic, trained or untrained, are not service animals for the purposes of this definition."); U.S. DEP'T OF JUST., *supra* note 41 ("Entities covered by the ADA must modify their policies to permit miniature horses where reasonable.").

other species, including cats, rabbits, and guinea pigs, are widely used as therapeutic companions due to their docile temperaments and receptiveness to training.[44]

Domesticated dogs were likely selected as trustworthy service animals due to certain inherent traits, such as tameness and their ability to pick up on human cues.[45] Thus, dogs can be trained to be specially attuned to their human companions.[46] Dogs can be trained to help patients recover after strokes, mitigate seizures, assist people with disabilities such as blindness, and assist people with mental conditions like post-traumatic stress disorder ("PTSD"), anxiety, and depression.[47] Other recognized service animal tasks include alerting deaf persons of nearby dangers, pulling wheelchairs, and reminding people to take their medication at scheduled times.[48]

3. Other Types of Working Animals

Working animals may be used for other functions beyond detection and service. For example, humans have used horses, oxen, and elephants, which have enormous strength, to transport heavy

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44. *See* Ryan Llera & Lynn Buzhardt, *Therapy Pets*, VCA ANIMAL HOSPS., https://vcahospitals.com/know-your-pet/therapy-pets (last visited Oct. 30, 2024) ("Therapeutic visitation is the most common type of pet therapy, in which owners take their personal pets to visit health care facilities. . . . Animal-assisted therapy involves animals specially trained to assist physical and occupational therapists with their patients. Pets can improve limb mobility and fine motor skills in patients as they stroke their coats. . . . Facility therapy . . . [is when] pets . . . reside at the care center and are trained to monitor and engage patients with Alzheimer's Disease or other mental illnesses . . . and help keep them safe.").

45. *See* Jeremy R. Shearman & Alan N. Wilton, *Origins of the Domestic Dog and the Rich Potential for Gene Mapping*, GENETICS RSCH. INT'L, Jan. 17, 2011, at 4 ("One of the most remarkable characteristics of domestic dogs is their ability to pick up and understand human cues and emotions.").

46. *See id.* at 4 ("Dogs show a strong attachment relationship with their caregiver and are more amenable to training than wolves raised in the same environment.").

47. *See The Benefits of Pet Therapy for Stroke Survivors*, SAEBO (July 3, 2017), https://www.saebo.com/benefits-pet-therapy-stroke-survivors/; *Seizure Dogs*, EPILEPSY FOUND. (Aug. 23, 2017), https://www.epilepsy.com/recognition/seizure-dogs; *see Is a Guide Dog Right for You?*, GUIDE DOGS OF AM., https://www.guidedogsofamerica.org/admissions/ (last visited Oct. 30, 2024); Margaret S. Mason & Christine B. Hagan, *Pet-Assisted Psychotherapy*, 84 PSYCH. Rep. 1235, 1235 (1999); GUIDE DOGS FOR THE BLIND, *supra* note 37; Yount et al., *supra* note 36, at 63; *see also* Sandra B. Barker & Kathryn S. Dawson, *The Effects of Animal-Assisted Therapy on Anxiety Ratings of Hospitalized Psychiatric Patients*, 49 PSYCHIATRIC SERVS. 797, 797 (1998); U.S. SERV. ANIMALS, *supra* note 37.

48. *See* U.S. DEP'T OF JUST., *supra* note 41.

materials.[49] Additionally, humans have trained dogs to attack on command,[50] pigeons to detect cancerous image scans on visual inspection,[51] and ferrets to lay cables in hard-to-reach places.[52]

However, not all animals must be specially trained to perform useful tasks. Rather, humans may utilize an untrained animal's natural abilities to achieve a particular function. For example, maggots are used in debridement therapy and leeches are employed to promote blood circulation.[53] In fact, both of these therapeutic uses are authorized by the FDA and are the subject of patents and patent applications worldwide.[54] Additionally, humans may use goats for vegetation management and pigs for managing certain bird populations near airports to avoid bird-airplane collisions.[55]

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49. *See* S.S. Bist et al., *The Domesticated Asian Elephant in India*, *in* GIANTS ON OUR HANDS: PROCEEDINGS OF THE INTERNATIONAL WORKSHOP ON THE DOMESTICATED ASIAN ELEPHANT 129, 134 (Iljas Baker & Masakazu Kashio ed., 2002); Joel A. Tarr & Clay Mcshane, *The Horse as an Urban Technology*, 26 J. URB. TECH. 5, 5–17 (2008).

50. *See* PHYLLIS RAYBIN EMERT, LAW ENFORCEMENT DOGS 31 (Howard Schroeder eds., 1985).

51. *See* Richard M. Levenson et al., *Pigeons* (Columba livia) *as Trainable Observers of Pathology and Radiology Breast Cancer Images*, PLOS ONE, Nov. 18, 2015, at 10, https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0141357&type=printable. The pigeons in this study averaged 87% accuracy for familiar tissue samples and 85% accuracy for tissue samples that they had not encountered previously.

52. *See* Michael Plant & Maggie Lloyd, *The Ferret*, *in* THE UFAW HANDBOOK ON THE CARE AND MANAGEMENT OF LABORATORY AND OTHER RESEARCH ANIMALS 418, 418 (Robert Hubrecht, 8th ed. 2010).

53. Kate Golembiewski, *Leeches and Maggots Are FDA-Approved and Still Used in Modern Medicine*, DISCOVER (Dec. 9, 2020, 3:48 PM), https://www.discovermagazine.com/health/leeches-and-maggots-are-fda-approved-and-still-used-in-modern-medicine. Maggots have proven to be quite useful in cases where human skin refuses to heal properly after injury or surgery, and leeches have the ability to restore blood circulation to an area after surgery. *See* Letter from Celia M. Witten, Dir., Office of Device Evaluation, FDA, to Brigitte Latrille, President, Ricarimpex SAS (May 11, 2004) (available at https://www.accessdata.fda.gov/cdrh_docs/pdf4/K040187.pdf) (allowing the marketing of a device that applies "leeches as an alternative medicinal treatment . . . [to treat] graft tissue when problems of venous congestion may delay healing."). As previously noted, maggots and leeches are not domesticated and trained by humans, and thus are not considered "working animals" as defined by this Article. *See supra* note 4.

54. Avery & Galvan, *supra* note 2, at 397–98; *see* Talbot, *supra* note 8; U.S. Patent No. 8,403,899 B2 (issued Mar. 26, 2013); *see also* Chinese Patent No. 103,190,380 A (issued Jan. 28, 2015).

55. *See* Brett Chedzoy, *Using Goats for Vegetation Management in the Northeast*, CORNELL SMALL FARMS PROGRAM (Apr. 2, 2011), https://smallfarms.cornell.edu/2011/04/using-goats-for-vegetation-management-in-the-northeast/ (describing the benefits of using goats for vegetation management, in particular in

Humans may also use animals for emotional support.[56] Emotional support animals, also known as comfort animals or therapy animals, may be any domesticated animal, including dogs, cats, mice, rabbits, birds, hedgehogs, etc.[57] Emotional support animals are not service animals because emotional support animals do not perform specific tasks.[58] Instead, emotional support animals help relieve loneliness, depression, or anxiety by providing companionship to their owners.[59]

B. Training Working Animals

For thousands of years, people have used a variety of techniques to domesticate and train animals. There are reports of animals trained for various military applications dating back to ancient times, zoo animals trained for entertainment and conservation, and animals trained to perform valuable services, as discussed *supra*.[60] And our society's need to train animals to behave in desired ways has not gone away. In the United States alone, the market for pet-training services is predicted to exceed over 820 million dollars by 2026.[61] The need for training services has fostered an environment for innovation in animal-training techniques and provides a unique opportunity for developers of trained working animals and related methods to commercialize their research findings.

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accessing hard-to-reach places or places which are off-limits to herbicides); *see also* Jack Guy, *Are Pigs the Answer to Bird Strikes? One Airport is Trying to Find Out*, CNN (Nov. 24, 2021, 10:55 AM), https://www.cnn.com/travel/article/schipol-airport-amsterdam-pigs-scli-intl/index.html.

56. *See Emotional Support Animals: The Basics*, UMASS CHAN MED. SCH., https://www.umassmed.edu/TransitionsACR/resources/emotional-support-animals-101/ (last visited Dec. 15, 2024).

57. *Id.*

58. *Id.*; s*ee also* Jacquie Brennan & Vinh Nguyen, *Service Animals and Emotional Support Animals*, ADA NAT'L NETWORK, at 3, https://adata.org/guide/service-animals-and-emotional-support-animals/ (last visited Nov. 2, 2024).

59. *See* Brennan & Nguyen, *supra* note 58, at 3; *see also* UMASS CHAN MED. SCH., *supra* note 56.

60. *See* John Sorenson, *Animals as Vehicles of War*, *in* ANIMALS AND WAR: CONFRONTING THE MILITARY-ANIMAL INDUSTRIAL COMPLEX 19, 19 (Anthony J. Nocella II et al. eds., 2013); *see also* Eduardo J. Fernandez et al., *Animal-Visitor Interactions in the Modern Zoo: Conflicts and Interventions*, APPLIED ANIMAL BEHAV. SCI., 2009, at 1.

61. Press Release, Rsch. & Mkts., The Pet Training Servs. Indus. in the U.S. is Expected to Grow at a CAGR of 6% During 2020 to 2026 (May 20, 2021), https://www.prnewswire.com/news-releases/the-pet-training-services-industry-in-the-united-states-is-expected-to-grow-at-a-cagr-of-6-during-2020-to-2026-301295977.html.

1. Training Methods

Many of the common animal training techniques are either considered reward-based, punishment-based, or both—in other words, "the carrot or the stick."[62] Generally, animals are trained through operant conditioning, which encompasses associating positive behavior with a reward, negative behavior with a punishment, or a combination thereof.[63] Rewards-based training, which is a type of operant conditioning, is widely regarded as the best way to train dogs.[64] In a survey of dog trainers, eighty-one percent of respondents said they used reward-based training with their dogs, though the vast majority combined this with punishments for some negative behavior.[65] Other animals are often trained this way as well. For example, people have used operant conditioning to train bees to distinguish between colors or odors, and rats to detect land mines.[66]

There are many organizations that claim to breed, certify, and train working animals, and these organizations create manuals and guidelines on training techniques.[67] However, there is no centralized authority that imposes standardized regulations on the working animal industry.[68] In fact, the Americans with Disabilities Act does not require service animals to be professionally trained.[69] Consequently,

62. *See* Elly Hiby et al., *Dog Training Methods: Their Use, Effectiveness and Interaction with Behaviour and Welfare*, 13 ANIMAL WELFARE 63, 63 (2004).

63. *See* Esther E. Matthew & Claire E. Relton, *Training Methodology for Canine Scent Detection of a Critically Endangered Lagomorph: A Conservation Case Study*, J. VERTEBRATE BIOLOGY, Jan. 8, 2021, at 2.

64. *See id.* at 2 ("Operant conditioning can be implemented using reward-based training, which is widely regarded as the best way to train a dog.").

65. *See* Hiby et al., *supra* note 62, at 66.

66. *See* C. Niggebrügge et al., *Fast Learning but Coarse Discrimination of Colours in Restrained Honeybees*, 212 J. EXPERIMENTAL BIOLOGY 1344, 1344 (2009); Maria Gabriela de Brito Sanchez et al., *Learning Context Modulates Aversive Taste Strength in Honey Bees*, 218 J. EXPERIMENTAL BIOLOGY 949, 949 (2015); *see also* Alan Poling et al., *Using Trained Pouched Rats to Detect Land Mines: Another Victory for Operant Conditioning*, 44 J. APPLIED BEHAV. ANALYSIS 351, 351 (2011).

67. *See* Mallie A. Myers, *Standardizing the Law on Working Animals*, 12 KY. J. EQUINE AGRIC. & NAT. RES. L. 117, 119 (2019); *see, e.g.*, U.S. DEP'T OF AGRIC., NATIONAL DETECTOR DOG MANUAL 1 (2012); KENNETH FURTON ET AL., NAT'L INST. OF JUST., THE SCIENTIFIC WORKING GROUP ON DOG AND ORTHOGONAL DETECTOR GUIDELINES 3 (Sep. 10, 2010), https://www.ojp.gov/ncjrs/virtual-library/abstracts/scientific-working-group-dog-and-orthogonal-detector-guidelines; *see also* U.S. Patent No. 2012/0111285A1.

68. *See* Myers, *supra* note 67, at 119.

69. *See Frequently Asked Questions About Service Animals and the ADA*, U.S. DEP'T OF JUST. (Feb. 28, 2020), https://www.ada.gov/regs2010/service_animal_qa.html.

these organizations are largely left to supervise themselves.[70] While there are no official training guidelines, training standards are influenced by research on animals, input from professional trainers, and ethical concerns regarding the welfare of animals.[71]

Training methods may vary depending on the purpose for which the animal will be used. When training detection animals, the most common method is reward-based operant conditioning, where a trainer teaches the animal to associate a target scent with a reward.[72] For example, to train a dog to detect illicit drugs, the trainer may first play a game with a dog's favorite toy, conditioning the dog to desire to play with the toy and constantly seek it out. The trainer then inserts a target odor (e.g., an odor associated with the illicit drug) in that toy so the dog begins to associate the smell of the target odor with its favorite toy. The trainer then hides the toy in various places and the dog is motivated to search for the target odor because it is associated with the toy. Over time, the trainer will continue to improve the dog's detection skills by making it more and more difficult to find the toy. For example, the trainer may increase the distance between the dog and the toy or hide the toy in places that are harder and harder to reach.[73] Eventually, the dog's association between the target odor and the toy is strong enough that it will continue to search for the toy in the presence of the target odor alone.[74] Thus, the fully-trained dog will search out the target odor, even in the absence of a reward.[75]

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70. *See* Myers, *supra* note 67, at 119.

71. Negative reinforcement, such as punishing dogs with choke collars or electronic collars, has largely fallen out of fashion as people become more concerned about dogs' welfare. *See* Ana Catarina Vieira de Castro et al., *Does Training Method Matter? Evidence for the Negative Impact of Aversive-Based Methods on Companion Dog Welfare*, PLOS ONE, Dec. 16, 2020, at 22.

72. *See* Matthew & Relton, *supra* note 63, at 1.

73. *See How Are Drug Sniffing Dogs Trained to Find Narcotics?*, 3DK9 DETECTION (Apr. 26, 2021), https://www.3dk9detection.com/news/how-are-drug-sniffing-dogs-trained-to-find-narcotics.

74. *See* Matthew & Relton, *supra* note 63, at 1; *How Are Explosive Detection Dogs Trains?: An Insider Look*, 3DK9 DETECTION (Nov 29, 2020), https://www.3dk9detection.com/news/how-are-explosive-detection-dogs-trains-an-insider-look.

75. Search dogs (i.e., dogs used to search for a missing person) are also trained using rewards-based training. For instance, a trainer may start by introducing a person's scent (e.g., an article of clothing previously worn by that person) to the dog, and place treats along a path that leads to the person. Gradually, the trainer reduces the amount of treats, increases the distance between the starting point and the person, and introduces various terrains. When the dog finds the search subject, the trainer rewards the dog with a toy, treats, praise, or a combination thereof. *See The 5 Phases*

Traditionally, trainers use a single-odor training method, where the trainer introduces animals to one odor at a time, followed by another.[76] However, some research suggests that training animals by mixing the odors together and training animals on that mixture (compound training), or presenting the odors separately but training animals on the odors at the same time (intermixed training), may be more effective.[77]

Like detection animals, reward-based operant conditioning is the most common training method for service animals. Guide dogs are commonly trained with positive reinforcement methods that reward desired behavior with food and praise.[78] Service dogs for veterans suffering from PTSD are trained with "positive methods of shaping behaviors."[79] For example, to train a service dog to respond to a panic or anxiety attack, a trainer may simulate such an attack (i.e., by trembling and breathing very fast to simulate the symptoms of a panic attack) and reward the dog with treats when the dog comes to the trainer to assist.[80] The trainer may teach a dog to fetch a specific item on command by repeatedly saying the name of an object and pointing at the object as the dog retrieves it.[81] Further, service animals must remain calm no matter what is happening around them.[82] Trainers teach this skill to service dogs by gradually introducing distractions to a dog and rewarding the dog when it successfully ignores these distractions.[83]

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of Search Dog Training: How to Train a Tracking Dog, ACTIVE DOGS (Nov. 25, 2019), https://activedogs.com/blog/the-5-phases-of-search-dog-training-how-to-train-a-tracking-dog/.

76. *See* Benjamin Keep et al., *The Impact of Training Method on Odour Learning and Generalisation in Detection Animals*, APPLIED ANIMAL BEHAV. SCI., Feb. 16, 2011, at 1.

77. *See id.*

78. *See* GUIDE DOGS FOR THE BLIND, *supra* note 37 ("Our dogs are trained with positive reinforcement methods that use high value rewards of both food and praise.").

79. Yount et al., *supra* note 36, at 64 ("The WCC training philosophy is based on positive methods of shaping behaviors . . . .").

80. *See, e.g.*, Veronica Morris & Bradley W. Morris, *How to Train a Service Dog Anxiety Alert/Response*, PSYCHIATRIC SERV. DOG PARTNERS, https://www.psychdogpartners.org/resources/work-tasks/how-to-train-a-service-dog-anxiety-alert-response (last visited Jan. 25, 2025).

81. *See* SERV. DOG REGISTRATION OF AM., *supra* note 39.

82. *See Service Dog for the Blind*, U.S. SERV. ANIMALS, https://usserviceanimals.org/blog/service-dog-for-the-blind/ (last visited Dec. 12, 2024).

83. *See* Stephanie Gibeault, *How to Use Clicker Training to Communicate With Your Dog*, AM. KENNEL CLUB (July 19, 2023), https://www.akc.org/expert-advice/training/clicker-training-your-dog-mark-and-reward/.

Trainers may also rely on punishment-based training techniques when a dog misbehaves or fails to follow instructions. For example, trainers may jerk the dog's leash or administer a shock on the dog's collar when the dog gets up from a sitting position in order to train the dog to stay seated next to its owner.[84] Alternatively, the trainer may withhold petting and attention when the dog does not behave correctly.[85] Critically, the punishment is immediately provided following the animal's undesired behavior, so the animal associates the bad behavior with the punishment.[86]

2. Training Tools

Trainers often use special tools, such as toys, treats, scent wheels, odor simulators, and other scent control devices to train detection animals. For example, scent wheels are special tools used for training detection dogs that consist of a base with several protruding arms, each arm having a compartment in which the trainer can place a scent.[87] Trainers may place target scents, controls, and distractors in various compartments of the scent wheel to teach an animal to discriminate between various scents.[88] Researchers trained dogs to detect COVID-19-infected patient samples by using scent wheels that held both infected samples and distractors (e.g., gloves and permanent markers) in the various ports of the scent wheel.[89]

There are many tools that give trainers control of a scent during training. For example, trainers may use devices that allow them to control the amount of scent exposure.[90] As another example, scientists at the National Institute of Standards and Technology developed a method of using a gelatin-like material called polydimethylsiloxane

84. *See* GENEVA INT'L CTR. FOR HUMANITARIAN DEMINING, MINE DETECTION DOGS: TRAINING, OPERATIONS AND ODOUR DETECTION 31 (Ian G. McLean ed., 2003).

85. *See id.*

86. *See* Oh et al., *supra* note 27, at 6 (describing training cancer-detecting rodents through a mix of positive reinforcement and punishment-based training).

87. *See TDK9's Detection Training Scent Wheel*, TDK9'S DETECTION TRAINING CAROUSEL, https://www.detectiontrainingcarousel.com (last visited Nov. 4, 2024).

88. *See* Jennifer L. Essler et al., *Discrimination of SARS-CoV-2 Infected Patient Samples by Detection Dogs: A Proof of Concept Study*, PLOS ONE, Apr. 14, 2021, at 5–6, https://doi.org/10.1371/journal.pone.0250158.

89. *See id.* at 6, 7.

90. *See, e.g.*, U.S. Patent No. 6,425,350 cl. 3 (claiming an apparatus comprising a housing, scent samples, and an adjustable portion to control the amount of exposure to the scent sample).

(PDMS) to train scent-detection animals.[91] PDMS can absorb the odors of other materials and then release the odors slowly over time.[92] Trainers can use PDMS to absorb odors from dangerous substances, such as fentanyl or explosive chemical compounds, thus reducing the need to expose either the animals or the handlers to these dangerous substances during training.[93] For example, when training dogs to identify dinitrotoluene (DNT), a highly reactive and hazardous organic compound present in many explosives, instead of using DNT directly, PDMS is infused with the scent of DNT, and the dogs are trained using these safe PDMS samples.[94] Thus, PDMS allows dogs to be trained to detect the odors of dangerous materials without actually being exposed to anything dangerous.[95]

Trainers can also train animals to perform certain tasks using sound-producing tools.[96] For example, a trainer may use a tool to create a clicking sound in response to a desired animal behavior.[97] When an animal performs a desired task, the trainer immediately makes the clicking sound and provides the animal with a reward.[98] In this way, the animal is trained to associate the clicking sound with the desired behavior and will perform that behavior in response to the sound.[99]

Trainers may also use punishment-based tools such as shock collars or choke collars when training detection dogs or service animals.[100] For example, a trainer may use a shock collar to dissuade the

91. *See* William MacCrehan et al., *Two-Temperature Preparation Method for PDMS-Based Canine Training Aids for Explosives*, FORENSIC CHEMISTRY, Oct. 15, 2020, at 1; *K9 Chemistry: A Safer Way to Train Detection Dogs*, NAT'L INST. OF STANDARDS & TECH. (Dec. 2, 2020), https://www.nist.gov/news-events/news/2020/12/k9-chemistry-safer-way-train-detection-dogs.

92. *See* NAT'L INST. OF STANDARDS & TECH., *supra* note 91.

93. *See id.* ("Some forms of fentanyl are so potent that inhaling a small amount can be harmful or fatal to humans and dogs.").

94. *See id.*

95. *See id.* Fentanyl, even in low concentrations, can be deadly to a dog. This method mitigates the risk of adverse interactions between dogs and dangerous substances.

96. *See* Lynna C. Feng et al., *Comparing Trainers' Reports of Clicker Use to the Use of Clickers in Applied Research Studies: Methodological Differences May Explain Conflicting Results*, PET BEHAV. SCI., Feb. 11, 2017, at 1, 6.

97. *See id.* at 6; *see also* Oh et al., *supra* note 27, at 6 ("[T]he clicker's click sound acts as a conditioned reinforcer, playing a role in strengthening the association between target odor and target behavior.").

98. *See* Feng et al., *supra* note 96, at 6.

99. *See id.* at 1.

100. *See* Jason Goldman, *The Science of Dog Training: Is It Okay to Use A Shock Collar?*, GIZMODO (Sept. 10, 2014), https://gizmodo.com/the-science-of-dog-

dog from performing undesired behavior as part of punishment-based training.[101] However, the use of shock collars and other punishment-based tools is controversial.[102]

C. The Challenges of Patenting Working Animals

Many practitioners are skeptical when first presented with the idea of patenting subject matter related to working animals. This skepticism likely traces its roots to cases where patent claims directed to living organisms were found invalid.[103] But such skepticism is ill-

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training-is-it-okay-to-use-a-shock-1632740695; Anamarie Clare Johnson, The State of Dog Training in the United States and Evaluation of Efficacy and Welfare of Contested Training Methods (May 2024) (Ph.D. dissertation, Arizona State University) (KEEP); *Service Dog Training*, APPALACHIAN DOG TRAINING, https://www.appalachiandogtraining.com/servicedogtraining.html (last visited Dec. 13, 2024).

101. *See id.*; GENEVA INT'L CTR. FOR HUMANITARIAN DEMINING, *supra* note 84, at 179 (discussing how "the termination of electroshocks" was used as motivation in training rats to detect buried explosives).

102. *See* Emily J. Blackwell et al., *The Use of Electronic Collars for Training Domestic Dogs: Estimated Prevalence, Reasons and Risk Factors for Use, and Owner Perceived Success as Compared to Other Training Methods*, BMC VETERINARY RSCH., June 29, 2012, at 1, https://bmcvetres.biomedcentral.com/articles/10.1186/1746-6148-8-93 (discussing the controversial use of electronic shock collars for dog training); *Why You Should Not Use Shock as a Training Tool*, DR. LISA RADOSTA, https://drlisaradosta.com/why-you-should-not-use-shock-as-a-training-tool/ (last visited Dec. 13, 2024); Joana Guilherme Fernandes et al., *Do Aversive-Based Training Methods Actually Compromise Dog Welfare? A Literature Review*, APPLIED ANIMAL BEHAV. SCI., July 20, 2017, at 11, https://www.sciencedirect.com/science/article/abs/pii/S0168159117302095 (evaluating controversial aversive-based training methods in dogs and concluding further research is needed to determine the effects of aversive-based training on animals); *see also* Goldman, *supra* note 100 (discussing that electronic shock collars are not more effective than positive reinforcement alone for improving obedience in dogs). Ethical considerations regarding training methods are beyond the scope of this Article.

103. *See, e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948) (holding that claims directed to an inoculum of naturally occurring bacteria were not directed to patentable subject matter because the invention was "no more than the discovery of some of the handiwork of nature . . . ."); *In re* Roslin Institute (Edinburgh), 750 F.3d 1333, 1337 (Fed. Cir. 2014) (holding that claims directed to Dolly, the cloned sheep, were not patent-eligible because "Dolly herself is an exact genetic replica of another sheep and does not possess 'markedly different characteristics from any farm animals found in nature.'") (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)); ChromaDex, Inc. v. Elysium Health, Inc., 59 F.4th 1280, 1284 (Fed. Cir.), *cert. denied*, 144 S. Ct. 330 (2023) (holding that a patent on an isolated dietary supplement was not patentable because "the act of isolating the [dietary supplement] compared to how [it] naturally exists in milk is not sufficient, on its own, to confer patent eligibility.") (citing Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 590–93 (2013)); Caredx, Inc. v. Natera, Inc., 40 F.4th 1371, 1381 (Fed. Cir. 2022), *cert. denied*, 144 S. Ct. 248 (2023) (holding that

founded—there is no general prohibition against patenting living organisms, and certainly not working animals in particular.[104] Congress famously noted that the Patent Act intended patentable subject matter to "include anything under the sun that is made by man."[105] There are, however, several hurdles which must be overcome in order to patent methods and tools associated with the training and handling of working animals. These hurdles, discussed further in Part II, *infra,* include showing that the invention is eligible subject matter, novel, and non-obvious.[106]

First, the patent applicant must meet the requirements for patent-eligible subject matter under Section 101 of the Patent Act.[107] Critically, courts have held that laws of nature, natural phenomena (including products of nature), and abstract ideas are not eligible subject matter.[108] With respect to working animals, an animal's ability to detect odor or its instincts to follow its human companion would likely be considered natural phenomena and thus not patentable. Furthermore, the relationship between particular odor profiles and naturally occurring things (e.g., the breath of COVID-infected patients, biopsies of cancerous cells) would likely be considered a law of nature or a natural phenomenon. Thus, patent applicants must show their invention does more than simply apply an animal's inherent odor-sniffing ability to detect the naturally occurring scent of a target, such as cancer cells.

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patents on noninvasive methods for determining organ transplant rejection were invalid because they were "directed to a natural law together with conventional steps to detect or quantify the manifestation of that law . . . ."); Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co., 933 F.3d 1302, 1318 (Fed. Cir. 2019) (holding that a patent directed toward in vitro method for genotyping Labrador Retrievers to determine if they carry a particular disease was invalid because "[t]he [a]sserted [c]laims do not recite an inventive concept that transforms the observation of a natural phenomenon into a patentable invention.").

104. *See, e.g.*, *Chakrabarty*, 447 U.S. at 310 (holding a claim to a genetically engineered bacterium patent-eligible because the claimed bacterium was not a product of nature); *see also* U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (9th ed., rev. Jan. 2024) [hereinafter MPEP]; *In re* Bergy, 596 F.2d 952, 973 (1979) (stating that "since 35 U.S.C. 101 does not expressly exclude patents to living organisms . . . [they] may be patented . . . .").

105. *Chakrabarty*, 447 U.S. at 309 (citing S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

106. This Article will not discuss utility, restriction requirements, and double-patenting because these are common patenting hurdles that do not raise specific issues related to patenting working animals.

107. 35 U.S.C. § 101 also has a utility requirement. *See* 35 U.S.C. § 101. However, this requirement is not often an issue in patent applications and thus will not be thoroughly discussed in this Article.

108. *See* Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014); *see also* MPEP, *supra* note 104, § 2106.04(b).

Moreover, the animal itself would likely be considered a product of nature, and the Supreme Court has ruled that living organisms are not patentable unless they are engineered by humans to do something that they cannot do in nature.[109]

Next, the patent applicant must satisfy the novelty and non-obviousness requirements under Sections 102 and 103 of the Patent Act, which require that the invention be new and more than an obvious iteration of known animal training tools and techniques.[110] To be considered new, the invention cannot have been in public use, on sale, or otherwise available to the public (e.g., described in a printed publication) prior to the filing date of the patent application.[111] The challenge with patenting subject matter related to working animals is that many training tools and methods are conventional and commonly known. For example, the core principles of positive reinforcement techniques (e.g., rewarding positive behavior with treats, toys, or affection) have been known for centuries, if not longer.[112] But even if the invention is technically novel, that is not sufficient to be patentable—the invention must also be non-obvious.[113] To assess obviousness, patent examiners and courts will look at the state of the existing technology and methods at the time the invention was conceived and evaluate whether a person of ordinary skill in the art would have found the invention to be obvious.[114] Similar to the novelty considerations, here, animal training tools and methods are generally widely known and have not significantly changed in the last decade.[115] Thus, new tools and methods that

109. *See Chakrabarty*, 447 U.S. at 309 (holding a claim to a genetically engineered bacterium capable of breaking down crude oil to be patent-eligible because the engineered claimed bacterium was a "nonnaturally occurring manufacture or composition of matter . . . .") (citing Hartranft v. Wiegmann, 121 U.S. 609, 614 (1887)).

110. *See* 35 U.S.C. §§ 102–103.

111. *See* 35 U.S.C. § 102(a).

112. *See* Mary R. Burch, *The Evolution of Modern-Day Dog Training & Obedience*, NAT'L ANIMAL INT. ALL. (July 15, 2002), http://www.naiaonline.org/articles/article/the-evolution-of-modern-day-dog-training#sthash.IVYmQMNr.dpbs ("By the 1980s positive behavioral procedures were commonplace in both dog training and human services settings.").

113. *See* 35 U.S.C. § 103 ("A patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.").

114. *See id.*

115. *See* Tadeusz Jezierski et al., *Operant Conditioning of Dogs* (Canis familiaris) *for Identification of Humans Using Scent Lineup*, 28 ANIMAL SCI. PAPERS

are only incremental improvements over the existing state of the art will need to show that the improvement is not merely an obvious variation of known tools and methods for training working animals.

II. OVERVIEW OF APPLICABLE PATENT LAW

The authority for the federal government to grant patents is grounded in the Constitution, which says Congress shall have the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[116]

Congress has codified patent law in Title 35 of the United States Code, which describes the requirements for patentability.[117] To obtain a patent in the United States, the invention described in a patent application must be (1) patentable subject matter, (2) new, (3) non-obvious, and (4) described in sufficient detail to allow one of skill in the art to make and use the invention.[118] These requirements are described in more detail below.

A. Patent-Eligible Subject Matter (35 U.S.C. § 101)

When seeking patent protection, the first hurdle to overcome is whether an invention is something eligible for patenting. The gatekeeper on patent eligible subject matter is Section 101 of the Patent Act, which states "[w]hoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor" and as noted previously, Congress explained that this language is meant to "include anything under the sun that is made by man."[119] Since the inception of Section 101 in 1952, the courts, including the Supreme

REPS. 81, 85 (2010) (discussing the use of clickers in training detection dogs); *see also Getting Results With Advanced Clicker Training*, AM. KENNEL CLUB CANINE HEALTH FOUND. (Apr. 29, 2009), https://www.akcchf.org/canine-health/your-dogs-health/caring-for-your-dog/getting-results-with-advanced.html (discussing the use of clickers in training dogs); Gibeault, *supra* note 83 (discussing the use of clickers in training dogs).

116. U.S. CONST. art. I, § 8, cl. 8.

117. *See* 35 U.S.C. §§ 101–112.

118. *See* 35 U.S.C. §§ 101, 102, 103, 112. The scope of this Article includes discussion of patentability for utility patents only. In the interest of brevity, the patentability of working animals under the design and plant patent regimes are not discussed herein, though they are likely not relevant to the patentability of working animals.

119. 35 U.S.C. § 101; S. REP. NO. 1979, at 5 (1952); *see* H.R. REP. NO. 1923, at 6 (1952).

Court, have joined the fray to outline the particulars of what constitutes patent-eligible subject matter. However, the Supreme Court has created numerous judicial exceptions to the scope of patentable subject matter, most recently in *Alice v. CLS Bank* and *Mayo v. Prometheus*.[120] To determine whether a claim is directed to patent-eligible subject matter, the USPTO applies a convoluted two-step test created in *Alice*.[121] At Step 1, if the examiner determines that the claim is directed to one of the patent-eligible statutory categories (a process, machine, manufacture, or composition of nature), then the examiner moves on to Step 2, which is divided into Steps 2A and 2B.[122] Step 2A asks whether the claim is directed to a judicial exception—i.e., "laws of nature, physical phenomena, and abstract ideas."[123] If the examiner determines at Step 2A that the claim is directed to a judicial exception, then Step 2B asks whether the claim recites additional elements that amount to significantly more than the judicial exception.[124] These judicial exceptions are described in more detail below in relation to working animals. If an invention is directed to a judicial exception, an inventor can overcome the presumption of non-patentability if the invention can be fairly characterized as a specific application of a law of nature, natural phenomenon, or abstract idea that is novel and useful.[125]

Further, even new discoveries can be considered judicial exceptions. For example, the Court held that newly discovered bodily

120. Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208 (2014); Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66 (2012).

121. *See* MPEP, *supra* note 104, § 2106; *Alice*, 573 U.S. at 217–18 (2014).

122. MPEP, *supra* note 104, § 2106; *Alice*, 573 U.S. at 217–18 (2014) ("First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts . . . .").

123. MPEP, *supra* note 104, § 2106.04; Diamond v. Diehr, 450 U.S. 175, 185 (1981).

124. Notice of 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019); *Alice*, 573 U.S. at 217–18 (2014) ("We have described step two of this analysis as a search for an 'inventive concept' — i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" (quoting *Mayo Collaborative Servs.*, 566 U.S. at 1292)).

125. *See, e.g.*, *Alice*, 573 U.S. at 217 (stating that "[i]n applying the §101 exception, we must distinguish between patents that claim the 'building blocks' of human ingenuity and those that integrate the building blocks into something more, thereby 'transforming' them into a patent-eligible invention.") (quoting *Mayo Collaborative Servs.*, 566 U.S. at 88–89)).

processes are not patentable, nor are newly discovered mathematical formulas.[126]

Although the Supreme Court's early decisions created judicial exceptions to patentability, these categories were construed fairly narrowly, and Section 101 was rarely a barrier to patentability for most of the Patent Act's history.[127] In more recent years, however, Supreme Court jurisprudence has rapidly expanded the scope of judicial exceptions to such a degree that district courts now commonly dispose of patent infringement cases early by summarily finding patents invalid under Section 101.[128] These decisions are regularly affirmed by the Federal Circuit, creating more and more judge-made roadblocks to patentability without predictable borders.[129] For example, in *American Axel v. Neapco*, the Federal Circuit found that a method for manufacturing a shaft assembly—something that was clearly human-made, physical, and technical—was an abstract idea.[130] This case and others

126. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 596 (2013) ("It found an important and useful gene . . . [but] [g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry."); *see also* Parker v. Flook, 437 U.S. 584, 591 (1978) ("[T]he novelty of the mathematical algorithm is not a determining factor at all.").

127. *See* Le Roy v. Tatham, 55 U.S. 156, 175 (1853) ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; and these cannot be patented, as no one can claim in either of them an exclusive right."); Shahrokh Falati, *To Promote Innovation, Congress Should Abolish the Supreme Court Created Exceptions to 35 U.S. Code § 101*, 28 TEX. INTELL. PROP. L.J. 1, 4 (2019); *see also* Christopher B. Seaman & Sheena X. Wang, *An Inside History of the Burger Court's Patent Eligibility Jurisprudence*, 53 AKRON L. REV. 915, 927–30 (2019).

128. *See generally* EMILY G. BLEVINS & KEVIN J. HICKEY, CONG. RSCH. SERV., IF12563, PATENT-ELIGIBLE SUBJECT MATTER REFORM: AN OVERVIEW 1 (2024); *see also* Falati, *supra* note 127, at 3.

129. *See, e.g.*, *In re* TLI Commc'ns LLC Patent Litig., 823 F.3d 607, 609 (Fed. Cir. 2016); Apple, Inc. v. Ameranth, Inc., 842 F.3d 1229, 1242–23 (Fed. Cir. 2016); Planet Bingo, LLC v. VKGS LLC, 576 Fed. App'x. 1005, 1008–09 (Fed. Cir. 2014); buySAFE, Inc. v. Google, Inc., 765 F.3d 1350, 1355 (Fed. Cir. 2014); Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 709, 722, 723 (Fed. Cir. 2014); *In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 757 (Fed. Cir. 2014); Content Extraction & Transmission LLC v. Wells Fargo Bank Nat'l Ass'n, 776 F.3d 1343, 1345 (Fed. Cir. 2014); *see also* Michael Borella et al., *91%: That is the Rate at Which the PTAB Affirms Examiner Section 101 Rejections*, PATENT DOCS (Aug. 12, 2024), https://www.patentdocs.org/2024/08/91-that-is-the-rate-at-which-the-ptab-affirms-examiner-section-101-rejections.html (presenting results from a study showing that Section 101 rejections by examiners during prosecution were affirmed on appeal at a rate of 91.11% in 2023).

130. *See* Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 967 F.3d 1285, 1292 (Fed. Cir. 2020) (finding the claim "ineligible under section 101 because it simply requires the application of Hooke's law to tune a propshaft liner to dampen certain vibrations."); *but see id.* at 1305 (Moore, C.J., dissenting) ("The claims at issue

demonstrate the ongoing confusion regarding the boundaries of patentable subject matter, and indeed, both academia and industry criticize the overbroad application of Section 101.[131] In fact, the Federal Circuit has criticized Section 101 case law in its own opinions, noting that the Supreme Court's exclusionary categories are overbroad, but that it is bound to follow precedent and render inventions unpatentable regardless.[132] As a result, developers of animal-based inventions may struggle to determine what inventions are actually patentable due to the unclear boundaries of Section 101.

1. Laws of Nature and Natural Phenomena

While laws of nature and natural phenomena are not patentable standing alone, applications of such laws and phenomena may be patentable.[133] However, merely adding "conventional steps, specified at

contain a specific, concrete solution (inserting a liner inside a propshaft) to a problem (vibrations in propshafts).").

131. *See* A. Sasha Hoyt, Note, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH. & LEE L. REV. 397, 452 (2022); *see also AIPLA/IPO/ABA – IPL Joint Principles on Section 101*, AM. INTELL. PROP. L. ASS'N, https://www.aipla.org/advocacy/legislative/aipla-ipo-aba—-ipl-joint-principles-paper-on-section-101 (last visited Sept. 6, 2024).

132. *See*, *e.g.*, Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (order denying rehearing en banc) ("New methods for diagnosing medical conditions, as a general matter, intuitively seem to be the kind of subject matter the patent system is designed for . . . . And it should be patentable subject matter in a well-functioning patent system. The most recent Supreme Court opinions are clear in my view on how to address claims like Athena's. Even though Athena's claims likely would be found patent-eligible under *Diehr's* framework, it is not an inferior court's role to dodge the clear, recent direction of the Supreme Court."); *In re* Killian, 45 F.4th 1373, 1383 (Fed. Cir. 2022) ("Even if we were persuaded . . . that the Alice/Mayo framework is insolubly unclear, both this court and the Board would still be bound to follow the Supreme Court's § 101 jurisprudence as best we can as we must follow the Supreme Court's precedent unless and until it is overruled by the Supreme Court."), *cert. denied sub nom.* Killian v. Vidal, 144 S. Ct. 100, 100 (2023).

133. "Laws of nature" and "natural phenomena" are often used interchangeably along with other terms, such as "physical phenomena," "products of nature," and "scientific principles." *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (describing characteristics of naturally-occurring bacteria as "laws of nature" and "phenomena of nature"); *see also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580 (2013) (stating that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated . . . ."); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 77 (2012) (finding a method of drug administration based on concentrations of certain metabolites in the blood to be unpatentable because "[t]he relation is a consequence of the ways in which thiopurine compounds are metabolized by the body-entirely natural processes.").

a high level of generality," is not sufficient to make a claim directed to a law of nature patentable.[134]

Laws of nature "include naturally occurring principles/relations and nature-based products that are naturally occurring or that do not have markedly different characteristics compared to what occurs in nature."[135] For example, in *Mayo v. Prometheus*, the court found relationships between blood concentrations of metabolites and drug efficacy to be unpatentable; in *Association for Molecular Pathology v. Myriad Genetics*, the court found isolated forms of naturally-occurring DNA to be unpatentable; in *In re Roslin Inst.*, the court found cloned sheep to be unpatentable.[136] In each of these cases, the courts found that the alleged inventions were laws of nature or natural phenomena because in each case, the underlying innovation was based on something that was already naturally occurring.[137] Furthermore, courts routinely find claims unpatentable where they do not include an inventive concept that is "significantly more" than the law of nature or natural phenomena alone.[138] This is especially evident in medical diagnostics inventions, where the Federal Circuit on many occasions has held that claims directed to newly discovered correlations between biomarkers

134. *Mayo Collaborative Servs*., 566 U.S. at 68.

135. MPEP, *supra* note 104, § 2106.04(b); *see, e.g.*, BRCA1- & BRCA2-Based Hereditary Cancer Test Pat. Litig. v. Ambry Genetics Corp., 774 F.3d 755, 760 (Fed. Cir. 2014) ("As the Supreme Court made clear, neither naturally occurring compositions of matter, nor synthetically created compositions that are structurally identical to the naturally occurring compositions, are patent eligible.") (citing *Ass'n for Molecular Pathology*, 569 U.S. at 591).

136. *See Mayo Collaborative Servs.*, 566 U.S. at 77 (finding a method of drug administration based on concentrations of certain metabolites in the blood to be unpatentable because "[t]he relation is a consequence of the ways in which thiopurine compounds are metabolized by the body entirely natural processes."); *see also Ass'n for Molecular Pathology*, 569 U.S. at 580 (finding that "a naturally occurring DNA segment is a product of nature and not patent eligible simply because it has been isolated . . . ."); *In re* Roslin Inst. (Edinburgh*)*, 750 F.3d 1333, 1337 (Fed. Cir. 2014) (finding cloned sheep to be unpatentable because the "claimed clones are exact copies of patent ineligible subject matter.").

137. *See Mayo Collaborative Servs*., 566 U.S. at 77; *see Ass'n for Molecular Pathology*., 569 U.S. at 580; *see In re* Roslin Inst. (Edinburgh*)*, 750 F.3d at 1337.

138. *See* Genetic Veterinary Scis., Inc. v. Canine EIC Genetics, LLC, 101 F. Supp. 3d 833, 843 (D. Minn. 2015) (granting summary judgment of patent ineligibility on claims because "[t]he patent claims at issue here are not directed at creating entirely new, non-natural genetic material. Instead, the [patent] uses non-natural processes to serve its purpose of identifying a natural law.") (citing *Ass'n for Molecular Pathology*, 569 U.S. at 591); *see also* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 751 (Fed. Cir. 2019) (holding the radioimmunoassay used to detect a newly discovered protein associated with a neurological disorder to be unpatentable because the claims recited conventional techniques used to detect the protein).

and disease states are unpatentable. For example, in *Athena v. Mayo*, the Federal Circuit held that a method of diagnosing neurological disorders by detecting a particular autoantibody using techniques known in the art was unpatentable because the claims were directed to a natural law.[139] The patentee argued that the diagnostic method was a new laboratory technique that made use of human-made molecules; however, the Federal Circuit was unpersuaded by the patentee's argument, noting that "the use of a man-made molecule is not decisive if it amounts to only a routine step in a conventional method for observing a natural law."[140] Similarly, in *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, in evaluating claims directed to detecting the risk of cardiovascular disease by determining the level of the enzyme myeloperoxidase (MPO), the Federal Circuit held that the claims were unpatentable because they were directed to methods of observing a law of nature using conventional testing techniques.[141] And in *Ariosa v. Sequenom*, the Federal Circuit determined that claims directed to a method for detecting cell-free fetal DNA (cffDNA) in maternal plasma or serum to determine fetal characteristics such as gender, in combination with well-understood, routine, and conventional techniques were unpatentable because the method "begins and ends with a natural phenomenon."[142]

Qualities of an organism, such as an animal's senses, strength, natural instincts, or naturally-occurring genetic code, standing alone, would likely be found to be unpatentable natural phenomena by a court.[143] For example, a dog's innate ability to smell, be trained, and

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139. *See Athena Diagnostics, Inc.*, 915 F.3d at 751 ("[T]he claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law.").

140. *Id.* at 752.

141. *See* Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352, 1360 (Fed. Cir. 2017) ("The claims of the testing patents are directed to multistep methods for observing the law of nature that MPO correlates to cardiovascular disease."); *id.* at 1362 ("Here too, Cleveland Clinic does not purport to derive new statistical methods to arrive at the predetermined or control levels of MPO that would indicate a patient's risk of cardiovascular disease. Known statistical models can be employed, as described, for example, in the specification of the '552 patent' . . . .").

142. *See* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376, 1378 (Fed. Cir. 2015) ("The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring.").

143. *See, e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations

detect the aromas of distinct chemical compounds are qualities of dogs that are likely unpatentable natural phenomena.[144] The same is likely true for the scent profiles of a human body or a bundle of cancer cells.[145] Additionally, newly discovered scent profiles of natural organisms, and correlations between newly discovered scent profiles and diseases, likely constitute natural phenomena, despite having been newly discovered.[146]

Accordingly, living animals themselves are *per se* unpatentable unless they are engineered by humans to do something that they could not naturally do.[147] Simply identifying an animal's innate abilities and training it to use them on command for a particular purpose likely falls within the judicial exceptions to patentability and creates challenges to working animal developers seeking intellectual property protection.

However, an invention that recites a law of nature or natural phenomena may be patentable if there is an inventive concept that integrates the law of nature or natural phenomena into a practical

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of laws of natures, free to all men and reserved exclusively to none."); *Ass'n. for Molecular Pathology*, 569 U.S. at 580 (holding that synthetically created human DNA is patent-eligible, but isolated naturally occurring DNA is not); Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG, 933 F.3d 1302, 1318 (Fed. Cir. 2019) (holding that a patent directed toward in vitro method for genotyping Labrador Retrievers to determine if they carry a particular disease was invalid because "the Asserted Claims do not recite an inventive concept that transforms the observation of a natural phenomenon into a patentable invention."); ChromaDex, Inc. v. Elysium Health, Inc., 59 F.4th 1280, 1284 (Fed. Cir. 2023) (holding that a patent on an isolated dietary supplement was not patentable because "the act of isolating the [dietary supplement] compared to how [it] naturally exists in milk is not sufficient, on its own, to confer patent eligibility.") (citing *Ass'n for Molecular Pathology*, 569 U.S. at 591); Caredx, Inc. v. Natera, Inc., 40 F.4th 1371, 1381 (Fed. Cir. 2022) (holding that patents on noninvasive methods for determining organ transplant rejection were invalid because they were "directed to a natural law together with conventional steps to detect or quantify the manifestation of that law . . . .").

144. *See, e.g.*, *Funk Bros. Seed Co.*, 333 U.S. at 130.

145. *See id.* In this case, scent profiles of cancer cells are naturally-occurring features of the cancer cells. *Id.*

146. A newly discovered but naturally-occurring characteristic is still a law of nature, rendering a claim on the characteristic itself to be unpatentable. *See id.*; *see also Ariosa Diagnostics, Inc.*, 788 F.3d at 1377 ("The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum.").

147. *See* Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (finding a new human-engineered strain of bacteria to be patent-eligible subject matter because it had "markedly different characteristics from any found in nature" and the potential to be significantly useful).

application.[148] The inventive concept must be something more than simply applying "well understood, routine, conventional activity already engaged in by the scientific community . . . ."[149] For example, in *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd.*, the Federal Circuit affirmed a finding that a claim involved a law of nature—the relationship between a patient's specific genotype and the risk of prolonging a particular disease—was patent-eligible because the claim included treating the patient with a particular medication that was tailored to the patient's specific genotype.[150] In that case, the Federal Circuit reasoned that the teaching of a particular drug administration regimen based on a patient's specific reaction to a drug was patent eligible at step one of the *Alice/Mayo* test because the patent claimed a treatment based on a natural law, rather than claiming a natural law itself.[151]

It is difficult to imagine getting a patent on a trained working animal without providing a new application, tool, or method of training/using the working animal that goes beyond any implicated laws of nature or natural phenomena. For example, at a high level, a patent on a working method for a detection animal (i.e., using a trained animal to perform a detection task in a particular way) appears to merely take advantage of the natural phenomena of an animal's natural olfactory abilities. Thus, the key question in patenting methods directed to training or using working animals is whether the claims include an inventive concept beyond the animal's natural abilities. If a court finds that the working animal method claim is directed to a law of nature or natural phenomena (e.g., the inherent olfactory abilities of animals), it must determine whether the claim incorporates any additional step that integrates the animal's inherent abilities into an inventive, practical

148. *See* Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 83, 84 (2012); Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319, 1328 (Fed. Cir. 2020) (holding that patents related to a method for DNA testing fetuses were valid because the patentee used "conventional separation technologies . . . in unconventional ways."); Endo Pharms. Inc. v. Teva Pharms. USA, Inc., 919 F.3d 1347, 1357 (Fed. Cir. 2019) (holding that a patent on a method of using oxymorphone to treat pain in patients with impaired kidney function was valid because it was directed "to a new treatment for an ailment, albeit using a natural law or phenomenon.").

149. *Mayo Collaborative Servs.*, 566 U.S. at 79–80.

150. *See* Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1134, 1135, 1136 (Fed. Cir. 2018).

151. *See id.* at 1136 ("[T]he claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.").

application.[152] Further, the invention must do more than apply well-understood, routine, or conventional activities, such as routine methods to command an animal to perform tasks.[153] Ultimately, developers of working animals should consider which aspects of their work go beyond merely taking advantage of the animals' inherent ability to perform the required tasks before seeking patent protection.

2. Abstract Ideas

Courts have identified three general categories of abstract ideas: mathematical concepts, certain methods of organizing human activity, and mental processes.[154] Methods of organizing human activity are particularly relevant to the patentability of working animals because they likely encompass training methods that lay out what trainers do while training animals. The framework for analyzing the patentability of abstract ideas is substantially identical to that used for laws of nature. That is, the court determines whether a claim that recites an abstract idea has an inventive concept, or whether there is something "significantly more" than an abstract idea.[155] The Federal Circuit has indicated that using conventional steps in an unconventional way, such as an unconventional order, is indicative of an inventive concept.[156]

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152. *See* Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 218 (2014) ("We must first determine whether the claims at issue are directed to a patent-ineligible concept."); *see also id.* at 221 ("At *Mayo* step two, we must examine the elements of the claim to determine whether it contains an '"inventive concept"' sufficient to 'transform' the claimed abstract idea into a patent-eligible application.") (quoting *Mayo Collaborative Servs.*, 566 U.S. at 72).

153. *See Mayo Collaborative Servs.*, 566 U.S. at 79–80 ("To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons, we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.").

154. *See* Parker v. Flook, 437 U.S. 584, 589 (1978) (describing mathematical concepts to be unpatentable); *see also* Bilski v. Kappos, 561 U.S. 593, 611–12 (2010) (describing certain methods of organizing human activity to be unpatentable); CyberSource Corp. v. Retail Decisions, Inc., 654 F.3d 1366, 1372 (Fed. Cir. 2011) (describing mental processes, which are thinking "that can be performed in the human mind" to be unpatentable).

155. *See In re* Rudy, 956 F.3d 1379, 1382 (Fed. Cir. 2020); *see also* MPEP, *supra* note 104103, § 2106.04(b)–(c).

156. *See, e.g.*, Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042, 1051 (Fed. Cir. 2016) (process reciting combination of individually well-known freezing and thawing steps was "far from routine and conventional" and thus eligible); *see also* BASCOM Glob. Internet Servs. v. AT&T Mobility LLC, 827 F.3d 1341, 1350

For example, in *In re Marco Guldenaar Holding B.V.*, the Federal Circuit held that a method of playing a dice game which included the steps of placing a wager, rolling the dice, and paying a payout amount was an abstract idea—namely, a method of organizing human activity—and that merely applying the steps on a computer fell short of reciting an inventive concept sufficient to transform the abstract idea into a patent-eligible application.[157] Similarly, in *People.ai v. Clari*, the Federal Circuit held that a method of tracking and filtering information related to customers, accounts, sales, and similar information was an abstract idea because the claimed invention did not differ from the "long-prevalent manual practice" of selecting and filtering information in a system of records and lacked an inventive concept, thus rendering it unpatentable.[158] And in *Repifi Vendor Logistics v. IntelliCentrics*, the Federal Circuit determined that a patent directed to a credentialing system for managing visitor access to access-controlled environments was directed to a method of organizing human activity, namely, a credentialing process, and merely using commercially available methods to implement this idea lacked the inventiveness to transform the invention into a patent-eligible application.[159] Critically, in all of these cases, the supposed inventions were merely automated versions of previously manual activities.

In contrast, in *Bascom Global v. AT&T Mobility*, the Federal Circuit determined that claims directed to a method for filtering content retrieved from the internet were patentable subject matter.[160] The court

(Fed. Cir. 2016) (inventive concept may be found in the non-conventional and non-generic arrangement of components that are individually well-known and conventional).

157. *See* In re Marco Guldenaar Holding B.V., 911 F.3d 1157, 1160–61 (Fed. Cir. 2018) ("Just as the claimed steps of shuffling and dealing playing cards fell short in *Smith*, and recitation of computer implementation fell short in *Alice*, the claimed activities here are purely conventional and are insufficient to recite an inventive concept.") (citing *Alice*, 573 U.S. at 223–24).

158. *See* People.ai, Inc. v. Clari Inc., No. 2022-1364, 2023 U.S. App. LEXIS 8294, at *18, *23 (Fed. Cir. Apr. 7, 2023) ("[T]his claimed system accomplishes the same ends using the same steps long undertaken by a salesperson or corporate mailroom sorting correspondence and setting aside certain correspondence for further processing and filing.").

159. *See* Repifi Vendor Logistics, Inc. v. IntelliCentrics, Inc., No. 2021-1906, 2022 U.S. App. LEXIS 6558, at *6 (Fed. Cir. Mar. 15, 2022) ("Indeed, none of the claim limitations are directed to improvements that enable the badge to change its display in real time or communicate with a smart phone. Instead, the claims merely recite the use of conventional abilities of a conventional electronic badge.") (citing Repifi Vendor Logistics, Inc. v. Intellicentrics, Inc., No. 4:20-CV-448, 2021 U.S. Dist. LEXIS 60434, at *8 (E.D. Tex. Mar. 30, 2021)).

160. *See BASCOM Glob. Internet Servs., Inc*, 827 F.3d at 1349, 1350.

noted that while filtering internet content is a method of organizing human activity, there was an inventive concept in the "specific, discrete implementation" of a filtering tool at a specific location, and that the filtering tool was an improvement over existing technologies.[161] Specifically, the Federal Circuit determined that, instead of merely automating a manual activity, the claims in the *Bascom* case were directed to "a technical improvement over [the] prior art . . . ."[162]

In the context of working animals, these cases teach that generic methods, such as training methods that merely instruct a person to reward desired behavior and punish undesired behavior by the working animal, would likely be found to be an unpatentable abstract idea. But a patent claim directed to a specific method using specific tools, such as the idea of teaching a dog not to bark with operant conditioning, may still be granted if the invention integrates some novel technique or device that provides a practical application, such as a novel autonomous device for training the dog to not bark, using a monitoring system that measures the sound level of a bark, or using a hydraulic system that sprays water on the dog if its bark exceeds a particular sound level.[163]

B. Patentability in View of the Prior Art (35 U.S.C. §§ 102, 103)

If the patentee is able to overcome the hurdle of having its claims be found patentable subject matter, the next hurdle is overcoming the novelty and non-obviousness thresholds in view of millennia of recorded history of people using animals for various working purposes. For example, researchers have identified evidence of domesticated and trained dogs to aid in hunting dating back to the last ice age.[164] Moreover, a simple internet search for "hunting dog training" returns countless websites offering services, products, and tips to help safely train a hunting dog in various ways.[165] To obtain a patent on a method to train a hunting dog, then, the patentee would need to identify a novel aspect of their method that is not just an obvious iteration of the numerous training methods already in the public domain.

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161. *Id.* at 1350.

162. *Id.*

163. *See, e.g.*, U.S. Patent No. 7,658,166 B1 (issued Feb. 9, 2010) (claiming a novel autonomous device that teaches a dog to not bark).

164. *See* Lahtinen et al., *supra* note 1, at 2; *see also* Perri, *supra* note 1, at 9, 10.

165. A search on Google for "hunting dog training" on Google, performed on Feb. 20, 2025, yielded 97.5 million results. GOOGLE, https://www.google.com/search?q=hunting+dog+training.

1. Novelty

Under Section 102 of the Patent Act, patent claims will be considered lacking novelty if a single item of prior art discloses each and every limitation of a claim, either expressly or inherently.[166] Prior art includes prior patents, publications, sales and offers to sell, public sales, or disclosures otherwise available to the public before the effective filing date of the claimed invention.[167]

If the patentee is attempting to protect a training method, they will need to show how their training method is different from how people have been training animals for much of our civilized history. Humans have been training animals to assist with tasks for centuries, if not millennia.[168] The earliest systematic instruction of dogs to help the blind dates back to the 1750s.[169] The United States military used bomb-sniffing dogs to detect hidden explosives during World War II.[170] Humans have traditionally trained dogs with positive reinforcement, negative reinforcement, or a combination thereof. For example, by the 1980s, positive reinforcement was commonplace in dog training.[171] Rewards-based training has been used for decades, if not centuries.[172] Thus, to obtain a patent on a training method for a working animal, the patent applicant must overcome the challenge of inventing a method that is not already well known. For instance, training methods

166. *See* Verdegaal Bros. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Circ. 1987) (interpreting the anticipation requirement under 35 U.S.C. § 102).

167. 35 U.S.C. § 102. The "effective filing date" of a patent application is (1) the actual filing date of the patent or the application for the patent containing the claimed invention or (2) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority or the benefit of an earlier filing date under. MPEP, *supra* note 104, § 2152.01.

168. *See The Story of the Plough*, NAT'L MUSEUMS SCOT., https://web.archive.org/web/20240424071338/https://www.nms.ac.uk/explore-our-collections/stories/science-and-technology/ploughs/ (last visited Jan. 5, 2025) ("Over 4,000 years ago . . . ploughs were usually pulled by oxen."); Roly Evans, *A Brief History of Mine Detection Dogs*, JAMES MADISON U., https://www.jmu.edu/news/cisr/2022/10/261-2/05-261-evans-mdd.shtml (last visited Nov. 9, 2024) (demonstrating that dogs have been used to detect mines in battlefields since at least 1942); *see also* Jennie Cohen, *Assistance Dogs: Learning New Tricks for Centuries*, HISTORY (Aug. 23, 2018), https://www.history.com/news/assistance-dogs-learning-new-tricks-for-centuries.

169. *See* Cohen, *supra* note 168.

170. *See* Robert R. Milner Jr., *Mighty Dogs of the Military*, AIR & SPACE FORCES MAG. (Feb. 1, 2008), https://www.airandspaceforces.com/article/0208dogs/.

171. *See* Burch, *supra* note 112.

172. *See* Evans, *supra* note 168 (relaying that dogs have been used to detect mines in battlefields since at least 1942); *see also* Cohen, *supra* note 168.

based on operant conditioning are documented in literature starting as early as the mid-20th century.[173]

Applicants face similar challenges for training tools, since this field is crowded with various toys, scent-training tools, and other miscellaneous tools used to help train animals.[174] An exemplary search on Google is illuminating—searching for "animal training tools" returns over 406 million results.[175] And even if a tool has not been used to specifically train working animals, its public use to train pets or zoo animals may preempt a patent directed to using the same tool in the working animal context.

However, if the patentee is attempting to protect a working method (i.e., using the trained animal to perform a particular task in a particular way), they will merely need to show how their working method uses the animal in a way that has never been done before. While animals have been used for a variety of tasks in the past, people continue to find new uses for working animals. Such innovative uses in recent years were the inspiration for this Article. For example, various species, including dogs, mice, bees, and fruit flies, have been trained to use their heightened sense of smell for detection purposes, including identifying asymptomatic COVID-19, malaria, various cancers, avian flu, and *C. difficile* infections.[176]

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173. *See generally* Pat Miller, *The Four Principles of Operant Conditioning for Dogs*, WHOLE DOG J. (Nov. 15, 2011), https://www.whole-dog-journal.com/training/the-four-principles-of-operant-conditioning-for-dogs/ (illustrating operant conditioning may have even become commonplace before the term "operant conditioning" became popular).

174. An Amazon.com search for "dog training tools" on Oct. 31, 2023 yielded more than 10,000 results. AMAZON, https://www.amazon.com/s?k=dog+training+tools&crid=MTHOVEE6XLKA&sprefix=%2Caps%2C118&ref=nb_sb_ss_recent_1_0_recent.

175. GOOGLE, https://www.google.com/search?q=animal+training+tools (last visited Feb. 20, 2025). Additionally, a Google Patents search for animal, dog, and canine training tools or devices returns over 5,800 patents. GOOGLE PAT., https://patents.google.com/?q=(%22animal+training%22+OR+%22dog+training%22+OR+%22canine+training%22)+AND+(tool+OR+device)&oq=(%22animal+training%22+OR+%22dog+training%22+OR+%22canine+training%22)+AND+(tool+OR+device) (last visited Feb. 20, 2025).

176. *See, e.g.*, Bomers et al., *supra* note 22, at 2 (describing dogs used to detect the presence of *C. difficile* bacteria); McCulloch et al., *supra* note 22, at 30, 32, 34 (describing dogs used to detect lung and breast cancers); Kimball et al., *supra* note 28, at 2, 3 (showing trained mice accurately discriminating between avian flu infected and non-infected duck feces 80% of the time); Strauch et al., *supra* note 29, at 7 (describing fruit flies' consistent responses to cancer odors in a controlled environment); Iati, *supra* note 31; Kelly McLaughlin & Aria Bendix, *Scientists Have Taught Bees to Smell the Coronavirus. They Can Identify a Case Within Seconds*,

Similarly, if the patentee is attempting to protect a working tool (i.e., a tool used while the working animal is performing a particular task), the patent application must illustrate how that tool is inventive over other tools used with working animals. The number of working tool patents is relatively small, as discussed in Part III.B.2, *infra*, so a patent application directed to one of these tools may not receive many novelty rejections on its path toward allowance and may be more difficult to invalidate due to a lack of relevant prior art.

2. Obviousness

The next criterion for patent-eligibility is non-obviousness. Under Section 103, patent claims will be considered unpatentable "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."[177] The court must make four factual inquiries (the "*Graham* test") to determine whether a claim is invalid under Section 103:

> [1] the scope and content of the prior art . . .
>
> [2] the level of ordinary skill in the art . . .
>
> [3] differences between the prior art and the claims at issue . . .
>
> [4] secondary considerations, such as commercial success, long-felt but unsolved needs, failure of others, etc., that may be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.[178]

Under the first prong of the *Graham* test, the scope and content of the prior art under Section 103 includes all references and information that qualify as prior art under Section 102.[179] The level of ordinary skill in the art is determined by considering many factors, including "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the

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BUS. INSIDER (May 6, 2021, 12:04 PM), https://www.businessinsider.com/scientists-taught-bees-to-smell-covid-19-infections-2021-5; Sonoda et al., *supra* note 22, at 1; Horvath et al., *supra* note 22, at 76; Willis et al., *supra* note 22, at 1; Pickel et al., *supra* note 22, at 107.

177. 35 U.S.C. § 103.

178. Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966). In KSR Int'l Co. v. Teleflex Inc., the Supreme Court reaffirmed the Graham test as an appropriate test for obviousness. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406–07 (2007).

179. *See* J.A. LaPorte, Inc. v. Norfolk Dredging Co., 787 F.2d 1577, 1580 n.4 (Fed. Cir. 1986).

field."[180] Differences between the prior art and the claims at issue are then evaluated to determine whether the claimed invention would have been obvious to a person of ordinary skill in the art at the time of the invention.[181] Secondary considerations include commercial success, the copying of the invention by others, or the filling of a long-felt need, among others.[182]

Here, similar to the novelty considerations discussed in Part II.B.1, *supra*, there are a breadth of methods and tools commonly known in the arts of training and handling animals that could render an invention obvious. Even if patent applicants overcome the novelty hurdle, they must also show their methods or tools are not obvious variants of existing methods and tools to train or use working animals.

A common obviousness argument that patentees of working animals will likely face is that the claimed method or tool is obvious in light of similar methods and tools disclosed in the prior art. When analyzing the obviousness of a method or tool in this context, a court will apply a two-part test to determine: (1) whether the prior art reference qualifies as analogous art (i.e., the reference is from the same field of endeavor as the inventor, or the reference is otherwise reasonably pertinent to the problem the inventor seeks to address);[183] and (2) whether the prior art would provide one of skill in the art a motivation to modify or combine the teachings in the prior art reference(s) to make the

180. Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986) (citing Env't Designs, Inc. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983)) ("The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art.").

181. *See, e.g.*, Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1342, 1343, 1344–45 (Fed. Cir. 2000).

182. *See Graham*, 383 U.S. at 17–18. Secondary considerations, also referred to as secondary indicia of non-obviousness, can be used to establish that the invention was in fact not obvious in light of the prior art. *Id.* These secondary considerations can serve to protect against the improper use of hindsight analysis in determining whether combinations of prior art references would have been obvious to a person of ordinary skill in the art. *See* Pharmastem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342, 1377 (Fed. Cir. 2007) (Newman, J., dissenting). The Court in *Graham* stated that secondary considerations can include "commercial success, long felt but unsolved needs, [and] the failure of others. . . ." *Graham*, 383 U.S. at 17. Other factors recognized by the Federal Circuit after *Graham* include whether the prior art teaches away from the invention, whether others have copied the invention, and whether the invention has received industry acclaim. *See* Ecolochem, Inc. v. S. California Edison Co., 227 F.3d 1361, 1379–80 (Fed. Cir. 2000), *cert. denied*, 532 U.S. 974 (2001). In 2007, the Supreme Court in *KSR Int'l Co.* reaffirmed the application of the approach articulated in *Graham* to determine non-obviousness, including the analysis of secondary considerations. *KSR Int'l Co.*, 550 U.S. at 415.

183. *See In re* Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

claimed method or tool with a reasonable expectation of success.[184] In the context of working animals, this means that any iterations on existing methods or tools for training or using animals must either come from non-analogous technology areas or be sufficiently inventive. For example, the use of a neck collar to deliver electroshock stimulation to train an animal not to bark is a well-known dog training technique. In this example, an applicant trying to patent an ankle monitor that delivers electric pulses to an animal's leg when it approaches a geofence would likely face a difficult obviousness rejection because the shock collar is arguably both analogous art (i.e., same field of endeavor of dog training tools) and one of skill in the art would be motivated to modify it with a reasonable expectation of success (i.e., moving it from the dog's neck to its leg).

Another common argument patentees may face is that the claimed invention was "obvious to try." In *KSR Int'l Co.*, the Supreme Court explained that a claimed invention can be rendered obvious when it would have been obvious to try a finite number of predictable solutions and where there was a reasonable expectation of success.[185] In the context of working animals, it may be considered obvious to try to train an animal to detect a novel scent using routine, reward-based operant conditioning. This is because training and using animals for scent detection is commonplace and routine, e.g., drug-detection dogs in airports. Moreover, the success of reward-based dog training techniques is well-known in the art, so there would likely be a reasonable expectation of success to try those same methods using a different scent compound.

C. Patentability in View of the Description of the Invention (35 U.S.C. § 112)

Section 112 of the Patent Act requires the specification to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."[186] This statutory section is the basis of the so-called "written description" and "enablement" requirements. Both are based on the state-of-the-art knowledge at the time the patent was filed. Researchers are

184. *See* Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286, 1291 (Fed. Cir. 2018).

185. *See KSR Int'l Co.*, 550 U.S. at 421.

186. 35 U.S.C. § 112(a).

continuously discovering new uses for working animals that are increasingly more complex, including intricate techniques for scent-based detection of unidentified human odors. And while the researchers may have identified specific and well-documented protocols for training their animals to perform those tasks, they may not fully understand why the animals are responding a certain way to the training techniques or how the animal is able to identify the correct odor. This presents a challenge for a patentee to provide an adequate written description that would sufficiently enable others to replicate their results.

1. Written Description

To satisfy the written description requirement, the specification must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date."[187] The scope of the disclosure needed "varies with the nature and scope of the invention at issue . . . ."[188] The Federal Circuit has held that an adequate written description in unpredictable arts like biotechnology or chemistry "requires a precise definition, such as by structure, formula, or chemical name" to distinguish the claimed subject matter from other materials.[189] This is somewhat of a high standard to meet should training and using working animals be classified as an unpredictable art. The underlying mechanisms for how animals are trained to perform tasks accurately and efficiently are not well-known, and thus may be difficult, if not impossible, to adequately describe in some instances.[190] For example, even if researchers know a canine can rely on its olfactory receptors (i.e., sense of smell) to determine the

187. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citing Ralston Purina Co. v. Far-Mar-Co., Inc. 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

188. Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005). According to the Federal Circuit, "[t]he purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" Amgen Inc. v. Hoechst Marion Roussel Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003) (citing Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991)).

189. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997) (alterations omitted) (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

190. *See* Avery & Galvan, *supra* note 2, at 386 ("In addition to being less predictable than conventional diagnostics, animal-based diagnostics are also less understood—it is still unclear if the animals are detecting the same analyte as the equivalent diagnostic kits or something else.") (citing Natalia Cernei et al., *Sarcosine as a Potential Prostate Cancer Biomarker—A Review*, 14 INT'L J. MOLECULAR SCIS. 13893, 13894–95 (2013)).

presence of disease in a human sample based on the sample's volatile organic compound (VOC) profile, researchers typically do not know *which* VOCs the canine is detecting and thus cannot fully explain how the canine is able to determine the presence of a disease.[191] Thus, an applicant trying to claim a method of training a canine to detect cancer in a human sample may not be able to provide the required "precise definition" of the distinguishing characteristic of the invention related to the specific biochemical pathway that the canine detects, or the specific VOC profile being detected.

Even if the patent applicant cannot directly determine the underlying mechanism, they can still provide their best understanding of the process. For example, researchers have successfully trained canines to detect the presence of prostate cancer in human urine samples.[192] Those canines were not detecting the presence of protein-specific antigen (PSA), the measured biomarker in most conventional prostate cancer diagnostic tests, however, because PSA is only found in blood.[193] Instead, additional research suggested that the VOC detected in the human urine samples is likely from sarcosine, another biomarker for prostate cancer.[194] Including specific details such as these in the specification for animal-based patents may allow the applicant to provide the "precise definition" required to satisfy the written description requirement for inventions considered unpredictable arts.[195]

However, when the patent applicant is unable to describe the underlying mechanisms for how the working animals function, the written description requirement may require the applicant to include detailed experimental results to demonstrate possession of the claimed

191. Roland Becker, *Non-Invasive Cancer Detection Using Volatile Biomarkers: Is Urine Superior to Breath?*, MED. HYPOTHESES, July 1, 2020, at 1 ("However, the actual compounds responsible for the scent are completely unknown and there is no correlation with the potential biomarkers suggested on basis of chemical trace analysis.").

192. *See* Avery & Galvan, *supra* note 2, at 372.

193. *See id.* at 378 n.44; Cernei et al., *supra* note 190, at 13894.

194. *See* Cernei et al., *supra* note 190 at 13894–95; *see also* Avery & Galvan, *supra* note 2, at 378 n.44.

195. *See* GlaxoSmithKline LLC v. Banner Pharmacaps, Inc., 744 F.3d 725, 731 (Fed. Cir. 2014) (affirming a district court's finding of adequate written description where "[t]he claim term and its corresponding description, however broad, identify certain structures produced by certain processes . . . [because] [t]he claim term does not assert coverage of yet-unidentified ways of achieving a desired result; it does not 'attempt to preempt the future before it has arrived.'") (citing Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

invention.[196] Such experimental results could include experiments showing that the animals are actually able to perform the task, under what environmental conditions the task is completed, and any supporting information relevant to the scope of the patent claims. For example, an applicant patenting a method to train a canine to detect the presence of a certain cancer in a patient sample where the VOC profile of the biomarker detected by the canine is unknown may need to provide experimental data demonstrating specific evidence of analytical and clinical validity.[197] In addition to experimental results, the applicant may want to include supporting information from available research studies about which biomarker is responsible for the VOC profile present in the sample indicating a positive test.[198]

2. Enablement

To satisfy the enablement requirement under 35 U.S.C. § 112(a), a patent specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'"[199] A "reasonable" amount of "routine experimentation" is not considered undue.[200] Whether "undue experimentation" is required to practice the claimed invention is not a factual determination but, rather, a legal conclusion based on factual considerations.[201]

Although a specification need not disclose what is well known in the art, it "must supply the novel aspects of an invention in order to

196. *See* Novartis Pharms. Corp. v. Accord Healthcare, Inc., 21 F.4th 1362, 1369 (Fed. Cir.), *rev'd on other grounds*, 38 F.4th 1013, 1020 (Fed. Cir. 2022) (affirming a district court's finding of adequate written description because, *inter alia*, the experimental data in the specification "describe[d] additional information which provides further written description for the 0.5 mg/day limitation.").

197. *See* Avery & Galvan, *supra* note 2, at 370 ("[The] FDA may be hesitant to allow approval of an animal-based diagnostic without specific evidence of analytical and clinical validity, though, because there would be limited data available to evaluate the safety and effectiveness of each animal-based diagnostic.").

198. *See id.* at 404 (discussing differences between conventional diagnostic testing and animal-based diagnostic testing methods).

199. Genentech Inc. v. Novo Nordisk A/*S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993)).

200. ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010); *but see* Wyeth & Cordis Corp. v. Abbott Lab'ys 720 F.3d 1380, 1384 (Fed. Cir. 2013) (holding that claims directed to a method of treatment using a family of rapamycin analogues were not enabled by a disclosure of a single species and instructions on how to assay additional species because it would have required screening of tens of thousands of candidates and spending weeks testing each candidate).

201. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

constitute adequate enablement."[202] In addition, when the claimed invention involves the application of an unpredictable technology, the specification must provide a "specific and useful teaching" regarding how to make and use the invention.[203] Because the training and use of working animals may be considered "unpredictable," patents related to working animals may be bound to this "specific and useful teaching" standard. Thus, patents directed to training and using working animals may need to include lengthy specifications that describe how animals are selected and prepared, details on all tools and techniques used to train and work with the animals, details of the environmental conditions in which the animals can work, and explanations of how animal-based variance may impact the ability of the animal to successfully be trained or worked, to the extent such information is relevant and available at the time of filing.[204]

III. PATENTABILITY OF WORKING ANIMALS

The skeptical reader may believe, upon first thought, that there is nothing patentable about working animals. However, clever practitioners have found numerous ways to patent training methods and tools related to working animals. In fact, there is a long history of patents related to training and using animals—a search on Orbit identified 341 patent application families[205] related to animal training

202. *Genentech, Inc.*, 108 F.3d at 1366; *see also* Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1283 (Fed. Cir. 2007) ("Although the knowledge of one skilled in the art is indeed relevant, the novel aspect of an invention must be enabled in the patent.").

203. *See Genentech, Inc.*, 108 F.3d at 1367–68; Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004); *see also* PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (explaining that, in unpredictable arts, the Federal Circuit has "refused to find broad generic claims enabled by specifications that do not specifically demonstrate how to make and use embodiments across the full scope of the claim.") (citing *In re* Goodman, 11 F.3d 1046, 1050–52 (Fed. Cir. 1993)).

204. *See* Avery & Galvan, *supra* note 2, at 399–40 (discussing how animal-related variance causes "inherent variation in diagnostic accuracy from animal to animal, and even between testing rounds using the same animal.").

205. Orbit is a proprietary patent analytics and research service provided by Questel. *See* QUESTEL, *Orbit Intelligence – IP Intelligence Software*, https://www.questel.com/patent/ip-intelligence-software/orbit-intelligence/ (last visited Oct. 12, 2024). The search results on Orbit are grouped by patent family. In other words, 341 unique patent families were identified. A patent family is a collection of patents and patent applications that cover the same or similar invention and are linked by a common priority date claim.

techniques and related tools in the United States since January 1, 2003.[206] To understand the patentability of animal training methods and tools with respect to modern patent law, this Article focuses its review on patent filings in the United States from only the past twenty years. The search query identifies patents wherein the claims include the words and variations of: (1) "train" and "animal"[207] in proximity, (2) animal and scent or odor in proximity, and (3) animal and detect in proximity.[208] Further, the search was narrowed to exclude CPC/IPC codes unrelated to animal training in the search results.[209] Out of the 356 patent applications identified by Orbit, 39.3% were granted, 6.2% are pending, 3.9% are expired, and 4.0% are revoked.

The number of patent filings related to training and using animals has remained relatively steady between 2003 and 2023.[210] Notably, there was a dip in 2011 and 2012, which is likely correlative to the Supreme Court's *Mayo v. Prometheus* decision, which came out in early 2012.[211] In that case, in a stark departure from its prior more

206. The following search query was run on Orbit on February 3, 2025: ((((train+ 7D (animal+ OR canine OR dog)) OR ((animal+ OR canine OR dog) 7D (scent OR odor)) OR ((animal+ OR canine OR dog) 3D (detect+)))/CLMS) AND (usa# OR usb# OR usc# OR use)/PN AND EAPD>=2003-01-01 AND EAPD<=2023-12-31)) NOT (c07h OR c12q OR b60l OR h02j OR a01m OR g06f OR a01h OR a01j OR b05b OR a61k OR c07d OR a61b OR g01s OR g06k OR b60q OR g05d OR g06q OR g08b OR a01n OR c01b OR c11d OR g01n OR b23b OR a61n OR f25b OR h05b OR a63b OR a21d OR a23l OR a01k-023 OR b01d OR g01m OR g03g OR a23k OR a01k-15 OR a01k-67 OR a63h OR h01f OR c12n OR a01k-13 OR a61d OR a41d OR a01k-61 OR a01k-001 OR f16d OR f16h OR f24f OR c12m OR a61d-007 OR g09b OR a61f OR a61m OR g06n OR b60k OR b65f OR h01l OR c08f OR f42b OR g03b OR a01k-011 OR a01k-013 OR a22b OR a22c OR a62c OR g04b OR b01j OR h04k OR h04l OR c05b OR c05g OR f41a OR b23q OR a01k-085 OR b60t OR e01f OR a47k OR f02b OR f24s OR b61j OR e03d OR a01g OR b60h OR h04n OR g01c)/CPC/IPC.

207. As used in the search query, "animal" refers to an animal, canine, or dog.

208. The "+" in the search query searches for variations of the word. For example, a search query containing "TRAIN+" searches for content containing variations of the word "train," including "training."

209. International Patent Classification (IPC) and Cooperative Patent Classification (CPC) codes are a hierarchal system used to classify patents according to the different areas of technology they cover. IPC/CPC codes are assigned by the patent office. *See About CPC,* COOP. PAT. CLASSIFICATION, https://www.cooperativepatentclassification.org/about (last visited Oct. 12, 2024).

210. Patent applications are generally published 18 months after filing. The drop-off in filings starting in 2023 is due to the delay in filed applications becoming published. *See* 35 U.S.C. § 122.

211. *See* Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 92 (2012). This decision, which found medical diagnostic methods that merely applied natural laws to be unpatentable, likely caused patent applicants to be more

relaxed guidance on Section 101, the Supreme Court updated the framework for determining patent eligibility, requiring courts to carefully examine each claim limitation.[212] These trends in the number of patent filings are illustrated in Figure 1, below.

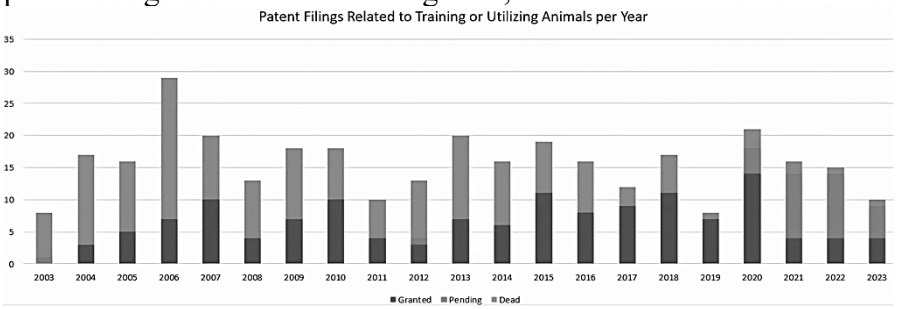

Figure 1. Patent Filings Related to Training or Utilizing Animals per Year

Figure 2, below, illustrates the patent filings by technology domain.[213] Notably, the most frequent technology domains include machines and technology, suggesting that inventions involving computer-based tools in conjunction with using or training the animal are more commonly patented. Over 60% of the patent filings fall into the technology domain of "other special machines," which is a subset of mechanical engineering inventions designed to be a "catch-all" of inventions not directed to engines, pumps, turbines, handling, machine tools, textile and paper machines, thermal processes, and transport.[214] Training tools, such as scent wheels, training collars, and controlled-odor release contraptions, would fall into the category of "other special machines."

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hesitant to patent animal-based inventions for fear that their applications would be rejected on the basis of merely relying on natural phenomena, such as a canine's sense of smell.

212. *Id.* at 78–79; *cf.* Diamond v. Diehr, 450 U.S. 175, 188 (1981) ("In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.").

213. The technology domain is determined by International Patent Classification (IPC) classes, which are a hierarchal system used to classify patents according to the different areas of technology they cover. *See* WORLD INTELL. PROP. ORG., INTERNATIONAL PATENT CLASSIFICATION 2 (2022).

214. *Orbit Intelligence*, QUESTEL, https://static.orbit.com/orbit/help/1.9.8/en/index.html#!Documents/technologies.html (last visited May 22, 2024).

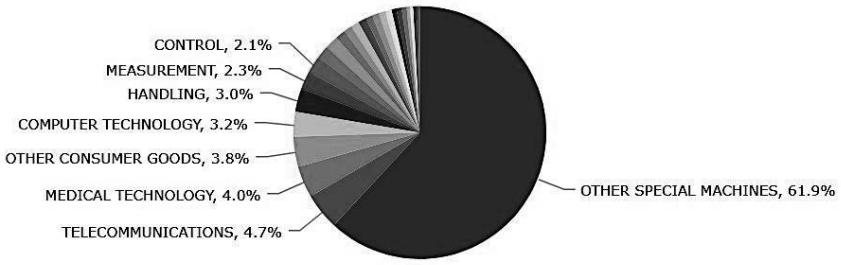

Figure 2. Patent Filings Related to Training or Utilizing Animals Grouped by Technology Domain

Figure 3, below, illustrates the percentage of patent filings which were granted, lapsed, pending, etc., for filings in CPC Code A01K-015. CPC Code A01K-015 was by far the most common CPC code, with approximately 64% of results falling into that category. CPC Code A01K-015 covers inventions directed to animal husbandry, aviculture, apiculture, pisciculture, fishing, rearing or breeding animals not otherwise provided for, and new breeds of animals.[215]

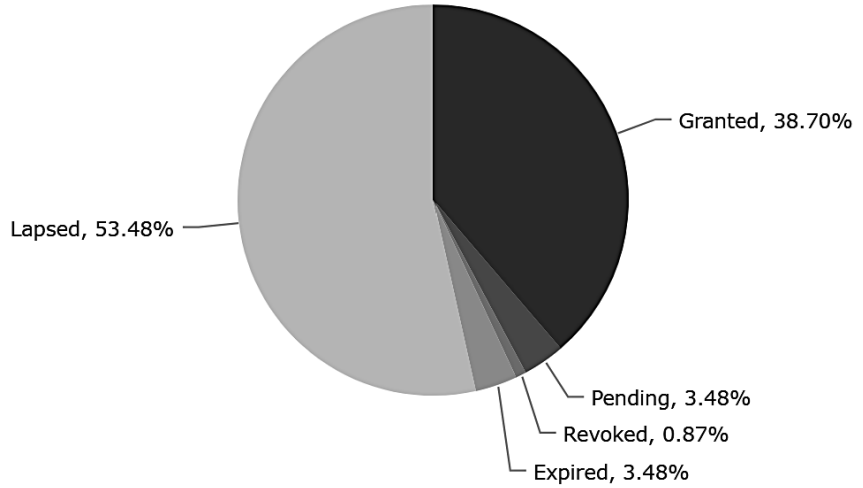

Figure 3. Patent Filings in CPC Code A01K-015 (Animal Husbandry etc.)

There are a variety of novel training methods and tools available to teach an animal how to accurately accomplish a task, as evidenced

215. *See Classification Resources*, U.S PAT. & TRADEMARK OFF., https://www.uspto.gov/web/patents/classification/cpc/html/cpc-A01K.html#A01K (last visited May 22, 2024).

by the numerous patents filed each year. However, as discussed in Part I.A, many of these training methods have common characteristics and use familiar tools, such as scent-based detection and reward-based training. The patent landscape around working animals was reviewed and various themes in the claims of these patents were identified, *supra*. Based on this review, this Article proposes the following seven categories to describe these different types of patent claims directed to aspects of working animals and their training:

Method Claims

1. Training Methods Using Novel Techniques (with Existing Tools) – i.e., patenting novel training methods using existing tools (method claim with novel step during training).

2. Training Methods Using Novel Tools (with Existing Techniques) – i.e., patenting existing training methods using novel tools (method claim with known steps using novel device/composition during training).

3. Working Methods Using Novel Techniques (with Existing Tools) – e.g., patenting novel methods for using the trained animal, alone or in combination with existing tools (method claim with novel step while working).

4. Working Methods Using Novel Tools (with Existing Techniques) – e.g., patenting existing methods for using the trained animal in combination with novel tools (method claim with known steps using novel device/composition while working).

Tool Claims (i.e., Device/Composition of Matter Claims)

5. Novel Training Tools – i.e., patenting the training tool itself (device/composition of matter claim).

6. Novel Working Tools – i.e., patenting the tools used in combination with the trained animal (device/composition of matter claim).

Animal Claims

7. Trained Working Animals – i.e., a claim on the animal itself.

These categories and examples of patents within these categories are discussed in detail in Parts III.A to III.C, below.[216]

216. The patents discussed in Parts III.A to III.C are merely provided as examples and not intended to represent a comprehensive list of patents within a respective

A. Method Claims

A method claim (also called a "process" claim) is used to define an inventive process as one or more steps.[217] Patents related to working animals include both methods used when training the animals, and methods used when working with the animals. For example, as discussed further below, a developer can seek patent protection for novel methods of training a dog to lead its handler toward a target scent, and/or for novel methods used when employing the trained dog to identify the target scent.[218] Furthermore, these methods may use both conventional tools and novel tools. For example, a novel method might include spraying a target scent on a conventional dog toy fitted with a radio-frequency identification (RFID) tag to confirm the toy's location in the search area.[219] Alternatively, an otherwise conventional method might instead rely on the step of using a novel permeable, multi-chamber scent capture device to allow for a controlled release of the target scent over time.[220] This Article proposes four categories of method claims related to working animals: (1) training methods using novel techniques, (2) training methods using novel tools, (3) working methods using novel techniques, and (4) working methods using novel tools.[221]

1. Training Methods Using Novel Techniques (with Existing Tools)

As discussed in Part I.B.1, *supra*, animals are typically trained using operant conditioning, in which positive behavior is rewarded

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category. The research for this Article identified many more patents within each category, which were not included in the discussion below for the sake of brevity. For the interested reader, the Authors have created an online resource describing additional example patents within each category, which can be found here: https://docs.google.com/document/d/1ptIdyUXWvxdeSLbdVto_bByZJV_tTUUl-RvOXrtjToVc/.

217. *See* MPEP, *supra* note 104, § 2106 ("A process defines 'actions', i.e., an invention that is claimed as an act or step, or a series of acts or steps."); 35 U.S.C. § 100(b) ("The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

218. *See, e.g.*, U.S. Patent No. 8,959,982 B2 (issued Feb. 24, 2015).

219. *See, e.g.*, U.S. Patent No. 9,578,855 B2 (issued Feb. 28, 2017).

220. *See, e.g.*, U.S. Patent No. 9,706,755 B2 (issued July 18, 2017).

221. Method patents which use both novel techniques and novel tools would clearly be considered patentable in both relevant categories. As such, the same examples may be discussed in both sections directed to novel techniques and novel tools herein. Similarly, method patents which use neither novel techniques nor novel tools would clearly not be considered patentable in any relevant categories.

and negative behavior is punished.[222] These methods typically rely on treats, toys, and scented objects to aid with training.[223] Because inventions must be distinguishable from the prior art to be patentable, as discussed in Part II.B, *supra*, developers seeking to patent training methods must show that their methods include a novel and nonobvious step in the training process that allows their trained animals to be useful in a way that leads to an improvement over existing training techniques. Additionally, developers must show that their training methods constitute patentable subject matter that goes beyond a mere law of nature, natural phenomena, or abstract idea.

A review of the patent landscape shows that training method claims were typically rejected for lacking novelty and for being obvious in view of the prior art. The rejections were often overcome by adding limitations to the claims, such as narrowing the claims to cover a particular use case scenario or by adding more detail about the training methodology, such as by identifying a specific tool or a specific animal utilized with the claimed method. A few patent applications reviewed were also rejected based on subject matter or enablement grounds, but these types of rejections were uncommon. In general, claims directed to using a particular device as part of the training were more likely to be allowed by the USPTO. Claims that cover narrow and specific use cases were also more likely to be allowed by the USPTO.

Example patents related to novel training methods are described below:

> *U.S. 8,959,982 B2 (Dynamic Canine Tracking Method for Hazardous and Illicit Substances), Issued February 24, 2015*

This patent is directed to a technique for training a dog to lead its handler while smelling moving targets and simultaneously avoiding the scents of stationary objects.[224] For example, a dog trained in this technique can be used at airports or other locations to screen crowds of people for drugs or explosives without the need for the handler to direct each person to remain still while the trained dog conducts its search.[225]

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222. *See* Matthew & Relton, *supra* note 63, at 1.

223. *See, e.g.*, Essler et al., *supra* note 88, at 7.

224. U.S. Patent No. 8,959,982 B2 cols. 1–2 (filed Dec. 26, 2013) (issued Feb. 24, 2015).

225. *Id.* at col. 1.

The patent application was rejected twice under Section 103 on obviousness grounds in view of prior art that taught selecting dogs for training based on a dog's traits that would aid in detection tasks, including the dog's ability to conduct an independent search of moving targets.[226] During prosecution, the applicant narrowed the claims to specify that the target odor is from a moving target only and clarified that the source of the target odor is that of a hazardous or illicit substance.[227] These amendments, which narrowed the scope and provided specific use cases, were sufficient to overcome the obviousness rejections.[228] Thus, the point of novelty appears to be utilizing a moving target representing a hazardous/illicit substance during training to train dogs to ignore stationary objects during detection.

U.S. 9,578,855 B2 (Animal Training System and Method), Issued February 28, 2017

This patent is directed to a technique for training an animal to detect odor from a target by (1) placing the target containing a target odor and a hidden marker (e.g., an RFID tag or fluorescent substance that indicates the presence of the target odor) in a search area, (2) bringing a trainer and the animal to the area, (3) having the animal indicate the location of the target, (4) using a detector (e.g., an RFID reader or UV light emitter) to confirm the identification of the target, and (5) rewarding the animal if the detector indicates the target is at the location.[229] For example, an object containing both the target odor and an RFID tag can be hidden in a search area for the animal to locate using scent.[230] The animal's handler is unaware of the location of the target object.[231] After the animal alerts to the scent, indicating to the handler that the animal has located the target object, the handler will confirm the identification using an RFID reader.[232] The use of RFID

226. *See* U.S. Patent Application No. 14/141,199, *Non-Final Office Action* dated March 20, 2014, p. 5–9 (citing U.S. Patent Pub. 2008/013671 A1 (filed Jan. 5, 2007)); U.S. Patent Application No. 14/141,199, *Final Office Action* dated July 23, 2014, p. 2–6.

227. *See* U.S. Patent Application No. 14/141,199, *Arguments/Remarks Made in an Amendment* dated May 7, 2014, p. 5–6; U.S. Patent Application No. 14/141,199, *Arguments/Remarks Made in an Amendment* dated September 23, 2014, p. 4-5.

228. *See* U.S. Patent Application No. 14/141,199, *Notice of Allowance and Fee(s) Due* dated October 15, 2015, p. 1.

229. U.S. Patent No. 9,578,855 B2 cols. 1–2 (filed Mar. 18, 2015) (issued Feb. 28, 2017).

230. *Id.*

231. *Id.*

232. *Id.*

confirmation eliminates any unconscious handler bias from the training and allows the animal to be rewarded for positive identifications only.[233]

The patent examiner rejected the claims under Section 101 on eligibility grounds, arguing that the patent was directed to an abstract idea of rewarding an animal that detected a target odor.[234] The applicant amended the claims to require the "detector" to include an electronic emitter (e.g., an RFID reader or a UV light emitter).[235] After this amendment, the method claims were allowed. Electronic emitters, such as RFID tags, are clearly well-known.[236] However, using RFID tags in the context of training an animal to detect an odor is apparently novel and sufficiently technical to be patentable. Thus, this amendment overcame the eligibility rejection, and the previously rejected claims were allowed.[237] The point of novelty appears to be the incorporation of an electronic emitter (e.g., an RFID tag) and a corresponding receiver device (e.g., an RFID reader) to confirm the animal's identification of the search target.

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233. *Id.*

234. *See* U.S. Patent Application No. 14/429,056, *Non-Final Office Action* dated June 30, 2016, p. 3 ("placing targets with and [sic] odor and a hidden marker (e.g.; a treat) is well-understood, routine, and conventional in the field."). The remainder of the office action focused on the applicant's system claims, which were rejected under Sections 102, 103, and 112(b). *Id.* at p. 2–6. Ultimately, the applicant cancelled the system claims after an unsuccessful attempt to overcome the Section 102 and 103 rejections without amendment. *See* U.S. Patent Application No. 14/429,056, *Arguments/Remarks Made in an Amendment* dated November 22, 2016. The patent issued on the method claims only. *See* U.S. Patent Application No. 14/429,056, *Notice of Allowance and Fee(s) Due* dated December 7, 2016.

235. *See* U.S. Patent Application No. 14/429,056, *Arguments/Remarks Made in an Amendment* dated August 2, 2016, p. 6. The applicant also amended the claims to overcome the Section 112(b) rejections. *Id.*

236. *See* Jane McGrath, *How Pet Microchipping Works*, HOWSTUFFWORKS (Apr. 21, 2008), https://science.howstuffworks.com/innovation/everyday-innovations/pet-microchip1.htm.

237. *See* U.S. Patent Application No. 14/429,056, *Final Office Action* dated September 28, 2016, p. 5–7. The examiner rejected other claims in a subsequent office action under Section 102 and 103 in view of prior art that taught training an animal to detect an odor, wherein the odor is associated with a hidden marker, and using a detector to identify the hidden marker. *See* U.S. Patent Application No. 14/429,056, *Notice of Allowance and Fee(s) Due* dated December 7, 2016. However, those claims were canceled, and the application was allowed.

U.S. 9,210,914 B2 (Method for Training Honeybees to Respond to Olfactory Stimuli and Enhancement of Memory Retention Therein), Issued December 15, 2015

This patent is directed to a method of training bees to exhibit a particular response to a target odor by exposing the bee to the target odor while simultaneously offering it a reward.[238] For example, a bee is trained by exposing it to a selected volatile organic compound while also feeding it a sugar solution.[239] While feeding, the bee extends its proboscis, which can be observed and recorded (for example, by a camera and pattern recognition software).[240] Thus, a trained bee forms an association between the selected volatile compound and a reward, and will extend its proboscis in response to sensing the specific odor of the volatile organic compound.[241]

This patent was allowed without any substantive rejections.[242] The point of novelty appears to be training bees to identify organic odors associated with agricultural compounds of interest and produce a physical response.[243] This patent illustrates the importance of identifying the specific use case for the invention and reciting it in the claims. For example, the preamble of the independent claim limits the method to "detecting agricultural volatile and semi-volatile organic compounds."[244]

U.S. 8,187,533 B2 (Descenting Systems and Methods), Issued May 29, 2012

This patent is directed to a method of training a dog to detect when scent-elimination systems were used to conceal a scent.[245] For example, in an attempt to avoid detection, narcotics traffickers

238. U.S. Patent No. 9,210,914 B2 col. 2 (filed Apr. 4, 2012) (issued Dec. 15, 2015).

239. *Id.*

240. *Id.* at cols. 7–8. A bee's proboscis is an elongated straw-like mouthpart that allows the bee to suck in fluids.

241. *Id.* at cols. 2–4.

242. *See* U.S. Patent Application No. 13/439,825, *Non-Final Office Action* dated May 8, 2015, p. 2–3. The application received a Non-Final Office Action, where the examiner indicated the claims were indefinite under 35 U.S.C. 112(b) and objected to some informalities. *See id.* However, the indefiniteness rejection merely focused on the use of abbreviations in the claims and was easily fixed by the applicant. *See id.* at p. 2.

243. *See* U.S. Patent Application No. 13/439,825, *Notice of Allowance and Fee(s) Due* dated August 31, 2015.

244. U.S. Patent No. 9,210,914 B2 col. 13 ll. 29–30.

245. U.S. Patent No. 8,187,533 B2 col. 10 ll. 25–29 (filed Dec. 2, 2008) (issued May 29, 2012).

sometimes use so-called "descenting" systems, such as those that introduce gaseous ozone to a container with narcotics, in order to eliminate narcotic odors that drug-detection dogs are trained to detect.[246] The claims cover training and employing detection dogs to identify the presence of ozone or other descenting compounds.[247]

The patent application was rejected once under Section 102 on novelty grounds in view of prior art that taught a method of using a scent elimination device to conceal a hunter's scent from wild game animals that are being hunted.[248] The original claim set discussed only methods of using a scent elimination device (i.e., a descenting system) but did not recite steps for training an animal to detect descented material.[249] To overcome the rejection, the applicant amended the claims to add additional steps of teaching an animal to distinguish between a descented item and a non-descented item.[250]

The application was also rejected under Section 112 for lack of enablement because the specification did not enable any other types of detection other than an animal's olfactory senses.[251] To overcome the rejection, the applicant amended the claims to add that detection is performed "using the service animal's olfactory senses."[252] These amendments limited the claims to training animals to detect the presence of descenting compounds via smell, which was sufficient to overcome the Section 112 rejection and move the case to allowance.[253] The point of novelty appears to be the use of the descenting system in a reward-based training method to train animals to identify the presence of contraband untreated by the de-scenting system using the animals'

246. *Id.* at col. 1 ll. 47–67, col. 2 ll. 1–6.

247. *Id.*

248. *See* U.S. Patent Application No. 12/326,240, *Non-Final Office Action* dated July 14, 2011, p. 4.

249. *See* U.S. Patent Application No. 12/326,240, *Claims* dated December 2, 2008.

250. *See* U.S. Patent Application No. 12/326,240, *Arguments/Remarks Made in an Amendment* dated October 10, 2011, p. 8–9.

251. *See* U.S. Patent Application No. 12/326,240, *Non-Final Office Action* dated July 14, 2011, p. 2.

252. *See* U.S. Patent Application No. 12/326,240, *Arguments/Remarks Made in an Amendment* dated October 10, 2011, p. 8; *see also* U.S. Patent Application No. 12/326,240, *Notice of Allowance and Fee(s) Due* dated January 26, 2012, p. 2.

253. *See* U.S. Patent Application No. 12/326,240, *Notice of Allowance and Fee(s) Due* dated January 26, 2012, p. 2. The application's claims directed to a method of employing the trained animals to identify the presence of de-scenting compounds received a Section 102 rejection, as discussed in Part III.A.1, *infra*.

sense of smell.[254] The prosecution history for this case serves as a reminder that claims directed to broad use cases (e.g., detecting the presence of contraband) may face Section 112 issues when only a single solution (e.g., detection via a dog's olfactory senses) is taught in the specification.

U.S. 10,278,365 B2 (Apparatus and Method for Dog Training), Issued May 7, 2019

This patent is directed to a technique for training a dog to perform odor-detecting operations in a confined space.[255] The technique involves bringing a dog into a structure where it may perform odor detection tasks.[256] After the dog successfully identifies a target odor, it is rewarded, and a handler adds a wall segment to decrease the size of the structure.[257] The primary independent claim recites a method with eight specific steps for training the dog and in particular, recites specific features about the structure where the dog sits during training.[258] For example, the claims describe the structure as having a "customized, rearwardly open compartment" with particular surfaces, wall heights, and dimensions.[259]

The patent application was rejected three times under Section 103 on obviousness grounds in view of prior art devices for training a dog to perform odor detection in a confined environment.[260] During prosecution, the applicant narrowed the claims by adding more detail about the structure of the compartment, such as the specific design of the modular compartment and wall segment structure.[261]

254. *See* U.S. Patent Application No. 12/326,240, *Notice of Allowance and Fee(s) Due* dated February 13, 2012.

255. U.S. Patent No. 10,278,365 B2 col. 2 (filed Apr. 21, 2015) (issued May 7, 2019).

256. *Id.* at col. 2.

257. *Id.* at cols. 3–4.

258. *Id.* at cols. 12–13.

259. *Id.* at col. 12.

260. *See* U.S. Patent Application No. 14/437,225, *Non-Final Office Action* dated March 23, 2017, p. 4–27 (citing U.S. Patent Application Pub. No. 2012/0077159 A1 (filed Sep. 24, 2010)).

261. *See* U.S. Patent Application No. 14/437,225, *Arguments/Remarks Made in an Amendment* dated August 22, 2017, p. 11–13; *see also* U.S. Patent Application No. 14/437,225, *Claims* dated August 22, 2017, p. 2–8; U.S. Patent Application No. 14/437,225, *Final Office Action* dated October 31, 2017; U.S. Patent Application No. 14/437,225, *Arguments/Remarks Made in an Amendment* dated January 2, 2018, p. 11–19; U.S. Patent Application No. 14/437,225, *Claims* dated January 2, 2018, p. 2, 5, 6.

The patent application was also rejected under Section 101 on statutory subject matter grounds in view of the examiner's assertion that the claims appeared to claim a dog.[262] In response to the subject matter rejection, the patentee cancelled the apparatus claims and amended the method claims to recite the training step with more specificity, including training the dog to "become accustomed to voluntarily remaining in [or entering the] confined compartment."[263] To overcome the subject matter rejection, the patentee argued that "a dog is not being claimed, but rather a method for training a dog is being claimed."[264] Thus, the point of novelty appears to be the training steps that involve adjusting the physical environment where the dog is working in order to train the dog to work in a confined environment. This patent illustrates the importance of clarifying that the animal itself is not being claimed, as such claims would likely be found *per se* unpatentable subject matter under Section 101, as discussed in Part III.C, *infra*.

2. Training Methods Using Novel Tools (with Existing Techniques)

The typical tools used to train working animals include treats and toys, scent wheels, odor simulators, scent control devices, electric collars, and choke collars, as discussed in Part I.B.2, *supra*. Some trainers use novel tools to aid with training, and the use of these novel tools may transform otherwise conventional training techniques into patentable methods. These tools may be incremental variations on conventional tools, or they may be radically different from what is typically used. Either way, developers can attempt to overcome patentability challenges where they are otherwise using a known training method by emphasizing the use of a new tool that interacts with the trainee animals in a way that increases effectiveness of training, reduces training time, or has other superior features over conventional methods. Developers of these novel tools can obviously attempt to patent the tool itself, as discussed in Part III.B.1, *infra*. Such developers may also

262. *See* U.S. Patent Application No. 14/437,225, *Non-Final Office Action* dated May 11, 2018, p. 7 (asserting that the claims do "not fall within at least one of the four categories of patent eligible subject matter because the claims appear to claim a dog, which does not fall within process, machine, manufacture, or composition of matter.").

263. U.S. Patent Application No. 14/437,225, *Claims* dated November 13, 2018, p. 5.

264. *See* U.S. Patent Application No. 14/437,225, *Arguments/Remarks Made in an Amendment* dated November 13, 2018, p. 11.

attempt to patent the methods of using these new tools, with claims that recite using known training techniques (e.g., reward-based training) with the new tool (e.g., a novel reward), as discussed below.

A review of the patent landscape indicates that claims in this category were rejected for lacking novelty and/or for being obvious in view of the prior art teaching conventional methods and/or tools. The rejections were often overcome by including additional distinguishing features that illustrate the claimed tool's novelty or by adding additional steps to the independent claims that emphasize the specific use of the novel tool. In general, claims directed to specific steps related to preparing and using the tool to accomplish the training task were more likely to be allowed by the USPTO. Claims that cover using the novel tools in specific ways were also more likely to be allowed by the USPTO.

Example patents related to methods using novel training tools are described below:

U.S. 9,706,755 B2 (Controlled Odor Mimic Permeation System), Issued July 18, 2017

This patent is directed to a method of training a dog to detect explosives using a tool that ensures consistent exposure to the target odor for effective detection training.[265] The tool is a multi-chamber box consisting of an inner container and an outer container.[266] The inner container houses the odor sample and is made of a permeable membrane selected to match the target odor and desired release rate, while the outer container is made of a non-permeable membrane.[267] The odor sample of the inner container is prepared by dissolving the target odor in an organic solvent, absorbing the dissolved target odor in an organic material, and evaporating the organic solvent from the absorbent material.[268] Upon removal of the inner container from the outer container, an immediate and reproducible source of the odor sample is

265. U.S. Patent No. 9,706,755 B2 cols. 1-2 (filed July 18, 2007) (issued July 18, 2017).

266. *Id.* at col. 1 ("This double bag design prevents the escape of odors from within the inner bag. Removal of the outer bag provides the odor from within the inner bag, at a controlled rate. We are calling this design the Controlled Odor Mimic Permeation System (COMPS).").

267. *Id.* at Abstract. A benefit of this design is that different odors (in different boxes) may be stored in the same area without worry about cross-contamination.

268. *Id.* at col. 27 ll. 37–50.

provided.[269] For example, when training an animal to detect multiple different target odors (e.g., illicit drugs or explosives), the trainer can bring multiple odor samples to the training area.[270] The system allows a small amount of the target odor to permeate from the inner container membrane without requiring a large concentration of the odor-producing substance.[271]

The application was rejected several times on Section 103 obviousness grounds in view of prior art that taught a method of training a dog to detect the smell of a volatile compound through a permeable, multi-chambered container using an organic solvent.[272] Indeed, as the examiner recognized, "it is old and well known in the art of training canines to select an odor component."[273] The applicant made several amendments, including specifying particular detectable target odors and the process for preparing the target odor sample. [274] As an example, the applicant's final amendment added a step for selecting a target odor based on its ability to volatilize at room temperature and remain in the headspace, or the space just above the top of the liquid or solid

269. The design facilitates the pre-equilibration of target odors, allowing the outer surface of the inner container to become saturated with odor during storage. *Id.* at col. 29 ll. 4–8 ("The concentration of analyte upon the fibre surface increases steadily, proportional to the length of exposure up to a certain maximum point; at which point the concentration can then be seen to reduce before achieving equilibrium."). Equilibrium is achieved when the gas pressure of the inner container and the outer container are equal.

270. U.S. Patent No. 9,706,755 B2 col. 19 (issued July 18, 2017).

271. *Id*. at col. 62 (disclosing that the inner container may be formed of a permeable membrane such as low-density polyethylene).

272. *See* U.S. Patent Application No. 11/779,815, *Non-Final Office Action* dated August 19, 2009, p. 3–8 (citing U.S. Patent Application Publication No. 2006/0037509 A1 (published Feb. 23, 2006)); U.S. Patent Application No. 11/779,815, *Final Office Action* dated February 18, 2010, p. 2–7; U.S. Patent Application No. 11/779,815, *Non-Final Office Action* dated August 24, 2010, p. 3–8; U.S. Patent Application No. 11/779,815, *Final Office Action* dated December 15, 2010, p. 2–6; U.S. Patent Application No. 11/779,815, *Non-Final Office Action* dated July 21, 2011, p. 2–6; U.S. Patent Application No. 11/779,815, *Final Office Action* dated October 21, 2011, p. 2–5; U.S. Patent Application No. 11/779,815, *Final Office Action* dated February 8, 2012, p. 4–8; U.S. Patent Application No. 11/779,815, *Non-Final Office Action* dated May 9, 2013, p. 3–11; U.S. Patent Application No. 11/779,815, *Final Office Action* dated November 29, 2013, p. 2–13.

273. *See* U.S. Patent Application No. 11/779,815, *Final Office Action* dated November 29, 2013, p. 3.

274. *See* U.S. Patent Application No. 11/779,815, *Claims* dated July 9, 2012, p. 2 (amending claims to add "wherein the material to be detected is selected from the group consisting of propellants, lead azide, lead styphenate, mercury fulminate, and sheet explosives . . . .").

material, of the inner container.[275] After receiving a ninth office action in response to that amendment, the applicant filed an appeal.[276] The Patent Trial and Appeal Board reversed the examiner's rejection and allowed the claims, finding that the examiner's rejection of the odor selection step was not supported by a preponderance of the evidence.[277] The examiner then issued a Notice of Allowance without further substantive amendment.[278] Thus, the point of novelty appears to be the claimed method of selecting and preparing the odor samples within the multi-chamber device to allow for a controlled release of the target odor during training.[279]

275. *See* U.S. Patent Application No. 11/779,815, *Arguments/Remarks Made in an Amendment* dated October 9, 2013, p. 7–8; *see also* CAL. DEP'T OF FOOD & AGRIC., DECEPTIVE CONTAINER DETERMINATIONS (Nov. 2009), https://www.cdfa.qca.gov/dms/programs/qc/QCManual/Sec11_DCPTV_CNTNR_DTRMN.pdf ("The term 'Headspace' is the distance from the top of the container to the top of the product.").

276. *See* U.S. Patent Application No. 11/779,815, *Appeal Brief* dated May 1, 2014, p. 14. The Patent Trial and Appeal Board also noted that the "Joshi" reference (Monica Joshi et al*., Detection of Odor Signatures of Smokeless Powders Using Solid Phase Microextraction Coupled to an Ion Mobility Spectrometer*, 188 FORENSIC SCI. INT'L 112–118 (2009)) was not prior art because it was published after the effective filing date. *See* U.S. Patent Application No. 11/779,815, *Decision of Appeal* dated October 26, 2016, p. 4–5.

277. *See* U.S. Patent Application No. 11/779,815, *Decision of Appeal* dated October 26, 2016, p. 4–6 ("Given that Joshi was published three years after the effective filing date of the instant application, [it] is not evidence of what was known to one skilled in the art at the time. As the Examiner provides no other evidence that 'DNT was known in the art as a detectable odor present in the headspace of smokeless powders, which can be used for the detection of smokeless powders by canines,' the Examiner's finding is not supported by a preponderance of the evidence."); *id.* ("In other words, Appellants challenge the Examiner's finding that permeability is a results-effective variable. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. It is not readily apparent that permeability is an art-recognized result-effective variable. Accordingly, the Examiner's finding is not supported by a preponderance of the evidence.").

278. *See* U.S. Patent Application No. 11/779,815, *Notice of Allowance and Fee(s) Due* dated December 9, 2016, p. 2 ("The prior art of record fails to show or render obvious the method of training canine [sic] to detect, by smell, an odor emanating from a material to be detected, of claims 1, 24 and 29.").

279. *See id.*

U.S. 8,248,248 B1 (Electronic Transmitter and Receiver System for Training of Cats and Other Domestic Animals and Method of Training Domestic Animals), Issued August 8, 2012

This patent is directed to a method of training animals using audible and visual effects from a device worn by the animal.[280] An animal trainer can control the wearable device, via a hand-held remote, to emit sounds, such as beeps or whistles, and visual effects, such as colored lights, in response to the animal's behavior.[281] For example, the trainer may reinforce a desired behavior, such as the animal moving toward a particular location, by associating a reward (e.g., treats) with an audible or visual effect from the wearable device.[282] After repeated exposure to the effects of the wearable device, the animal can be trained to perform the desired behavior in response to those same emitted effects.

The patent application was rejected once on novelty and obviousness grounds in view of prior art that taught an electronic device, worn on an animal, that emits an audible and visual output.[283] During prosecution, the applicant canceled the originally filed claims,[284] which were primarily system claims directed to the wearable electronic device, and submitted new claims primarily consisting of method claims directed to training an animal using the wearable electronic device.[285] This newly filed claim set was allowed without any rejections.[286] Using electronic devices, such as wearable sound-emitting devices, is not a new concept, nor was it back in 2012 when this application was

280. U.S. Patent No. 8,248,248 B1 col. 3 (filed June 15, 2011) (issued Aug. 21, 2012).

281. *Id.* at col. 6.

282. *Id.* at col. 4.

283. *See* U.S. Patent Application No. 13/160,641, *Non-Final Office Action* dated November 22, 2011, p. 10 (citing U.S. Patent Application Pub. No. 2005/0139168 A1 (published Jun. 2, 2006)). The *Non-Final Office Action* inadvertently considered Claims 1-12, which were canceled in a preliminary amendment.

284. During prosecution, the applicant filed a preliminary amendment prior to the first rejection from the examiner. *See* U.S. Patent Application No. 13/160,641, *Preliminary Amendment* dated June 15, 2011 (canceling Claims 1-12 and adding Claims 13-18, which were directed to training an animal using an electronic device).

285. *See* U.S. Patent Application No. 13/160,641, *Arguments/Remarks Made in an Amendment* dated February 17, 2012, p. 6 (explaining applicant's response merely re-numbered the claims from the preliminary amendment); U.S. Patent Application No. 13/160,641, *Claims* dated February 17, 2012, p. 3.

286. *See* U.S. Patent Application No. 13/160,641, *Notice of Allowance and Fee(s) Due* dated June 7, 2012 (approving application for issuance as a patent).

issued.[287] Thus, the point of novelty appears to be the specific, multi-step approach of using both audio and visual outputs in sequence to elicit a specific behavior in the animal.

3. Working Methods Using Novel Techniques (with Existing Tools)

Detection animals and service animals, as discussed in Parts I.A.1 and I.A.2, are often trained to work simply by bringing the animal to a particular location and having the animal perform its task. This alone may be patentable to the extent that the animal is doing something that has never been done before. Sometimes tools, commands, or other steps are used while the animal is working to assist the animal with its task. When these tools, commands, or other steps are used in novel ways, that similarly may make the working method patentable. Developers can attempt to overcome prior art rejections by showing that the working method includes a novel and nonobvious step that allows their trained animals to be useful in a way that leads to an improvement on existing methods. Additionally, in all cases, the developers will need to show that their working method is more than a mere law of nature, natural phenomena, or abstract idea.

A review of the patent landscape indicated that working method claims were commonly rejected in view of the prior art for reasons of novelty or obviousness. The rejections were often overcome by elaborating on the specific use of the tools in the method or by adding additional steps to narrow the claimed working method to a specific scenario. In general, claims directed to working methods that recited particular structural elements of a device or system used by that method were more likely to be allowed by the USPTO.

Example patents related to methods using novel working techniques are described below:

U.S. 10,274,469 B2 (Target Odor Detection and Security Method), Issued April 30, 2019

This patent is directed to a method of screening people and things in confined spaces, and is specifically designed for security applications, such as in airports.[288] For example, an airport can have a screening point that people walk through to control entry to the airport. The

287. *See, e.g.*, U.S. Patent Application Pub. No. 2011/0017150 A1 (published Jan. 27, 2011) (discussing a wearable sound system for animals).

288. U.S. Patent No. 10,274,469 B2, col. 1 ll. 33–49 (filed Nov. 1, 2017) (issued Apr. 30, 2019).

screening point contains a rotatable door and is configured to carry scents—via airflow—from the screening point to a nearby room.[289] A detection animal in the nearby room is trained to detect target odors, such as illicit substances.[290] Furthermore, the rotatable door may be locked to trap people suspected of carrying illicit substances.[291]

The patent was allowed without any substantive rejections.[292] The point of novelty appears to be the particular structural details of how the screening station, the observation room, and the conduit before the screening room and the observation room are connected. For example, the claims recite a screening station that includes an enclosure, with an ingress portal connected to the enclosure, as well as an egress portal that provides access to the security zone, along with an egress lockable door. While the ingress and egress portals appear to be conventional, it is likely that the use of these specific structural elements in this specific odor screening use case was the key technical improvement over existing techniques.

U.S. 10,123,509 B2 (Dynamic Canine Tracking Method for Hazardous and Illicit Substances), Issued November 13, 2018

This patent is directed to a working technique of having a detection dog lead its handler while in pursuit of a moving target, allowing the canine to move without influence from the handler.[293] For example, a canine can be placed in a crowd of moving people to search for a target odor by sniffing the vapor trails of the moving people. When the canine detects the target odor, it exhibits a change of behavior, thus alerting its handler to the source of the target odor.

The application was rejected once on novelty and obviousness grounds in view of prior art that taught implementing a scent detection method in a defined location to identify target odors contained within multiple vapor trails from multiple sources.[294] During prosecution, the

289. *Id.* at col. 2 ll. 12–26.

290. *Id.* at cols. 5-6.

291. *Id.* at col. 2 ll. 37–40.

292. *See* U.S. Patent Application No. 15/800,169, *Non-Final Office Action* dated July 26, 2018, p. 2 (receiving rejections based on Section 112 for patent formalities (antecedent basis) and double patenting).

293. U.S. Patent No. 10,123,509 B2 cols. 1–2 (filed Dec. 26, 2013) (issued Nov. 13, 2018). Note this patent was issued from a continuing application (U.S. Patent Application No. 15/212,467) with a priority claim that includes U.S. Patent No. 8,959,982 B2, discussed in Part. III.A.1, *supra*.

294. *See* U.S. Patent Application No. 15/701,077, *Non-Final Rejection* dated January 4, 2018 (citing "Search Dog Handbook," available at https://www.sarbc.org/sarbc/pdfs/sardog.pdf (May 1992)).

applicant narrowed the claims to clarify that the target odor is identified in a single vapor trail out of the numerous vapor trails being tested.[295] This amendment, which narrowed the scope to recite a specific scenario—detecting a target odor from one of many moving people—was sufficient to overcome the rejections.[296] Thus, the point of novelty appears to be utilizing the detection dog to assess the vapor trails from *multiple* people and identifying whether a particular vapor trail from a single person contains the target odor.

U.S. 10,455,817 B2 (Animal Olfactory Detection of Disease as Control for Health Metrics Collected by Medical Toilet), Issued October 29, 2019

This patent is directed to a technique for using animals to detect disease in bodily waste, such as stool or urine.[297] The bodily waste is collected in a medical toilet that is fitted with a medical device that performs a traditional diagnostic test for detecting a disease and a port that dispenses scent from the bodily waste to a detection animal.[298] The detection animal is trained to alert its handler when it perceives a scent associated with a disease.[299] In particular, the detection animal is used as a control for the first medical device.[300] For example, a medical device of the medical toilet measures a physiological function to determine whether a disease is present in the patient.[301] Then, the medical toilet dispenses the scent of the bodily waste to a detection animal that smells the scent to separately determine whether a disease is present in the patient.[302] The medical device and the detection animal

295. *See* U.S. Patent Application No. 15/701,077, *Applicant Arguments/Remarks Made in an Amendment* dated March 28, 2018, p. 7-8 (amending claims to highlight distinctions from cited art).

296. *See* U.S. Patent Application No. 15/701,077, *Notice of Allowance and Fee(s) Due* dated July 9, 2018, p. 2–3 (approving application for issuance as a patent).

297. U.S. Patent No. 10,455,817 B2 col. 2 (filed Oct. 4, 2016) (issued Oct. 29, 2019).

298. *Id.* at cols. 1–2.

299. *Id.* at col. 4 ll. 36–38.

300. *Id.* at col. 4 ll. 53–59 ("Consequently, both the medical device and the scent dispenser are used to test for the presence of bladder cancer in the user. While the health metric may be a quantitative assay conducted by measuring a known analyte, the response from the animal is a qualitative assessment which is used as a control for the quantitative health metric.").

301. *Id.* at cols. 3 l. 61–65 ("For example, the medical device on the medical toilet may perform an electrocardiogram (EKG) measurement to assess the user's cardiovascular health. The bodily waste deposited in the toilet may emit VOCs that are indicative of myocardial damage and which the animal is trained to recognize.").

302. '817 Patent at col. 4 ll. 6–8.

measure different physiological indicators of the patient.[303] Both the results from the medical device and the detection animal are used to determine whether a disease is present in the patient.[304]

The patent application was rejected three times under Section 103 on obviousness grounds in view of three unrelated prior art references that taught: (1) a dog's ability to identify *Clostridium difficile* in stools, (2) a toilet with a ventilation system, and (3) a toilet with sensors in or on it.[305] During prosecution, the applicant narrowed the claims several times to specify that the animal and the assay use different physiological indicators to detect the same disease.[306] Further, the applicant amended the claims to state that the medical device provides a quantitative assessment while the animal only provides a qualitative assessment of the disease.[307] Thus, the point of novelty appears to be the combination of using both a traditional medical device and a detection animal to detect a disease, in particular by measuring different physiological parameters of the disease.

U.S. 11,200,786 B1 (Canine Assisted Home Monitoring), Issued December 14, 2021

This patent is directed to a technique for using a canine as part of a home security monitoring system.[308] The home monitoring system contains sensors, such as microphones and cameras, installed throughout the property, as well as a canine.[309] The canine may be wearing sensors, such as a microphone or an RFID tag.[310] For example, a sensor in the home, such as a microphone, receives an audio recording of a dog's bark.[311] The audio recording is sent to a computing system that is programmed to associate types of barks with different types of

303. *Id.* at col. 4 l. 67, col. 5 ll. 1–3.

304. *Id.* at col. 4 ll. 45–49.

305. *See* U.S. Patent Application No. 15/284,817, *Non-Final Office Action* dated August 28, 2018, p. 2–4; U.S. Patent Application No. 15/284,817, *Final Office Action* dated January 2, 2019, p. 2–4; U.S. Patent Application No. 15/284,817, *Final Office Action* dated April 26, 2019, p. 2–4.

306. *See* U.S. Patent Application No. 15/284,817, *Arguments/Remarks Made in an Amendment* dated August 7, 2019, p. 9 (amending claims to state that the medical device collects a first health metric by measuring a property of "a different physiological function of the disease than the bodily waste that the animal and scent dispenser analyses . . . .").

307. *Id.* at p. 10.

308. U.S. Patent No. 11,200,786 B1 col. 3 ll. 30–34 (filed Apr. 10, 2019) (issued Dec. 14, 2021).

309. *Id.* at col. 3 ll. 34–37.

310. *Id.* at cols. 3–4.

311. *See id.*

events.[312] For example, a first type of bark could be associated with the dog sensing a known person returning home, while a second type of bark could be associated with the dog sensing a stranger at the property.[313] The system could then analyze the recording of the bark, and, in response to determining it corresponds to a stranger at the property, send a notification to the homeowner.[314]

The patent application was rejected twice in view of prior art that described a system for using audio data of an animal to determine whether an event occurred.[315] During prosecution, the applicant narrowed the claims to describe a multi-step approach of receiving a signal (e.g., an audio recording of a bark) from the animal, setting the received signal as a "reference signal" if the received signal from the animal corresponds to an event, and comparing future signals to the "reference signal" to determine whether an event is occurring at the property.[316] These amendments, which narrowed the scope of the claims to recite a system that is set up in a specific manner, were sufficient to overcome the obviousness rejections.[317] Thus, the point of novelty appears to be the specific steps of establishing the reference signal and then comparing future signals with the reference signal.

4. Working Methods Using Novel Tools (with Existing Techniques)

While a variety of tools are often used to train working animals, as discussed in Part I.B.2, *supra*, it is less common for tools to be used

312. *See id.* at col. 5 ll. 46–49 ("For example, a bark from the animal may be assigned to bark type A corresponding to aggression, while a bark from the animal may be assigned to bark type B corresponding to distress.").

313. *Id.* at col. 9.

314. *Id.* at col. 9.

315. *See* U.S. Patent Application No. 16/380,291, *Non-Final Action* dated October 28, 2020, p. 3 (rejecting under Section 102 as being anticipated by U.S. Patent No. 9,743,643 B1 (issued Aug. 29, 2017)); U.S. Patent Application No. 16/380,291, *Final Action* dated April 29, 2021, p. 2 (rejecting under Section 103 as being obvious in view of U.S. Patent No. 9,743,643 B1 (issued Aug. 29, 2017)).

316. *See* U.S. Patent Application No. 16/380,291, *Arguments/Remarks Made in an Amendment* dated July 12, 2021, p. 8–10; U.S. Patent Application No. 16/380,291, *Claims* dated July 12, 2021, p. 2–7. The prior art (U.S. Patent No. 9,743,643 B1 (issued Aug. 29, 2017)) described a monitoring system that utilized a wearable device (e.g., an RFID tag) worn by the animal in conjunction with sensors placed throughout an environment, such as a home. However, the prior art did not teach the steps setting a "reference signal" based on (1) a signal received from the animal and (2) a signal received from a sensor at the property, and comparing future signals from the animal to the "reference signal."

317. *See* U.S. Patent Application No. 16/380,291, *Notice of Allowance and Fee(s) Due* dated August 11, 2021.

while the animal is working. Instead, trained animals will often work once brought to a particular location and given a command. However, sometimes specialized tools are used while the animal is working to assist the animal with its task. For example, guide dogs for the blind often have special harnesses that assist them with guiding their blind owners.[318] When these tools are novel, that may make the working method patentable, even when the tools are used in an otherwise conventional way. Thus, to overcome patentability challenges, the developer may want their patent application to emphasize how the novel working tool interacts with a working animal in a way that increases the efficiency of the working animal or has other superior features over conventional methods. Such a patent would include method claims with known or otherwise previously patented steps but incorporate a novel device and/or composition during the working method.

A review of the patent landscape indicated that working method claims were typically rejected in view of the prior art for reasons of obviousness. The rejections were often overcome by adding additional details about the tools to emphasize their novelty or how the novel aspects of the tool are specifically used while the animal is working. In general, claims that recited specific features of the tool, along with how the tool is used while working, were more likely to be allowed by the USPTO.

Example patents related to methods using novel training tools are described below:

> *U.S. 7,633,397 B2 (Detection System Employing Trained Animals), Issued December 15, 2009*

This patent is directed to a method of odor detection using a detection animal that wears an electronic monitoring system.[319] The electronic monitoring system worn by the detection animal contains a GPS unit as well as sensors that monitor physical or behavioral changes of the animal, such as changes in the animal's body position, respiratory patterns, or temperature.[320] Data collected by the electronic

318. *See* Ruffwear, *Leading the Way*, GUIDE DOGS, https://ruffwear.com/pages/guide-dogs (last visited Oct. 6, 2024).

319. U.S. Patent No. 7,633,397 B2 cols. 2–3 (filed Jan. 5, 2007) (issued Dec. 15, 2009).

320. *Id.* at col. 2, ll. 40–43 ("The biometric sensor identifies respiratory patterns, temperature variations and the like, which would be indicative of both trained/in-training and natural responses to target odors.").

monitoring system is transmitted to a remote unit for analysis to determine whether the animal has detected the target odor.[321]

The patent application was initially rejected under Section 103 on obviousness grounds in view of prior art that described a wearable device containing a location sensor to be worn by a detection animal.[322] During prosecution, the applicant narrowed the claims to clarify that the biometric signals from the wearable device correspond to whether the detection animal "identified a target odor," after which the examiner allowed the application.[323] Thus, the point of novelty appears to be the particular method of using a wearable monitoring device that receives biometric signals from the detection animal to confirm the presence of a target odor.

B. Tool Claims

Patent claims directed to the tools used with working animals clearly fall within the scope of patentable subject matter under the broad definition of Section 101, which includes "machine, manufacture, or composition of matter, and any new and useful improvement thereof . . . ."[324] Both incremental improvements on existing tools and entirely new tools may be patented. For example, as discussed further below, a developer can seek patent protection for a novel tool to increase efficiency in administering training samples to an animal by incorporating a sensor in a training scent wheel that detects when the animal engages with the present sample and rotates to deliver a new sample to the animal.[325] Furthermore, these novel tools may be used in both conventional and novel methods. For example, a novel tool might be a wearable sensor used to integrate human, canine, and robot interactions by monitoring the canine's location and biometrics as it searches for improvised explosive devices (IED) in combat. When the

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321. *Id.*

322. *See* U.S. Patent Application No. 11/649,825, *Non-Final Rejection* dated March 27, 2009, p. 2 (citing U.S. Patent No. 6,721,681 B1 (issued Apr. 13, 2004)). The examiner cited U.S. Patent Application Pub. No. 2006/0170541 A1 (published Aug. 3, 2006) as a secondary reference that described portable biometric sensors.

323. *See* U.S. Patent Application No. 11/649,825, *Arguments/Remarks Made in an Amendment* dated June 26, 2009, p. 7; U.S. Patent Application No. 11/649,825, *Claims* dated June 26, 2009, p. 2. Applicant's amendments were distinguishable from the prior art references because the references did not describe sensors that indicated the detection of an odor. *See also* U.S. Patent Application No. 11/649,825, *Notice of Allowance and Fees Due* dated Oct. 1, 2009.

324. 35 U.S.C. § 101.

325. *See* U.S. Patent No. 10,709,108 B2 cols. 1–2 (filed Sept. 5, 2018) (issued July 14, 2020).

detection canine identifies the location of an IED, the control system can dispatch a robot to disarm it.[326] As another example, an otherwise conventional method might rely on the step of using a novel shock collar with GPS capabilities to deliver electronic stimulus to an animal to promote desired behaviors or deter unwelcome ones.[327] This Article proposes two categories of tool-based claims related to working animals: (1) novel tools used while training an animal, and (2) novel tools used while working with an animal. Oftentimes the same tools are used during training and working, such that the novel tool could fall within both categories.

1. Novel Training Tools

As discussed in Part III.A.2, *supra*, some training methods may use novel tools to aid with training. Such tools may include treats and toys, scent wheels, odor simulators, scent control devices, electric collars, and choke collars. These novel tools may be separately patentable. For instance, patented tools have included improved systems for delivering various scents to an animal during training, and a device which has GPS and an electric shock function.

A review of the patent landscape indicated that training tool claims were frequently rejected for lacking novelty and for being obvious in view of the prior art.[328] The rejections were often overcome by adding additional structural details to the tools or by adding additional steps to the independent claims. In general, claims directed to specific structural details of the tools in combination with their intended use to train animals were more likely to be allowed by the USPTO.

Example patents related to novel training tools are described below:

U.S. 7,198,008 B2 (Device for the Training of Scent Discriminating Detector Dogs), Issued April 3, 2007

This patent is directed to a scent-wheel for training detection dogs to discriminate between scents.[329] The scent-wheel has a rotatable base

326. *See* U.S. Patent No. 9,031,714 B1 cols. 2–4 (filed Jan. 30, 2013) (issued May 12, 2015).

327. *See* U.S. Patent No. 8,786,446 B2 cols. 1–3, 7 (issued July 22, 2014).

328. *See e.g.*, U.S. Patent Application Pub. No. 2010/0192281 A1 (pub. Aug. 5, 2010) (publication of an abandoned patent application for a protective glove for animal training following numerous rejections for lack of novelty and obviousness).

329. *See* U.S. Patent No. 7,198,008 B2 cols. 1–2 (filed Feb. 10, 2005) (issued Apr. 3, 2007).

with multiple spokes coming out of the base and a compartment at the end of each spoke.[330] Scented material may be placed in each compartment.[331] For example, a trainer may place different samples into each compartment of the scent-wheel to efficiently teach the dog to distinguish between scents.[332]

This application was rejected on obviousness grounds in view of art that taught an adjustable, rotating carousel for shoe storage.[333] During prosecution, the applicant amended the claim to recite the structural detail of the device and to state that the purpose of the device is to "train the dogs how to recognize specific scents."[334] These amendments, which provided additional structural detail and specific use cases for the device, were sufficient to overcome the obviousness rejection.[335] Thus, the point of novelty appears to be utilizing a specific structure to expose the detection dog to several different scents.

U.S. 9,781,905 B2 (Positive Position Training Leashes and Methods of Using the Leashes for Training a Dog), Issued October 10, 2017

This patent is directed to a dog leash to assist a trainer in teaching, reinforcing, and testing a learned behavior in a dog.[336] For example, a trainer may use the leash which contains a chin cradle to control the head position of the dog to train the dog on where to look or focus.[337]

The patent application was rejected three times on novelty and obviousness grounds in view of prior art that taught a leash comprising a chin cradle and a horse harness.[338] During prosecution, the applicant narrowed the claims to specify structural details of the device,

330. *See id.*

331. *See id.*

332. *See id.*

333. *See* U.S. Patent Application No. 11/054,101, *Non-Final Action* dated October 6, 2006, p. 2 (citing U.S. Patent No. 4,946,048 (issued Aug. 7, 1990)).

334. *See* U.S. Patent Application No. 11/054,101, *Arguments/Remarks Made in an Amendment* dated December 26, 2006, p. 6.

335. *See* U.S. Patent Application No. 11/054,101, *Notice of Allowance and Fee(s) Due* dated February 5, 2007.

336. *See* U.S. Patent No. 9,781,905 B2 col. 3 (filed Oct. 8, 2014) (issued Oct. 10, 2017).

337. *Id.*

338. *See* U.S. Patent Application No. 14/509,678, *Non-Final Action* dated March 9, 2016, p. 6 (citing U.S. Patent No. 6,796,274 B1, p. 6 (issued Sep. 28, 2004)); U.S. Patent Application No. 14/509,678, *Final Action* dated September 20, 2016, p. 6 (citing U.S. Patent No. 6,796,274 B1 (issued Sep. 28, 2004)); *see also* U.S. Patent Application No. 14/509,678, *Non-Final Action* dated March 30, 2017, p. 6 (citing U.S. Patent No. 4,459,795 (issued July 17, 1984)).

including specifying that "the guide is a continuous piece of flexible material" and specifying that a part of the chin cradle is hollow.[339] These amendments, which recited additional structural details of the device, were sufficient to overcome the novelty and obviousness rejections.[340] Thus, the point novelty appears to be the specific structure of the chin cradle and the guide connection components of the leash.

U.S. 7,434,541 B2 (Training Guidance System for Canines, Felines, or Other Animals), Issued October 14, 2008

The patent is directed to an automated animal training system.[341] The automated training system includes a variety of behavior sensors, including cameras and audio recorders to monitor the behavior of the animal.[342] The automated training system also includes a collar, to be worn by the animal, that monitors the animal's behavior.[343] For example, the automated training system may train an animal by providing training commands via video and/or speakers, and provide feedback to the animal either by providing a reward to the animal when it has performed the desired action, or providing a corrective shock to the animal when it has performed an undesired action.[344]

The patent application was rejected under Section 102 for lack of novelty in view of prior art that taught a computer-based animal management system comprising an image sensor, a vibrator, a shock device, and a speaker.[345] Rather than amending its claims, the applicant pointed out features of the claimed invention which were not present in the prior art, including that the cited references do not include a collar worn by the animal that has a camera, vibrating device, shock device, and speaker, and that the prior art references do not include bi-

339. *See* U.S. Patent Application No. 14/509,678, *Arguments/Remarks Made in an Amendment* dated January 20, 2017, p. 10; U.S. Patent Application No. 14/509,678, *Arguments/Remarks Made in an Amendment* dated June 30, 2017, p. 6.

340. *See* U.S. Patent Application No. 14/509,678, *Notice of Allowance and Fee(s) Due* dated July 28, 2017.

341. U.S. Patent No. 7,434,541 B2 cols. 1–3 (filed Jan. 4, 2005) (issued Oct. 14, 2008).

342. *Id.* at col. 1 ("These and other problems are solved by a computer-aided training and management system that uses a computer [in] wireless communication with an instrumented dog collar and/or optionally[,] video monitors, loudspeakers, video cameras, training toys (e.g., ball, bone, moving toy, etc.)").

343. *Id.*

344. *Id.* at cols. 4–5.

345. *See* U.S. Patent Application No. 11/029,567, *Non-Final Action* dated September 25, 2007, p. 2–4 (citing U.S. Patent No. 6,651,592 B2 (issued Nov. 25, 2003), U.S. Patent No. U.S. 5,815,077 (issued Sep. 29, 1998), and (U.S. Patent No. 5,195,455 (issued Mar. 23, 1993)).

directional communication between the computer system and the wearable collar.[346] These arguments successfully overcame the rejection.[347] Thus, the point of novelty appears to be the combination of specific system components (e.g., an image sensor, vibrator, shock device, and speaker) which communicate with the computer system for automated training of the animal.

U.S. 10,932,446 B2 (Mixed Odor Delivery Device (MODD)), Issued March 2, 2021

This patent is directed to a device that can house multiple odors for training detection canines.[348] The device contains two wells, each capable of housing a different odor.[349] Vapors from the wells may diffuse into a vapor mixing chamber that is connected to the two wells.[350] By exposing the canines to the vapor mix, canines may be trained to detect complex hazardous substances within odor mixtures.[351]

The patent application was rejected twice under Section 102 for lack of novelty and once under Section 103 for obviousness in view of prior art that taught a multi-well device for performing assays.[352] During prosecution, the applicant narrowed the claims to specify structural details of a tube within the device.[353] These amendments, which added more detail about the structure of the device, were sufficient to overcome the novelty and obviousness rejections.[354] Thus, the point of

346. *See* U.S. Patent Application No. 11/029,567, *Arguments/Remarks Made in an Amendment* dated February 25, 2008, p. 7–9.

347. *See* U.S. Patent Application No. 11/029,567, *Notice of Allowance and Fee(s) Due* dated July 31, 2008.

348. U.S. Patent No. 10,932,446 B2 col. 1 (filed June 3, 2018) (issued Mar. 2, 2021).

349. *Id.*

350. *Id.*

351. *Id.*

352. *See* U.S. Patent Application No. 15/996,995, *Non-Final Action* dated May 14, 2020, p. 6–17 (citing U.S. Patent No. 5,011,779 (issued Apr. 30, 1991)); *see also* U.S. Patent Application No. 15/996,995, *Non-Final Action* dated September 11, 2020, p. 4 (citing U.S. Patent No. 5,011,779 (issued Apr. 30, 1991)). The application also received an objection regarding informalities and rejections under Section 112, both of which are outside the scope of this article. *See* U.S. Patent Application No. 15/996,995, *Non-Final Action* dated May 14, 2020, p. 2.

353. *See* U.S. Patent Application No. 15/996,995, *Claims* dated November 9, 2020, p. 2. Applicant clarified that the device has "a tube configured to be positioned within the passageway, the tube having a first end that has a lip adapted to rest on a shoulder within the passageway." *Id.*

354. *See* U.S. Patent Application No. 15/996,995, *Notice of Allowance and Fee(s) Due* dated January 1, 2021.

novelty appears to be the particular structural design of the odor-mixture device.

> *U.S. 9,049,845 B2 (System Apparatus and Method of Training Dogs to Detect Complex Hazardous Substances), Issued June 9, 2015*

This patent is directed to a device for training detection dogs to detect hazardous substances by exposing the dogs to odor mixtures formed from at least two different explosive components.[355] The device is formed of PVC (polyvinyl chloride) pipes and fittings.[356] For example, the system includes multiple containers that can house separate explosive components.[357] The containers are connected to a pipe that contains the odor mixture from the separated components, and the pipe is connected to an assembly that is exposed to the dogs during training.[358]

This patent was allowed without any rejections.[359] While not clear from the prosecution history, the point of novelty appears to be the specific structure of the device recited in the claims. For example, the allowed claims detail how the plurality of elbow-shaped pipes are connected together, the end caps which seal the containers, and the specific design features of the adapter pipe and the drain assembly.[360]

2. Novel Working Tools

Similarly, as discussed in Part III.A.4, *supra*, novel tools may be used with working animals while they are performing tasks. These novel tools may be patented separately from the working methods.

A review of the patent landscape indicated that claims on working tools were regularly rejected as obvious in view of the prior art. The rejections were often overcome by adding additional details about functional aspects of the tools, or how the novel aspects of the tools related to their intended use. In general, claims that recite structural elements of the device or system used with the animal, or claims that describe the electronic tool used to aid with the determination of a

355. U.S. Patent No. 9,049,845 B2 col. 3 (filed Jan. 31, 2014) (issued June 9, 2015).

356. *See id.*

357. *See id.*

358. *See id.*

359. *See* U.S. Patent Application No. 14/169,455, *Notice of Allowance and Fee(s) Due* dated January 31, 2014.

360. *See* U.S. Patent Application No. 14/169,455, *Claims* dated January 31, 2014, p. 1–2.

specific outcome while the animal is working, were more likely to be allowed by the USPTO.

Example patents related to novel working tools are described below:

U.S. 7,633,397 B2 (Detection System Employing Trained Animals), Issued December 15, 2009

This patent, which was also discussed in Part III.A.4, *supra*, is directed to an odor detection system using a detection animal that wears an electronic monitoring system.[361] The electronic monitoring system worn by the detection animal contains a GPS unit as well as sensors that monitor physical or behavioral changes of the animal, such as changes in the animal's body position, changes in the animal's respiratory patterns, or changes in the animal's temperature.[362] Data collected by the electronic monitoring system is input into a detection algorithm to determine if the animal detected a target odor.[363]

The patent application was rejected under Section 103 on obviousness grounds in view of prior art that described a wearable device containing a location sensor to be worn by a detection animal.[364] During prosecution, the applicant narrowed the claims to clarify that the biometric signals from the wearable device correspond to whether the detection animal "identified a target odor."[365] Thus, the point of novelty appears to be specifically using biometric signals from the detection animal to detect a specific odor.

361. *See* U.S. Patent No. 7,633,397 B2 cols. 2–3 (filed Jan. 5, 2007) (issued Dec. 15, 2009).

362. *See id.* at col. 2, ll. 40–43 ("The biometric sensor identifies respiratory patterns, temperature variations and the like, which would be indicative of both trained/in-training and natural responses to target odors.").

363. *See id.* at cols. 2–3.

364. *See* U.S. Patent Application No. 11/649,825, *Non-Final Action* dated March 27, 2009, p. 2 (citing U.S. Patent No. 6,721,681 B1 (issued Apr. 13, 2004)). The examiner cited U.S. Patent Application Pub. 2006/0170541 A1 (published Aug. 3, 2006) as a secondary reference that described portable biometric sensors. *See id.*

365. *See* U.S. Patent Application No. 11/649,825, *Arguments/Remarks Made in an Amendment* dated June 26, 2009, p. 7–10; *see also* U.S. Patent Application No. 11/649,825, *Claims* dated June 26, 2009, p. 2. Applicant's amendments were distinguishable from the prior art references because the references did not describe sensors that indicated the detection of an odor. *See also* U.S. Patent Application No. 11/649,825, *Notice of Allowance and Fee(s) Due* dated October 1, 2009.

U.S. 9,031,714 B1 (Command and Control System for Integrated Human-Canine-Robot Interaction), Issued May 12, 2015

This patent is directed to a system for integrated human, canine, and robot interaction for detecting and neutralizing improvised explosive devices (IEDs).[366] The system includes a wearable sensor for detecting terrain information that is worn by a detection animal.[367] For example, the sensor worn by the detection animal may gather GPS, audio/visual information, or inertial measurements to be sent to the control system as the detection animal searches for the IED.[368] When the detection animal has identified the location of an IED, the control system sends a robot to disarm the IED.[369]

This patent application was rejected once on obviousness grounds in view of prior art that taught a control unit linked to receive trained canine detection information of the location of potential IEDs and provide information to an unmanned robotic vehicle to neutralize the IED.[370] During prosecution, the applicant narrowed the claims to specify that a sensor collar or vest is worn by the trained canine, and that said sensor gathers terrain information, including the terrain difficulty.[371] These amendments, which narrowed the scope and provided specific examples of the type of sensor data gathered by a wearable sensor on the canine, were sufficient to overcome the obviousness rejection.[372] Thus, the point of novelty appears to be the specific combination of data being gathered by the sensor worn by the canine.

C. Animal Claims

The category likely viewed with the most uncertainty regarding its patentability is patents on the trained animals themselves. The Authors admit to being skeptical about patentability here—and assume the reader is similarly skeptical—based on patent policy and case law

366. *See* U.S. Patent No. 9,031,714 B1 cols. 2–4 (filed Jan. 30, 2013) (issued May 12, 2015).

367. *See id.*

368. *See id.*

369. *See id.*

370. *See* U.S. Patent Application No. 13/753,614, *Non-Final Action* dated January 12, 2015, p. 2-3 (citing U.S. Patent Application Publication No. 2008/0163671 A1 (published July 10, 2008).

371. *See* U.S. Patent Application No. 13/753,614, *Arguments/Remarks Made in an Amendment* dated February 26, 2015, p. 6–7.

372. *See* U.S. Patent Application No. 13/753,614, *Notice of Allowance and Fee(s) Due* dated April 6, 2015.

that generally prohibits patenting living animals.[373] Notably, a review of the patent landscape did not identify any patents within this category. However, this does not mean that it is impossible to directly patent a trained working animal. The Supreme Court has ruled that living organisms that are human-made and not naturally occurring are patentable and do not fall within the judicial exceptions under Section 101.[374] This includes genetically-modified organisms and transgenic animals.[375] For example, in *Diamond v. Chakrabarty*, the court held that genetically engineered bacteria was patentable.[376] Further, the USPTO has granted a patent directed to a genetically modified mouse which had a cancer-promoting gene inserted into its genome.[377] As another example, the USPTO granted a patent on transgenic rodents that were genetically modified to express canine-based

373. *See* 35 U.S.C. § 101; *see also* Diamond v. Diehr, 450 U.S. 175, 185 (1981); *In re* Roslin Inst. (Edinburgh), 750 F.3d 1333, 1337 (Fed. Cir. 2014). Further, even if the patent applicant overcomes the Section 101 hurdle, the patent applicant must also meet all of the other statutory requirements of patentability. *See In re* Ditto, No. 2012-1182, 2012 U.S. App. LEXIS 25067, at *3 (Fed. Cir. 2012) (nonprecedential) (affirming USPTO finding that claims directed to a new breed of a cat formed by mating a Bobcat Lynx with a domestic cat was unpatentable due to anticipation under Section 102. The court did not consider the Section 101 issue, having reached a decision based on Section 102.).

374. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding that genetically engineered bacteria was patentable); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580 (2013) (holding that isolated and non-naturally occurring DNA was patentable); U.S. Patent No. 4,736,866 col. 1 (filed June 22, 1984) (issued Apr. 12, 1988) (a patent directed to a genetically modified mouse which had a cancer-promoting gene inserted into its genome); U.S. Patent No. 10,662,256 B2 Abstract (filed May 23, 2017) (issued May 26, 2020) ("The present invention relates to transgenic mammals that express canine-based immunoglobulins, including transgenic rodents that express canine-based immunoglobulins for the development of canine therapeutic antibodies.").

375. It is well-settled law that genetically modified organisms are patentable. *See, e.g.*, Shanna Lisberg, *Animal Law: Five Things Every Lawyer Should Know*, 70 N.W. LAWYER 36, 37 (2016) ("The U.S. Patent and Trademark Office has been issuing patents for genetically engineered animals since 1988."); Carolyn Brown, *Patenting Life: Genetically Altered Mice an Invention, Court Declares*, 163 CANADIAN MED. ASS'N J. 867 (Oct. 3, 2000) ("The mouse has been patented for many years in the US. In fact, 'transgenic' animals such as the oncomouse can be patented in the US, Japan and many European countries.").

376. *See Chakrabarty*, 447 U.S. at 310.

377. *See* U.S. Patent No. 4,736,866 Abstract (filed June 22, 1984) (issued Apr. 12, 1988) ("A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.").

immunoglobulins for the development of canine therapeutic antibodies.[378] As yet another example, the USPTO granted a patent on transgenic salmon that was genetically engineered to grow at a faster rate than naturally-occurring salmon.[379]

Therefore, it is natural for developers to wonder whether an animal that is trained by a person to do something "unnatural" could possibly constitute a patentable human-made creation. For example, could a developer obtain a patent on an animal, such as a pigeon, trained to perform a task it would not do in nature, such as differentiating between cancerous and non-cancerous breast tissue cells? A method of using such a pigeon may be patentable, as discussed above. But a court is unlikely to find claims directed to the pigeon itself as patentable. Invoking a novel ability in an animal, even if such ability is radically different from anything that the animal could do naturally, would likely be deemed an unpatentable product of nature or natural phenomena. Unlike the genetically-engineered bacteria of *Chakrabarty,* the trained pigeon in this hypothetical situation is still a naturally-occurring pigeon. Thus, a transgenic dog that is genetically modified to detect seizures for example, may be patentable under the law, but a naturally-occurring animal that is trained to perform the exact same task is likely unpatentable. The goal of the patent system is to promote the progress of science – but the absence of patents in this category shows that current patent policy is clearly failing developers of working animals by not providing direct ways to protect their innovations.

IV. PRACTICAL ADVICE – DOS AND DON'TS (PRACTITIONER ADVICE)

While the notion of securing patent protection for working animals might seem counterintuitive initially, a thorough examination of the patent landscape reveals a nuanced reality. As detailed above, a

378. *See* U.S. Patent No. 10,662,256 B2 col. 119 ll. 34–45 (filed May 23, 2017) (issued May 26, 2020) ("A transgenic mouse with a genome in which an entire endogenous immunoglobulin variable gene locus has been deleted and replaced with an engineered partly canine immunoglobulin locus comprising canine immunoglobulin variable gene VH, D and JH and/or canine VL and JL coding sequences and mouse immunoglobulin variable gene locus non-coding regulatory sequences, wherein the engineered partly canine immunoglobulin locus of the transgenic mouse is functional and expresses immunoglobulin chains comprised of canine variable domains and mouse constant domains.").

379. *See* U.S. Patent No. 5,545,808 col. 19 (filed Mar. 10. 1994) (issued Aug. 13, 1996) ("A transgenic salmonid fish containing in its germline a salmonid growth hormone gene operably linked to a type 3 antifreeze protein promoter wherein said salmonid fish expresses said growth hormone gene at levels which increase the rate of its growth at least four times that of a salmonid fish lacking said growth hormone gene operably linked to said antifreeze protein promoter.").

substantial body of patents covers diverse facets of training methods, tools, and applications for working animals. Insights gleaned from the file histories of these patents can provide invaluable guidance for developers aiming to protect their intellectual property in this unique domain. To navigate the intricacies of patent prosecution successfully, patent practitioners and their clients should consider the following tips and considerations. These insights aim to streamline the patenting process for inventions related to working animals, offering strategic guidance to minimize office actions and rejections during prosecution, and maximize the likelihood of securing a patent from the USPTO.

A. Novelty and Non-Obviousness Considerations

Teachings related to domesticated animals stretch back to the dawn of civilization. Practitioners should ensure that patent applications directed to working animals provide detailed descriptions of how the novel methods or tools differ from, or represent a nonobvious advancement over, historical human practices in utilizing working animals over the past millennia.

A review of the patent landscape shows that training method claims, as discussed in Parts III.A.1 and III.A.2, *supra*, were often rejected for lacking novelty or being obvious in view of the prior art. When amending the claims to differentiate them from the cited prior art, applicants should consider amendments that focus the claims on a specific use case involving the working animal. While some practitioners may consider such amendments to be overly limiting, such claims, once allowed, often still provide substantial protection for the developer's invention, particularly if the developer is an early-stage company that only plans to commercialize its animal-based invention in a specific use case for the foreseeable future or has otherwise not identified additional use cases that could generate monetary value. For example, if a patent application is directed to a method of training an animal to detect a target odor using a scent wheel, the practitioner can attempt to narrow the claims to overcome a prior art rejection under Sections 102 or 103 by adding limitations to cover a particular use case, such as using a specific type of animal to detect a specific target odor (e.g., using canines to detect narcotics). If the novelty of the invention instead centers around the tool used, the practitioner may find it helpful to add limitations that describe narrower or additional features of the tool that relate to the particular use case. In the above example, the amended claim could include additional limitations related to the properties of the scent wheel (e.g., multiple chambers capable

of separately emitting different narcotic odors in various combinations).

The patent prosecution trends for working methods, as discussed in Parts III.A.3 and III.A.4, *supra*, differed slightly from training methods. Among the patents reviewed for this Article, those with claims directed towards working methods typically included key details on the structural elements of a device or system used while the animal is working, suggesting that working methods relying on novel working techniques for patentability are harder to patent than those relying on a novel tool.[380] However, should the patentee identify a new use for a working animal, they may want to attempt more broadly claiming that use first (e.g., more broadly detecting a target odor rather than more narrowly detecting a particular biomarker of a disease), only narrowing their claims if faced with a prior art rejection based on their working methods alone.

In anticipation of facing difficult obviousness rejections, practitioners should proactively develop evidence of and arguments supporting secondary indicia of non-obviousness early in the patent process to reinforce their applications. Particularly for patents directed to incremental improvements, secondary details that support a finding that the improvement is not obvious can help prevent or limit hindsight bias, and, more importantly, help overcome the *prima facie* case of obviousness.[381] Given the long history of using animals for a variety of working purposes, patent applicants should assume there will be a high likelihood of facing obviousness rejections, even for clearly novel inventions. Secondary indicia of non-obviousness can include factors like unexpected results, commercial success, long-unsolved needs being met, the failure of others, professional approval, skepticism of experts, and other similar objective evidence that tends to show that the animal-based invention was not obvious despite the long history of training and using animals to serve certain functions.[382]

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380. *See infra* Part III.A.3 and III.A.4.

381. *See* Sivakami Dhulap & MG Kulkarni, *Avoiding Hindsight in Non-Obviousness Determination: Case Law Review of Pharmaceutical Patents and Guidance from the KSR v Teleflex Decision*, 31 EXPERT OPINION ON THERAPEUTIC PATENTS 951, 954 (2021) ("the author enlisted few considerations that may reduce the influence of hindsight. These include i) if the problem was well defined in the industry, ii) if the solution was from a finite set of known solutions and iii) consideration of objective indicia or secondary considerations may contribute to reduce the influence of hindsight while determining the non-obviousness determinations").

382. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 419–22 (2007); Natalie A. Thomas, *Secondary Considerations in Nonobviousness Analysis: The Use of Objective Indicia Following* KSR v. Teleflex, 86 N.Y.U. L. REV. 2070, 2076–77 (2011).

For animal-based patents, the fact that certain training methods for working animals have existed for centuries could actually serve as a helpful secondary indicium of non-obviousness if the applicant can show that others have failed to find a solution to a particular problem despite the longstanding training method or the applicant's particular results are unexpected given the previously known application of the training method. If faced with the argument that using such well-established methods is obvious, an applicant can counter by arguing that if it was obvious, it would not have taken centuries for someone to use the method to arrive at the solution that the applicant did.[383] Evidence of industry praise or recognition of the applicant's animal-based invention can also serve as secondary indicia of non-obviousness, though this type of objective evidence is unlikely to be available at the time of filing. For animal-based patents directed to incremental improvements, practitioners should be prepared to argue that their evidence of secondary indicia of non-obviousness is the direct result of their unique improvement and not related to some aspect of their claim already present in the prior art. Critically, the burden is on the applicant to show that secondary indicia are sufficient to outweigh a *prima facie* case of obviousness.[384] Because it can take substantial time to develop sufficient evidence to overcome a *prima facie* case of obviousness, early development of such evidence is critical to ensure applicants are able to overcome the inevitable Section 103 rejections.

B. Patentable Subject Matter Considerations

As noted in Part II.A, *supra*, patent applications filed by developers of animal-based inventions are also likely to face subject-matter

383. *See* Thomas, *supra* note 382, at 2077–78; *see also* Ritchie v. Vast Resources, Inc., 563 F.3d 1334, 1336 (Fed. Cir. 2009) ("[G]iven that Pyrex, made originally as we said from borosilicate glass, has been sold by Corning for almost a century (and it was sold under other names beginning in 1893, when borosilicate glass was first invented), to call its use in [the patented invention] "obvious" may seem the triumph of hindsight over insight."); *but see* Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Absent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness.") (citing *In re* Wright, 569 F.2d 1124, 1127 (C.C.P.A. 1976)).

384. MPEP, *supra* note 104, § 2142 ("Once the examiner sets out this prima facie case, the burden shifts to the patentee to provide evidence, in the prior art or beyond it, or argument sufficient to rebut the examiner's evidence."). Note this burden shifting may not be proper when obviousness is litigated in court. *See In re* Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation, 676 F.3d 1063, 1079–80 (Fed. Cir. 2012) (finding that the district court erred by "imposed a burden-shifting framework in a context in which none exists").

rejections under Section 101 given that any claims related to trained animals or training methods will likely invoke one of the judicial exceptions to patentability. To preempt these subject-matter rejections, applicants should consider how to characterize their invention in the specification and claims as a specific application of a law of nature, natural phenomenon, or abstract idea that is novel and useful over the prior art.[385] For example, a claim directed to a method of training an animal to detect various scents would likely provoke a Section 101 rejection – but the prudent applicant should make sure to detail the steps of the training method that are improvements over prior technologies and explain the aspects of the invention that go beyond the animal's inherent abilities to smell and be trained, thereby qualifying it as patent-eligible subject matter under step two of the *Alice/Mayo* test.

It is also possible for practitioners to characterize their inventions in such a way that the application gets routed to a more favorable art unit with a higher average allowance rate. The allowance rate during prosecution for each technology center is shown in the table below. Technology centers with lower average allowance rates tend to have "tougher" examiners that issue more rejections and fewer allowances.[386] Unfortunately, applicants cannot directly control the choice of examiner or technology center. Instead, the USPTO primarily analyzes the claims, abstract, and technical field of a patent application to determine which art unit the application should be assigned.[387] By modifying the terms and phrases in these portions of the patent application, the applicant may be able to manipulate where the application

385. *See, e.g.*, Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014) ("Accordingly, in applying the §101 exception, we must distinguish between patents that claim the 'building blocks' of human ingenuity and those that integrate the building blocks into something more, thereby 'transforming' them into a patent-eligible invention.") (quoting Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 89, 72 (2012)).

386. *See* Henry Metro, Arya Moshiri & Matthew Avery, *The Myth of "Bad" Patents: Impact of Prosecution Length on Patent Litigation Outcomes*, 38 HARV. J.L. & TECH. 227, 241 (2024).

387. *See* MPEP, *supra* note 104, § 903 ("Utility patents, applications, and patent application publications receive a classification designation under the Cooperative Patent Classification (CPC) system."); *see also* MPEP, *supra* note 104, § 909.01(b) ("Once the application has received these classifications, the automated routing system can assign the application to an examiner . . . Utility applications are routed to an examiner using an automated routing system. The automated routing system takes into account the CPC classifications of an application and compares them to examiner portfolios (i.e. the classification areas to which the examiner has been assigned).").

is sent.[388] As an example, if the invention is related to a computer device that can track the locations of RFID sensors in remote objects that are used to train canines to detect explosives or narcotics, it could arguably fall within multiple technology fields in the below table depending on which portions of the invention are emphasized.

Technology Center	**Field**	**Overall Allowance Rate:**[389]
1600	Biotechnology and Organic Chemistry	57.9%
1700	Chemical and Materials Engineering	65.1%
2100	Computer Architecture and Software	75.8%
2400	Networking, Multiplexing, Cable, and Security	78.7%
2600	Communications	79.7%
2800	Semiconductors/Memory, Circuits/Measuring and Testing, Optics/Photocopying, Printing/Measuring and Testing	83.1%
2900	Designs	94.0%
3600	Transportation, Construction, Electronic Commerce, Agriculture, and National Security	68.1%
3700	Mechanical Engineering, Manufacturing, and Products	71.3%

To illustrate, if the claims in the above example are drafted to focus on the RFID sensor and the technical components of the detection system, this may increase the likelihood of the application being assigned to an art unit focused on hardware or mechanical tools with

388. *See Using Drafting*, JURISTAT (Jan. 20, 2017), https://blog.juristat.com/help/2017/1/20/using-drafting ("[Y]ou can make an informed decision about whether to change the language of your claim to alter your likelihood of being assigned to a problematic technology center, art unit, or class.").

389. *See, e.g.*, *Biotechnology and Organic Chemistry Search Results*, PATENTADVISOR, https://go.patentadvisor.com/statistics.php?Parent=TechnologyCenter&TechnologyCenter=1. This data was retrieved February 23, 2024, and covers patent applications with electronic file histories that were filed on or after November 29, 2000. Patent Advisor regularly updates this data, and these values reflect Patent Advisor's data as of February 23, 2024. The overall allowance rates listed here were calculated by Patent Advisor by taking the number of issued patents from a Technology Center and dividing it by the sum of issue patents and abandoned patents from the Technology Center.

relatively higher allowance rates and lower Section 101 rejection rates, such as a unit in technology centers 2400 or 2800.[390] In contrast, if the claims in this example are drafted to focus on a working method of using a canine to detect explosives in combination with an RFID sensor, this may increase the likelihood of the application being assigned to an art unit in technology center 3600, which has a higher frequency of subject matter rejections under Section 101 and a significantly lower overall allowance rate, making it much more difficult for applicants to receive an allowance.

Given the wide variance in the overall allowance rates among art units, practitioners should consider whether it makes sense to draft the application in a way that increases the chances that the application is routed to an art unit with higher allowance rates. In the above example, drafting the initial claim set to cover the RFID sensor to get the application in the mechanical and/or hardware art units could pave the way to an easier allowance. Then, once a patent allowance is secured, the applicant can file a continuation patent with claims more broadly directed to the working methods. Because the parent application in this example was assigned to an examiner in an easier art unit (e.g., a unit in technology centers 2400 or 2800), the continuation application is very likely to be assigned to the same examiner, making it easier to get the method claim allowed than if it were initially assigned to an examiner in a more difficult art unit (e.g., a unit in technology center 3600).[391]

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390. *See* Matthew Avery & Arya Moshiri, *The Impact of the January 2019 USPTO Guidance: One Year Later*, BAKER BOTTS: THOUGHT LEADERSHIP (Mar. 26, 2020), https://www.bakerbotts.com/thought-leadership/publications/2020/april/the-impact-of-the-january-2019-uspto-guidance ((Figure 1, showing Technology Center 2400 had significantly lower rate of Section 101 rejections than Technology Centers 2100 and 3600); *see also* Michael Borella, *On Alice Rejections per USPTO Technical Center*, PAT. DOCS: PAT. L. WEBLOG (Mar. 6, 2023), https://www.patentdocs.org/2023/03/on-alice-rejections-per-uspto-technical-center.html (showing technology centers 2400 and 2800 have significantly higher ratios of Section 103 rejections to Section 101 rejections—and thus a lower frequency of Section 101 rejections—than Technology Centers 2100 and 3600).

391. *See* Julian Boulanger, The Examination of Continuation Applications and the Problem of Invalid Patents in the U.S. 13 (Feb. 14, 2019) (unpublished manuscript), https://ssrn.com/abstract=3347131 ("The incidence of related-ness is pretty high, with 84% of all continuations being examined by a related examiner [i.e., the same examiner], reflecting the established practice at the PTO of assigning continuations to the same examiner who examined the parent application.").

C. Strategic Considerations

In addition to the challenges of navigating an application through the gauntlet of the USPTO, there are various business challenges related to the development and commercialization of working animals that may impact the developer's ability to protect its intellectual property. Thoughtful planning and preemptive measures are essential to mitigate risks and challenges unique to the domain of working animals.

Firstly, it is critical to counsel clients on public disclosures and potential bars on patentability. The Patent Act requires that the invention be novel, not in the public use, on sale, or otherwise available to the public (e.g., described in a printed publication) prior to the filing date of the patent application.[392] There is an exception for an applicant's own public disclosure or use of the invention; however, the applicant has one year from the first public disclosure or use to file a U.S. patent application.[393] Otherwise, their prior disclosure or use will be considered prior art to their patent application and possibly bar patentability.[394] For working animals that are deployed in potentially public settings, developers should implement stringent controls for their use to prevent inadvertent public disclosures.[395] When working animals are involved in testing samples from external sources, it is imperative to establish protocols that mandate all involved parties sign

392. *See* 35 U.S.C. § 102(a) ("(a) Novelty; Prior Art.—A person shall be entitled to a patent unless— (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention . . . .").

393. *See id.* § 102(b)(1) ("(b) Exceptions.— (1) Disclosures made 1 year or less before the effective filing date of the claimed invention.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if— (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.").

394. *See id.* § 102(b)(1); *see also Intellectual Property (IP)*, WRIGHT STATE UNIV.: TECH. TRANSFER, https://www.wright.edu/research/technology-transfer/intellectual-property (last visited Dec. 13, 2024). Notably, this one-year exception in the United States is generally not recognized by other countries. As such, an applicant's public disclosure or use could potentially bar their foreign patent rights entirely.

395. *See* BASF Corp. v. SNF Holding Co., 955 F.3d 958, 966 (Fed. Cir. 2020) (citing Egbert v. Lippmann, 104 U.S. 333, 336 (1881) (holding that a use "not successfully concealed or hidden from those who lack any limitation or restriction, or injunction of secrecy" constitutes a public use within the meaning of Section 102(b)).

comprehensive non-disclosure agreements (NDAs) to uphold confidentiality.[396] For example, if a working animal is being used for medical diagnostic purposes prior to patenting, the developer should ensure that NDAs are executed by both patients and medical practitioners. In scenarios involving external contractors, such as animal trainers engaged on a short-term basis, developers must ensure the implementation of rigorous NDAs to safeguard proprietary information and intellectual property.[397]

Secondly, prior to filing a patent application, it is paramount for a working animal developer to consider whether patent protection is even worth the time and expense given the potential value of a patent on the underlying innovation. The average cost for preparing and prosecuting a U.S. non-provisional utility patent can exceed $50,000, which includes attorney fees and USPTO fees.[398] Furthermore, there is an ongoing cost associated with holding an issued patent and keeping it valid—the USPTO requires patent owners to pay maintenance fees of $2150, $4040, and $8280 at 3.5, 7.5, and 11.5 years after issuance of the patent, respectively.[399] If the patent owner is unable to

396. *See* Ingenico Inc. v. Ioengine, LLC, No. 18-826, 2022 U.S. Dist. LEXIS 246090, at *59 (D. Del. Dec. 9, 2022) ("a third party's use of the invention will be deemed an invalidating public use even if the use does not disclose the details of the invention to the public" unless the use is "secret, subject to a pledge of confidentiality, or experimental in nature.").

397. *See* Sunoco v. Powder Springs Logistics, No. 17-1390, 2020 U.S. Dist. LEXIS 253765, at *6 (D. Del. Feb. 20, 2020) (disclosure to third party potential buyer of patentee company not a bar to patentability where third party was subject to confidentiality agreement); *cf.* Netscape Commc'ns Corp. v. Konrad, 295 F.3d 1315, 1323 (Fed. Cir. 2002) (holding patentee's failure to impose confidentiality agreements and failure to monitor the use of his invention by third parties placed it in public use).

398. *See* Russ Krajec, *How Much Does a Patent Cost?*, BLUEIRON IP (Jan. 16, 2022), https://blueironip.com/how-much-does-a-patent-cost/. This does not cover the cost of enforcing a patent, which typically runs in the six to seven-figure range. *See id.*; *see also* Russ Krajec, *What Are the Costs to Enforce or Defend a Patent?*, BLUEIRON IP (Jan. 1, 2020), https://blueironip.com/what-are-the-costs-to-enforce-or-defend-a-patent/ (estimating costs through the claim construction phase of litigation between $250,000 and $2,375,000, and costs through trial between $700,000 and $4,000,000).

399. *See* Setting and Adjusting Patent Fees During Fiscal Year 2025, 89 Fed. Reg. 91898 (Nov. 20, 2024); *USPTO Fee Schedule*, USPTO, https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule (last visited Jan. 19, 2025). These are the standard fees for a "large" entity. The fees for "small entities" are discounted by 60% off these standard fees. *See also Maintain Your Patent*, USPTO, https://www.uspto.gov/patents/maintain (last visited Jan. 19, 2025). Failure to pay maintenance fees will cause the issued patent to lapse. *See Maintain Your Patent*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/maintain (last visited Jan. 19, 2025).

effectively monetize the patent asset, for example, by bringing infringement claims on a patent, or subsequently, if the patent is more likely to be deemed invalid when subject to litigation – the cost associated with prosecuting an application to issuance or maintaining an issued patent may not be worth it. For example, if the invention is a novel training method or tool, then it may be difficult to determine whether a competitor is actually infringing the patent because training is typically not publicly demonstrated. In such a case, the patentee may not be able to bring a patent infringement suit because it does not know if a competitor is actually infringing its patent. Thus, developers of novel training methods should consider whether keeping the invention as a trade secret is more practical than seeking patent protection. In contrast, working methods and tools are more likely to be publicly demonstrated and thus, from an enforcement perspective, such patents are likely to be easier to assert and to be more valuable.

Finally, the feasibility of commercialization is a critical concern for developers of working animals, such that incurring patent-related expenses may be best spent closer to when the products are finalized and ready to enter the market. In the Authors' research and experience talking with developers, it became apparent that using trained animals to do anything is challenging, and bringing these animal-based inventions to market is even more challenging. There are questions related to reliability, consistency, and regulatory uncertainty, particularly when animals are used in heavily regulated industries, such as medical diagnostics.[400] Notably, training environments are often strictly controlled and distraction-free – these trained animals may struggle to perform reliably when working in a real-world environment filled with distractions that were not present or accounted for during training.[401] As such, early training and working techniques may need to significantly evolve during the course of the research and development process and many iterations and innovations may occur over time.[402] Because techniques and tools may change many times from conception until commercialization, developers may want to make liberal use of provisional applications to capture these incremental evolutions in their inventions, and delay the expense of filing formal non-provisional applications until their inventions are finalized and closer to

400. *See* Avery & Galvan, *supra* note 2, at 386–87.
401. *See id.*
402. *See id.*

being ready for public use.[403] This way, developers can deploy their limited resources where they need them most, while also ensuring that priority for patent purposes is established.

V. SUGGESTIONS FOR PROMOTING ANIMAL-BASED PATENTS

Working animals show enormous potential in a range of fields, including aiding with life-saving medical diagnostics, detecting dangerous or illicit chemical compounds, and in a variety of other ways through the skills they can learn with training.[404] But researching and developing methods to train animals can be costly, as can maintaining these skills in working animals after they are trained. With the current state of patent eligibility law, there are several obstacles for developers of working animals to secure legal protection for their investments. Absent patent protection, sponsors of working animals capable of providing valuable benefits may be disincentivized to invest the time and money to commercialize their innovations in the United States. Moreover, the uncertainty and confusion surrounding how examiners treat patent applications directed to working animals under Section 101 could dissuade those sponsors from filing patent applications over fears of being rejected ad nauseam due to subject-matter eligibility concerns. The failure of the patent system to protect these inventions could deter further innovation in this area and place the United States behind other countries in developing new uses for working animals.[405] To solve these problems, we propose the following solutions.

A. Reforming the Laws of Patentable Subject Matter

Some hurdles to securing a patent on working animals could be assuaged through amendments to the Patent Act. The patents reviewed for this Article frequently faced subject matter rejections under Section 101 for allegedly being directed to a natural phenomenon or an abstract idea.[406] And more broadly, the current state of patent law, with

403. *See How Much Does a Patent Cost?*, *supra* note 398 (The average cost of preparing and filing a provisional patent application is $11,500, while the average cost of preparing and prosecuting a non-provisional utility patent application can exceed $50,000, which includes attorney fees and USPTO fees. This does not cover the cost of enforcing a patent, which typically runs in the six to seven-figure range.); *see also What are the Costs to Enforce or Defend a Patent?*, *supra* note 398.

404. *See supra* Part I.

405. *See generally The State of Patent Eligibility in America: Hearing on Section 101 Legislation Before the S. Comm on the Judiciary*, 116th Cong. (2019) (statement of Henry Hadad, President, Intellectual Property Owners Association) [hereinafter Hadad].

406. *See supra* Part III.

its numerous judge-made exceptions to patentable subject matter, has been widely criticized for being incoherent, overreaching, and deterring innovation in a variety of fields.[407] Congress should amend the Patent Act to narrow or eliminate the list of judicial exceptions to more generally clarify the scope of patent-eligible subject matter—this would have the effect of also clarifying the scope of Section 101 concerning animal-based inventions and encourage the development of further inventions related to working animals.

The first federal patent legislation was enacted in 1790, and many fundamental components of that legislation are substantially the same today.[408] Although the scope of Section 101 eligibility has remained relatively fixed, Congress has a "rich history of expanding and refining (but not limiting) patent eligibility" through small, *incremental* changes.[409] For example, the legislative history shows much Congressional deliberation over the years about including "discoveries" along with inventions in the patent eligibility threshold language.[410] The record shows that Congress ultimately chose to include discoveries and inventions in the Section 101 language that remains today to ensure a broad scope for patent eligibility, and that they did so while aware of the fact that patent eligibility for discoveries was "inconsistent with the decisions of the Supreme Court."[411] Although the changes to patent eligibility law have been minor, actions of Congress in this area reflect an intent to maintain a broad scope for patent eligibility in spite of limiting jurisprudence.[412]

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407. *See* KEVIN J. HICKEY, CONG. RSCH. SERV., R45918, PATENT-ELIGIBLE SUBJECT MATTER REFORM: BACKGROUND AND ISSUES FOR CONGRESS 24 (2022); Charles Bieneman, *Patent-Eligibility Legislative Reform Is Not Coming Soon*, BEJIN BIENEMAN INTELL. PROP. ATT'YS (Jan. 1, 2020), https://b2iplaw.com/swip-report/patent-eligibility-legislative-reform-is-not-coming-soon/; Hadad, *supra* note 405.

408. *See* BLEVINS & HICKEY, *supra* note 128, at 1.

409. Sherry Knowles & Anthony Prosser, *Unconstitutional Application of 35 U.S.C. § 101 by the U.S. Supreme Court*, 18 J. MARSHALL REV. INTELL. PROP. L. 144, 151 (2018).

410. *See id.*

411. At a hearing on the proposed language that re-introduced the word discoveries to the eligibility definition, the DOJ requested that the word discoveries be removed so that it would not be inconsistent with Supreme Court jurisprudence, but Congress declined to adopt their suggestion. *See id.*

412. Although recent decades of Supreme Court decisions have restricted patent eligibility even further, courts have consistently been the limiting factor in patent eligibility throughout the history of patent law. This is especially true when courts apply the law to things that fall more clearly into the discovery category than the invention category, which can be an obstacle to patentability for animal-based

While the statutory definition of patent-eligible subject matter has remained essentially the same for over 200 years, the scope of patent eligibility has changed significantly over time due to judicial interpretation.[413] In the last few decades, patent decisions from the Supreme Court have broadened the scope of judicial exceptions to patent eligibility and consequently narrowed the scope of patent-eligible subject matter.[414] In effect, this has significantly constrained what kinds of inventions are patentable in the United States today—not only in the context of animal-based inventions, as discussed previously, but also in more prominent technical fields, such as computer software and biomedical technology.[415] Some stakeholders report positive effects from judicially created exceptions to patent eligibility, such as a reduction in unmeritorious patent litigation, prevention of overly broad patents, and prevention of monopolies on "basic research tools and concepts."[416] However, many stakeholders have raised concerns that modern Supreme Court jurisprudence places the United States at a disadvantage when it comes to maintaining a foothold as a global leader in innovation and have called the current patent eligibility standards vague, subjective, and unworkable.[417] In the context of this Article, this is evidenced by the lack of patents on animals outside of the GMO context and the challenges to securing patents on tools and methods related to working animals discussed above.

Many modern reform efforts for patent eligibility have focused on eliminating or limiting judicial exceptions in order to bring the scope of patentable subject matter back into alignment with Congress's original intent in enacting Section 101, which was to broadly define the categories of subject matter eligibility for patent protection

inventions. *See, e.g.*, Morton v. New York Eye Infirmary, 17 F. Cas. 879, 884 (C.C.S.D.N.Y. 1862) (No. 9,865) (describing a patent application for a gas-inhalation method to desensitize animals to pain: "Neither the natural functions of an animal upon which or through which it may be designed to operate, nor any of the useful purposes to which it may be applied, can form any essential parts of the combination, however, they may illustrate and establish its usefulness."); *see also* Knowles & Prosser, *supra* note 409, at 150–53.

413. *See* BLEVINS & HICKEY, *supra* note 128, at 1.

414. *See* Bilski v. Kappos, 561 U.S. 593, 612 (2010); Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 73 (2012); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014); *see also supra* Part II.A.1.

415. *See* HICKEY, *supra* note 407, at 2–3.

416. BLEVINS & HICKEY, *supra* note 128, at 1–2.

417. *See* HICKEY, *supra* note 407, at 2; Bieneman, *supra* note 407.

in order to promote science, progress, and economic development.[418] Some stakeholders believe congressional action is needed to "increase certainty, consistency, and predictability for patent owners and promote innovation, investment and job creation."[419] In 2017, both the Intellectual Property Owners Association (IPO) and the American Intellectual Property Law Association (AIPLA) proposed substantially similar amendments to Section 101 that aimed to replace judicially created exceptions with a new framework.[420] This new framework would supersede modern Supreme Court decisions and expand the scope of subject matter eligibility by clearly and narrowly defining the exclusive exceptions to patent eligibility.[421] The proposed legislation would accomplish this by eliminating the word "new" from the definition of patent eligible subject matter and by adding a subsection that defines the sole exceptions to patent eligibility: "[a] claimed invention is ineligible under subsection (a) if and only if the claimed invention as a whole . . . [(i)] exists in nature independently of and prior to any human activity, or [(ii)] exists solely in the human mind."[422] Another subsection would set forth the "sole eligibility standard" under Section 101:

> The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to:
> (i) the requirements or conditions of sections 102, 103, and 112 of this title;
> (ii) the manner in which the claimed invention was made or discovered;
> (iii) whether the claimed invention includes an inventive concept. [423]

418. *See, e.g.*, AM. INTELL. PROP. L. ASS'N, AIPLA LEGISLATIVE PROPOSAL AND REPORT ON PATENT ELIGIBLE SUBJECT MATTER 2 (2017); SECTION 101 LEGIS. TASK FORCE, INTELL. PROP. OWNERS ASS'N, PROPOSED AMENDMENTS TO PATENT ELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. § 101, at 4 (2017); *see also* Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980) ("[S]ubject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the useful Arts' with all that means for the social and economic benefits . . . .").

419. Hadad, *supra* note 405, at 3.

420. *See* AM. INTELL. PROP. L. ASS'N, *supra* note 418, at 2, 4; SECTION 101 LEGIS. TASK FORCE, *supra* note 418, at 1–2.

421. *See* SECTION 101 LEGIS. TASK FORCE, *supra* note 418, at 1–2.

422. *Id.* at 1.

423. *See id.*; *see also* AM. INTELL. PROP. L. ASS'N, *supra* note 418, at 4.

Eliminating broad judicial exceptions to patent eligibility and creating narrower categories of excluded subject matter would reduce the uncertainty inventors and developers face when seeking to protect their investment into working animals. The proposed Patent Eligibility Restoration Act would replace broad judicial exceptions so that those seeking to patent working animals would only need to demonstrate that the animal, or the tools and methods used in training and working the animal, are not processes that "occur[] in nature wholly independent of, and prior to, any human activity" or "unmodified natural material, as that material exists in nature" to be eligible subject matter.[424] Arguably, the act of training the working animals to perform tasks would fall outside of this definition and meet the patent eligibility requirements of this proposed legislation because the working animals are otherwise not capable of performing the trained tasks "wholly independent of, and prior to, any human activity." For example, an animal would not naturally identify and alert its handler of explosive compounds or diseased tissue without prior training by a human. This overhaul of the subject matter eligibility requirements could increase the incentive for further innovation and investment into working animals by clarifying how their inventions can meet eligibility requirements, and by providing practitioners with much-needed guidance on how to successfully prepare and prosecute patent applications related to working animals at the USPTO.

Unfortunately, after many attempts, reform of the patent eligibility laws has yet to happen. In 2018, IPO and AIPLA joined forces and released a joint proposal for amending patent eligibility that was adopted by many other significant bar associations, and in 2019, a bipartisan, bicameral group of Congress members released a draft outline of Section 101 reforms responsive to the concerns addressed by the joint proposal.[425] After three hearings on the draft bill, the "vast majority" of the diverse group of witnesses "agreed that our current

424. Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. § 3(a)(2) (2023).

425. The draft bill defined sole exceptions to patent eligibility as "fundamental scientific principles; products that exist solely and exclusively in nature; pure mathematical formulas; economic or commercial principles; and mental activities." Michael Rosen, *Patent Eligibility Reform Comes Roaring Back*, AM. ENTER. INST.: AEIDEAS (Aug. 8, 2022), https://www.aei.org/technology-and-innovation/patent-eligibility-reform-comes-roaring-back/. Although this would have a similar effect to the AIPLA-IPO proposal in eliminating judicial exceptions to eligibility, the draft bill maintained more categories of ineligible concepts than earlier proposals. *See id.*

eligibility standard is unworkable and having a negative impact on research, development, and innovation across all sectors."[426]

In 2019, the USPTO issued revised guidance to reduce uncertainty and confusion after examiners struggled to apply the Supreme Court's current test for subject matter eligibility—but absent legislative action, USPTO "guidance is constrained by the . . . Court's jurisprudence."[427] Bipartisan support for patent eligibility reform has continued to grow, and Senator Tillis later introduced the Patent Eligibility Restoration Act of 2022.[428] Although Senator Tillis's bill failed to gain enough Congressional support for any legislative action in 2022, or in 2023 and 2024 upon reintroduction, the widespread consensus remains that patent eligibility reform is essential.[429] In fact, "all 12 judges of the United States Court of Appeals for the Federal Circuit have lamented the state of the law."[430] Patent eligibility reform could improve the landscape for innovation across a variety of industries, including those related to working animals, and bring greater investment into research and development in these industries.

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426. *Special Feature: Q&A with Sen. Thom Tillis*, INTELL. PROP. OWNERS ASS'N (Jan. 29, 2020), https://ipo.org/index.php/exclusive-qa-with-sen-thom-tillis/. The draft amendment was opposed by some stakeholders with concerns about abrogating patent eligibility precedent completely. *See, e.g.*, *The State of Patent Eligibility in America: Part II: Hearing on Section 101 Legislation Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 116th Cong. 2–5 (2019) (statement of Jeff Francer, Senior Vice President and General Counsel, Association for Accessible Medicines).

427. *See* Hadad, *supra* note 405, at 6.

428. This bill maintained the overall framework of Senator Tillis's earlier draft but had a more extensive and specific list of categories excluded from patent eligibility to resolve "legitimate concerns over the patenting of mere ideas, the mere discovery of what already exists in nature, and social and cultural content . . . ." *See* Press Release, Sen. Thom Tillis, Tillis Introduces Landmark Legislation to Restore American Innovation (Aug. 3, 2022), https://www.tillis.senate.gov/2022/8/tillis-introduces-landmark-legislation-to-restore-american-innovation.

429. *See* Press Release, Sen. Thom Tillis, Tillis, Coons Introduce Landmark Legislation to Restore American Innovation (June 22, 2023), https://www.tillis.senate.gov/2023/6/tillis-coons-introduce-landmark-legislation-to-restore-american-innovation; Press Release, Sen. Kevin Killey, Representatives Kiley, Peters Introduce the Patent Eligibility Restoration Act (Sept. 06, 2024), https://kiley.house.gov/posts/representatives-kiley-peters-introduce-the-patent-eligibility-restoration-act.

430. Press Release, Sen. Thom Tillis, Tillis, Coons Introduce Landmark Legislation to Restore American Innovation (June 22, 2023), https://www.tillis.senate.gov/2023/6/tillis-coons-introduce-landmark-legislation-to-restore-american-innovation.

B. Special Legislation for Animal Patents

Given the potential for working animals to revolutionize various technologies, Congress should act to explicitly bring animal-based inventions into the framework of the Patent Act. This could be done most directly by amending the Patent Act to include a new type of patent—an "animal patent"—specifically for protecting animal-based inventions. Like plant patents, which are a special type of patent created by the Plant Patent Act of 1930 for protecting new plant varieties, a clear pathway to procuring animal patents would ease the burden on developers by allowing them to seek patent protection for their innovations with more clarity regarding how to meet the written description, enablement, and patent eligible subject matter requirements for animal-based inventions.

Historically, courts have been reluctant to afford patent protection to living things, as discussed in Part II.A, *supra*. While the language of Section 101 does not necessarily demand that courts exclude living things from patent eligibility, the legislative history of the general patent laws does not provide any insight into Congress's intent in this regard.[431] Although the first Congress may not have considered on the record how the patent laws would apply to living things, legislation had been proposed to afford patent protection to one type of living thing—plants—as early as 1892.[432] Patenting a naturally occurring, living thing presents unique obstacles that had not previously been addressed by patent law. The belief that plants were products of nature even when altered by humans meant that new human-made varieties

431. *See Implications of the Plant Patent Act for the Patentability of Microorganisms*, 39 MD. L. REV. 376, 377–78 (1979).

432. *See* A Bill for the Advancement of the Science of Agriculture, H.R. 5435, 52d Cong. (1892). Supporters of the plant patent legislation proposed in 1892 included figures like Thomas Edison, and a number of different bills proposing patent legislation covering plants were introduced in the years following, but it still took decades for plant breeders to gain enough momentum to pursue plant patent legislation in earnest. *See, e.g.*, A Bill to Amend the Laws of the United States Relating to Patents in the Interest of the Originators of Horticultural Products, H.R. 18851, 59th Cong. (1906); A Bill to Constitute United States Relating to Patents Effect of Montana and the Originators of Horticultural Products, S. 59, 60th Cong. (1907); A Bill to Amend the Laws of the United States Relating to Patents in the Interest of the Originators of Horticultural Products, H.R. 21951, 60th Cong. (1908); A Bill to Amend the Laws of the United States Relating to Patents in the Interest of the Originators of Horticultural Products, H.R. 24010, 61st Cong. (1910); Imazio Nursery, Inc. v. Greenhouses, 69 F.3d 1560, 1562 (Fed. Cir. 1995); *see also* Cary Fowler, *The Plant Patent Act of 1930: A Sociological History of Its Creation*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 621 (2000).

of plants were not considered patentable subject matter.[433] The written description requirement of the Patent Act posed another problem: describing a plant, or any other living thing, with adequate detail to enable someone skilled in the art to reproduce it.[434] Furthermore, because seed-propagated plants may not always reproduce identical plants every time (i.e., true-to-type), some argued that plants simply were not the kind of uniform, stable material suitable for patent protection.[435]

Animal-based patents face similar issues regarding the subject matter, written description, and enablement requirements. Sponsors of animal-based patents face opposition arguing that such patents are both legally and morally problematic.[436] Furthermore, natural variances from one individual animal to the next could make it extremely difficult to adequately describe the methods for developing a working animal capable of performing the desired tasks or functions. Additionally, the working method may need to be replicable with either different animals, or the same animal over time under the same conditions to satisfy the enablement requirements.

The Plant Patent Act of 1930 was the first federal patent legislation passed by Congress to address living things and it was also the first legislation to afford agriculture and plant breeders some of the same incentives and protections enjoyed by other industries under

433. *See Implications of the Plant Patent Act for the Patentability of Microorganisms*, *supra* note 431, at 382.

434. *See Imazio Nursery*, 69 F.3d at 1563.

435. At the time, most thought that seed-propagated plants could not be reliably reproduced true-to-type. *See* Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980) ("As the Government acknowledges, sexually reproduced plants were not included under the 1930 Act because new varieties could not be reproduced true-to-type through seedlings. By 1970, however, it was generally recognized that true-to-type reproduction was possible and that plant patent protection was therefore appropriate. The 1970 Act extended that protection." (internal citations omitted)). However, advancements in plant breeding have since proven seed-propagated plants can be reproduced true-to-type. *See* OFF. OF TECH. ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE: SPECIAL REPORT 70–71 (U.S. Gov't Printing Off. 1989).

436. According to one interest group that has successfully challenged two animal patents issued by the USPTO, they hope their opposition efforts will "help bring attention to the fact that animal patents are neither legally valid nor morally acceptable, and will hopefully bring an end to a system that treats animals as if they were human inventions." *Our Work*, AM. ANTI-VIVISECTION SOC'Y, https://aavs.org/our-work/campaigns/animal-patents/ (last visited Feb. 13, 2024). Patents on working methods for training working animals are generally not the focus of this kind of opposition, which is concerned more with patents on the animals themselves or issues related to genetic modifications.

patent law.[437] Extending patent law in this manner first required the acknowledgment that selective breeding and cultivation of new plant varieties are sufficiently "inventive" to fall within Congress's constitutional power to grant exclusive rights to inventors.[438] The Plant Patent Act amended the Patent Act to include "the work of the plant breeder 'in aid of nature'" as patentable subject matter.[439] It also relaxed the written description requirement for plant patents to "a description . . . as complete as is reasonably possible," making it more feasible for a plant to meet the requirement using traditional botanical descriptions.[440] The Plant Patent Act describes plant patents as available to "whoever invents or discovers and asexually reproduces any distinct and new variety of plant . . . ."[441] It also defines the different kinds of plants that could be eligible under the new amendment, notably, excluding plants "found in an uncultivated state . . . ."[442]

Animal-specific patent legislation, like the plant-specific patent legislation of the Plant Patent Act, could provide guidance as to what requirements must be met for animal-based inventions to be eligible for patent protections and greater certainty for developers seeking to protect their investments. This animal-specific legislation could clarify what degree of human intervention is necessary to take the animal

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437. *See Implications of the Plant Patent Act for the Patentability of Microorganisms*, *supra* note 431, at 385. In 1952, the Patent Act was again amended to separate out the plant-related patent provisions from the general patent provisions in a new chapter. *See* MPEP, *supra* note 104, § 1601. The 1952 Patent Act also clarified the scope of patent eligibility for plants, as did a subsequent amendment in 1954. *See id.* Sexually reproduced plants gained intellectual property protection in 1970 when the Plant Variety Protection Act was enacted. Plant variety protection certificates are weaker than plant or general utility patents because there are more exemptions that allow specific use of protected varieties by researchers and farmers, but it does prevent others from commercialized use of the variety. *See* Philip Pardey et al., *The Evolving Landscape of Plant Varietal Rights in the United States, 1930-2008*, 31 NATURE BIOTECHNOLOGY 25, 25 (2013); OFF. OF TECH. ASSESSMENT, *supra* note 435, at 73–74.

438. *Implications of the Plant Patent Act for the Patentability of Microorganisms*, *supra* note 431, at 385–86.

439. MPEP, *supra* note 104, § 1601 (quoting S. REP. NO. 314, at 6–8 (1930)).

440. *Id.* (quoting 35 U.S.C. § 162); *see* OFF. OF TECH. ASSESSMENT, *supra* note 435, at 70–71.

441. 35 U.S.C. § 161. Sexually reproduced plants gained intellectual property protection in 1970 when the Plant Variety Protection Act was enacted. Plant variety protection certificates are weaker than plant or general utility patents because there are more exemptions that allow specific use of protected varieties by researchers and farmers, but it does prevent others from commercialized use of the variety. S*ee also* Pardey et al., *supra* note 437, at 25; *see* OFF. OF TECH. ASSESSMENT, *supra* note 435, at 70.

442. 35 U.S.C. § 161.

itself out of the "naturally occurring" exclusion or could explicitly limit the application of this judicial exception to animal patents. The legislation could also clarify the difference between utilizing an animal's natural abilities, which is not patentable, and the development of new training and working methods and tools that allow animals to perform tasks that they would not be able to absent human intervention.[443] More explicit guidance from the legislature or the USPTO could provide patent practitioners with a clear path to patent methods directed to training or employing working animals by more clearly defining what constitutes "an inventive concept" that goes beyond the animal's natural abilities. A relaxed or altered written description requirement would also make it more feasible to sufficiently describe a method for training an animal to perform certain tasks or functions. Subject matter-specific patent legislation could eliminate, or at least reduce, many of the current patentability issues facing working animals, and could go a long way to drive innovation in this area.

Although there are now plant-specific patent protections, plants and other living things are eligible for utility patent protection if they can meet the statute's requirements.[444] The Supreme Court confirmed this in *Diamond vs. Chakrabarty* when they stated that "anything under the sun that is made by man" is patentable and upheld the first patent on a newly created bacterium designed to digest crude oil in spills.[445] Since then, there have been more findings of patent eligibility for living things. In *Ex Parte Allen*, the Board of Patent Appeals decided that polyploid oysters that were non-naturally occurring without human intervention were manufactures or compositions of matter and fell within Section 101 eligibility.[446] A patent has also been secured for a method of creating genetically-modified salmon with unique

443. *See supra* Part II.A.1.

444. *See In re* Bergy, 596 F.2d 952, 973–84 (C.C.P.A. 1979); *see also 1601 Introduction: The Act, Scope, Type of Plants Covered* [R-11.2013], USPTO, https://www.uspto.gov/web/offices/pac/mpep/s1601.html (last visited Jan. 1, 2024); *see also* OFF. OF TECH. ASSESSMENT, *supra* note 435, at 370–73.

445. *Implications of Plant Patent Act*, *supra* note 431, at 377 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

446. *Ex parte* Allen, No. 647,963 (B.P.A.I. 1987). Allen's patent was rejected on obviousness grounds because a paper had already been published describing a method to induce polyploidy in oysters that Allen was a co-author of, and "one of ordinary skill in the art would have a reasonable expectation that the Stanley et al. method would be successful in inducing polyploidy in Crassostrea gigas oysters based on the success by Stanley et al. with Crassostrea virginica oysters and the recommendation by Stanley et al. to utilize the method with cultured oysters." *Id.*

characteristics for farming.[447] By 2011, over 660 patents had been issued in the United States for animals, including patents directed to transgenic mice, pigs, and dogs.[448]

Although living things are potentially eligible for patent protection, some U.S. industries today face a similar competitive disadvantage on the global stage as plant breeders did before plant-specific patent legislation was enacted. Major economic powers like China and the European Union have more expansive protections in areas like microbiology, biotechnology, medical diagnostics, and computer software.[449] Despite the fact that many inventions in these areas could fall under Section 101 eligibility in theory, the current landscape of patent law discourages inventors from pursuing development and disincentivizes investment into research in areas where legal protections are questionable.[450] The broad judicial application of the law of nature and natural phenomena exceptions remains a problem for the patentability of living things, including working animals, and could lead to the United States falling behind in critical areas like biotechnology and medical diagnostics.[451]

Working animals show enormous potential in a variety of fields, including detecting diseases, explosives, and contraband.[452] However, training and maintaining working animals to accomplish these tasks requires significant resources. The difficulty of obtaining intellectual property protections for working animals in the United States may stunt domestic investment and research in this area unless changes are made to the current landscape of patent law. Subject matter-specific patent legislation could significantly mitigate many of the current patentability issues facing animal-based inventions, fostering innovation in this area.

CONCLUSION

Throughout history, humans have leveraged the abilities of animals for various tasks, such as hunting, security, labor, and transportation. Today, working animals hold tremendous potential to revolutionize numerous industries, offering invaluable assistance in aiding

447. *See* Transgenic Salmonid Fish Expressing Exogenous Salmonid Growth Hormone, U.S. Patent No. 5,545,808 (filed Mar. 10, 1994).

448. *See* Dustin Mauck, *Animal Patents*, ANIMAL L. SECTION (June 7, 2011), https://www.animallawsection.org/animal-patents/.

449. *See* Hadad, *supra* note 405, at 9.

450. *See id.*

451. *Id*.

452. *See supra* Part I.

persons with disabilities, detecting diseases, identifying hazardous substances, and a range of other tasks. However, despite their clear benefits over conventional techniques, the patent landscape for working animals remains uncertain and challenging.

The introduction of animal-based inventions into the patent realm poses unique challenges, from subject matter eligibility concerns to difficulties in adequately describing and reproducing living organisms. While the value of working animals is clear, the current patent framework fails to provide adequate protections for these innovative endeavors. As a result, developers may be deterred from investing in the research, development, and commercialization of working animals, hindering progress and innovation in this critical area.

In light of these challenges, this Article has explored potential pitfalls and offered practical advice for patenting working animals and related training techniques. Notably, this Article has developed a framework identifying seven overarching categories to describe the various types of patent claims covering working animals and related training. This framework primarily categorizes inventions based on whether they are directed to training or working methods, and whether novel or conventional tools are used in these methods. By categorizing various aspects of training and developing working animals in this framework, we have identified areas ripe for patent protection and those facing obstacles at the USPTO.

Furthermore, we have proposed solutions to promote innovation and investment in working animals. Reforming patent eligibility laws to clarify the scope of patentable subject matter and enacting special legislation for animal patents could provide much-needed clarity and certainty for developers seeking to protect their investments. These legislative efforts would not only incentivize innovation in the field of working animals but also drive progress in various industries reliant on their abilities.

In conclusion, the potential of working animals to transform numerous sectors is undisputed. However, realizing this potential requires a supportive legal framework that fosters innovation and provides adequate protections for developers. By addressing the challenges facing patenting of working animals, we can unlock new possibilities and harness the full potential of these remarkable creatures for the betterment of society.