# The Role of Intellectual Property Rights Protection in Veterinary Digital Pathology

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**Abstract**

Using light microscopy to describe the microarchitecture of normal and diseased tissues has changed very little since the middle of the ١٩th century. While the premise of histologic analysis remains intact, our relationship with the microscope is changing dramatically. Veterinary digital pathology offers new forms of visualization, and delivery of images is facilitated in unprecedented ways. This new technology can untether us entirely from our light microscopes, with many pathologists already performing their jobs using virtual microscopy. Several veterinary colleges have integrated virtual microscopy in their curriculum, and some diagnostic histopathology labs are switching to virtual microscopy as their main tool for the assessment of histologic specimens. While some aspects, such as whole-slide imaging for archiving, consulting, and teaching, have gained broader acceptance, other facets such as quantitative tissue image analysis and artificial intelligence–based assessments are still met with some reservations. While most vendors in this space have focused on diagnostic applications, that is, viewing one or few slides at a time, some are developing solutions tailored more specifically to the various aspects of veterinary pathology including updated diagnostic, discovery, and research applications.

**Keywords**

Veterinary digital pathology, whole-slide imaging, image analysis, artificial intelligence.

## Introduction

Veterinary digital pathology refers to the application of digital imaging technology and computational methods in the field of veterinary pathology. Veterinary pathology involves the study and diagnosis of diseases in animals and poultry. The diseases mainly caused by bacteria as *E.Coli* and Salmonella (Soufy et al., ٢٠١٦: Abu El Hammed et al., ٢٠٢٢) or virus (Fotouh et al., ٢٠٢٤) by examining tissue samples and cells under a microscope. Digital pathology involves the digitization of pathology slides, where high-resolution images of tissue samples are captured using specialized scanners. These digital images can then be stored, analyzed, and shared electronically. Veterinary digital pathology utilizes these digital images to aid in the diagnosis, research, and education related to animal and poultry diseases (Colling et al., ٢٠١٩).

The main purpose and benefits of veterinary digital pathology is to enhance the efficiency, accuracy, and accessibility of pathology services in veterinary medicine including improved diagnostic accuracy, faster turnaround time for results, enhanced data management, and the potential for large-scale data analysis for epidemiological studies and research (Ferreira et al., ٢٠١٩).

By digitizing pathology slides, veterinarians and pathologists can remotely access and review images, collaborate with colleagues, and consult with experts from different locations (Bertram and Klopfleisch ٢٠١٧). It also enables the integration of computer-aided analysis and artificial intelligence algorithms to assist in the interpretation and diagnosis of animal diseases.

Veterinary digital pathology, which encompasses the digitization of pathology slides and the application of computational methods in diagnosing animal and poultry diseases, often involves substantial investments in research and development (Jones-Hall et al., ٢٠٢١).

Intellectual Property Rights (IPRs) protection becomes crucial for entities involved in creating and commercializing innovations in this field. IPRs can apply to various aspects of veterinary digital pathology, including hardware and software components of digital imaging systems, image analysis algorithms, data management and storage methodologies, and even the digitized pathology slides themselves. Obtaining patents, copyrights, or trademarks enables developers and manufacturers to protect their intellectual property, preventing unauthorized use, reproduction, or commercial exploitation.

Artificial intelligence (AI) has the potential to revolutionize veterinary digital pathology by assisting veterinarians in diagnosing diseases, analyzing tissue samples, and improving overall healthcare outcomes for animals and poultry. Some specific applications of AI in veterinary digital pathology as; automated image analysis, disease identification, tumor detection and grading, digital pathology workflow optimization and research and data mining (Bouchemla et al., ٢٠٢٣). It's important to note that while AI has shown promising results in veterinary digital pathology, it should be considered as a supportive tool rather than a replacement for veterinary expertise.

Veterinarians will continue to play a critical role in interpreting AI-generated results and making informed decisions for the well-being of animals. Also, AI can serve as an image analysis tool to aid the expert in their work. The neural networks of deep learning AI models can today be taught to identify, quantify, measure, and gather other data from microscopic images. This frees up valuable resources, as a big part of analyzing samples can now reliably be computerized (Zuraw and Aeffner ٢٠٢٢). Software platforms allow pathologists to effectively examine microscopic slides with the help of Whole Slide Imaging (WSI), and ready-to-use AI tools for image analysis.

***Problem of the Study***

These are some potential problems or challenges that could be explored in this study:

١- Access to data in which veterinary digital pathology relies on access to large and diverse datasets of annotated pathology images for training AI algorithms. However, data availability can be limited due to data privacy concerns, proprietary datasets, or lack of sharing mechanisms.

٢- Data annotation and labeling through high-quality annotations and labels are crucial for training AI algorithms effectively. The process of annotating pathology images requires expertise and effort. IPRs protection may create challenges when it comes to sharing annotated datasets, as there may be restrictions on the use and distribution of these labeled datasets.

٣- Algorithm Development and Patenting that AI algorithms and techniques used in veterinary digital pathology can be subject to patent protection. While patents encourage innovation and investment, they can also create barriers to entry for other researchers and developers.

***Importance of the Study***

Studying the role of IPRs protection in veterinary digital pathology provides insights into the complex interplay between intellectual property rights, innovation, access to technology, collaboration, and ethical considerations. Such research is valuable for shaping policies, fostering innovation, and ensuring that advancements in AI technologies contribute to improved veterinary healthcare outcomes.

**Aim of the Study**

١. Assess the impact of IPRs protection on veterinary digital

pathology. This involves understanding how intellectual property rights, such as patents, copyrights, and trade secrets, influence the development, adoption, and accessibility of AI technologies in veterinary medicine.

٢. Identify barriers and incentives created by IPRs protection in veterinary digital pathology. This includes exploring how intellectual property rights affect data sharing, collaboration, innovation, and market competition.

٣. Evaluate the impact of IPRs protection on the accessibility and affordability of AI-based veterinary digital pathology solutions. It examines whether IPRs create limitations or facilitate the availability of these technologies.

**Study Questions**

١. How does IPRs protection, such as patents and copyrights, impact the development and adoption of AI technologies in veterinary digital pathology?

٢. What are the barriers and incentives created by IPRs protection in veterinary digital pathology, and how do they influence data sharing, collaboration, and innovation in the field?

٣. What is the impact of IPRs protection on the accessibility and affordability of AI-based veterinary digital pathology solutions?

**Study Hypothesis**

*H١:* there is a positive relationship between protection of IPRs and development of veterinary digital pathology.

## *Methodology of the Study*

An inductive approach to studying the role of IPRs protection on veterinary digital pathology involves gathering empirical data and observations to develop insights and theories. It focuses on exploring specific cases, analyzing patterns, and generating hypotheses based on the information collected. By employing an inductive approach, researchers can gain a nuanced understanding of the role of IPRs protection on veterinary digital pathology from the ground up. This approach allows for the exploration of emerging trends, identification of novel insights, and the development of theories that can contribute to the knowledge and understanding of the topic.

In the context of the role of IPR protection on veterinary digital pathology, an inductive study may involve the following steps:

١. Data Collection: we will collect qualitative or quantitative data related to IPR protection and its impact on veterinary digital pathology. This may include interviews, surveys, case studies, patent analysis, literature review, and analysis of policies and regulations.

٢. Data Analysis: The collected data is analyzed to identify patterns, themes, and recurring trends. We may use coding techniques, thematic analysis, or other qualitative and quantitative analysis methods to identify key factors and relationships.

٣. Hypothesis Generation: Based on the identified patterns and observations, we will develop hypotheses or tentative explanations to explain the role of IPRs protection on veterinary digital pathology. These hypotheses are derived from the data and serve as starting points for further investigation

## *Study plan*

This study analyses the phenomena at hand as follows:

**Traditional and digital veterinary pathology**

Light microscopy has played a vital role in many scientific discoveries and has provided major advances in all biological fields. Traditionally, pathologists have used the light microscope to assess tissue architecture (normal and diseased) the major advantage being the ability to study cells in situ (Jones-Hall et al., ٢٠٢١).

However, with the integration of digital pathology into the workflow of veterinary laboratories, curricula, and research, we are able to move beyond the light microscope to the use of the virtual microscope (VM). Digital pathology (DP), at its most basic level, only requires Internet and computer access to visualize microscopic images after glass slides have been scanned (Jones-Hall et al., ٢٠٢١).. Software to manage and analyze the data that are generated from the digitized glass slides can also be added to the workflow, increasing the capability of the digital platform.

However, the first step in both the traditional and DP workflow is to properly process a tissue sample and make a high-quality glass slide (Figure ١).The next step in the DP workflow requires a slide scanner to make a digital version of the glass slide, referred to as a whole slide image (WSI). Software (most often provided as an accompaniment to the scanner) is then used to view and/ or analyze the digital slide. The viewing of digital images has progressed to the point that resolution of a slide on a computer screen is a remarkably close equivalent to that viewed with a light microscope (Jones-Hall ٢٠٢١).

The starting point of the increasing integration of DP was the development of fast and reliable slide scanners, which are able to

digitalize entire glass slides. These whole-slide images (WSI) can be viewed, evaluated, and stored potentially forever with constant quality. Viewing of a digital WSI in the sense of DP is, however, not restricted to a static image but includes options to move horizontally (x- and y-axis), to zoom in and out, and sometimes even to fine focus in the slide (z-axis) comparable with light microscopy (LM) (Jones-Hall et al., ٢٠٢١)..

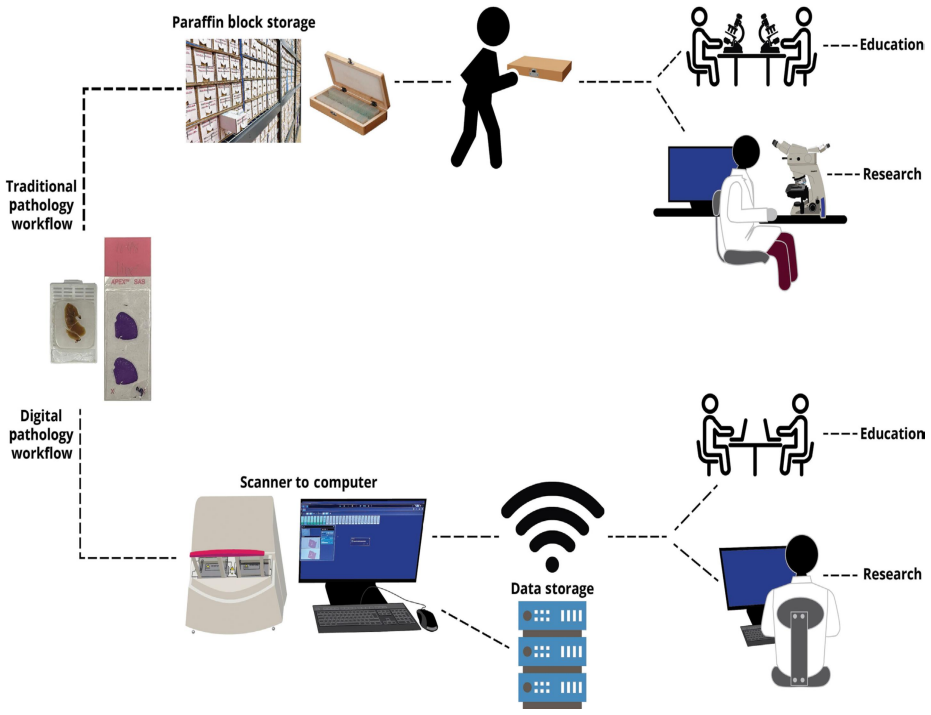


**Figure ١: Comparison of the traditional pathology versus the digital pathology workflow *Note:* The traditional (top pathway) and digital (bottom pathway) workflows both start with making a high-quality glass slide.**

## Digitization, Digitalization, and Digital Transformation

The digital pathology as an application of the process of digital transformation. This process entails ٣ main parts: digitization, digitalization, and the transformation itself. In digitization, information that was previously only available in an analog format is converted into

a digital configuration. In pathology, digitization refers to the process of making a digital copy of a glass slide, for example, through using whole-slide scanning technology (Gartner ٢٠٢١). Digitalization has a broader meaning and refers to integrating and leveraging of digital technologies in everyday life and business. In pathology, an example of digitalization is leveraging a digital pathology system for primary diagnosis in a diagnostic laboratory. Lastly, digital transformation refers to the effect digitalization has on an organization implementing it or on the people using it. Often this results in a significant change of a business model. In veterinary pathology, digital transformation has taken place at diagnostic companies that have established a digital pathology workflow for their entire enterprise (Bloomberg ٢٠٢٠).

**Potential benefits of integrating AI into veterinary digital pathology**

١. Disease diagnosis for companion, livestock and zoo animals. This includes biopsies to determine the ongoing disease, and necropsies in order to determine the cause of death. Disease diagnosis can be performed for:

a. Private sector - e.g. companion or sport animal owners, who need to diagnose their animals' disease for treatment or breeding.

b. Public health sector - where it serves the purpose of improving human health by e.g. improving the agriculture and addressing and preventing zoonotic diseases like rabies and food-borne diseases. In the USA veterinary pathologists in this sector work for such government regulatory agencies as the Food and Drug Administration, US Department of Agriculture, Centers for Disease Control and Prevention, and Environmental Protection Agency (Zuraw and Aeffner ٢٠٢٢).

٢. Drug development support which includes toxicological pathology. In the development of every drug approved for human treatment, there is a pre-clinical and a clinical phase. During the pre-clinical phase the drugs are being tested on animals and during the clinical phase, on people. Veterinary pathologists are crucial to the pre-clinical phase of

drug development, where they evaluate the tissue of laboratory animals in pharmaceutical studies for signs of toxicity caused by the drugs the animal were given; ٩٩٪ of the drug candidates from pre-clinical studies never make it to the clinical phase. The job of a veterinary pathologist is to identify the safe ١٪ which can be taken further.

٣- Academia

Adoption and availability of digital pathology varies widely between academic institutions. While some veterinary pathology training programs incorporated digital slides review of training sets and whole-slide scanning capabilities into their curriculum over a decade ago, other institutions may still not have in-house access to these resources. When available, whole-slide images are mainly utilized for teaching, collaborations/ consulting, and research (Zuraw and Aeffner ٢٠٢٢). However, most academic veterinary pathology institutions have not adopted a fully digital workflow for their routine diagnostic services. In education, many institutions now teach the histology and histopathology curriculum via access to digitized slides (Bertram and Klopfleisch ٢٠١٧). This has the advantage that all students review the same specimen, they have continuous access via an online repository, and instructors can include image annotations to highlight specific features for teaching.

٤. Research**,** which can be performed in academic institutions, government organizations like the National Institute of Health as well as in pharmaceutical, biotech and chemical companies (Zuraw and Aeffner ٢٠٢٢).

٥. Minimizing subjectivity: Analysis results may vary between pathologists. Even the same pathologist can produce different results depending on the time of the day or the level of stress. The same can be true for histology technicians who develop different staining protocols. The characteristics of a staining may vary from batch to batch and from person to person. To minimize the subjectivity and reduce the error rate,

implementation of digital pathology is imperative. The information contained in tissue, like the number of positive cells in immunohistochemistry can be quantified with computer algorithms if the slides are digitized, which significantly reduces the inter- and intrapersonal variability of semi-quantitative scoring (figure ٢). Analyzing the pathology images with standardized algorithms can make the discipline of pathology more objective and increase the accuracy.

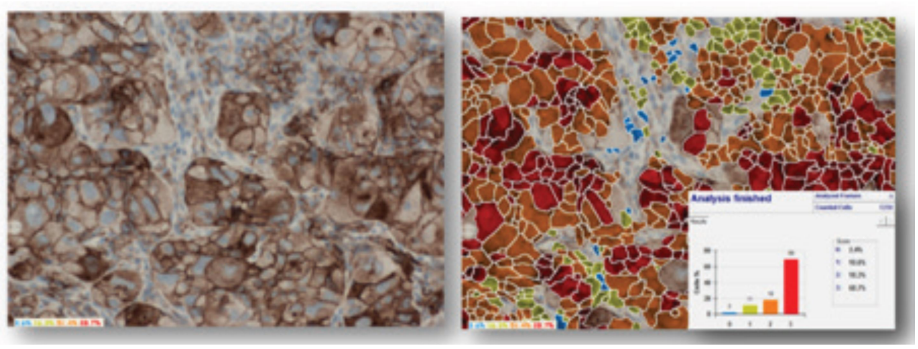


**Figure ٢: IHC slide, before and after analysis. Automatic cell classification with statistical analysis on thousands of cells with a unique Bright field imaging & analysis system for a variety of histopathology needs, including quantitative IHC Scoring and Whole Slide Imaging of H&E/IHC samples.**

## Machine Learning and Veterinary digital Pathology

During the recent course of strategic planning conducted by the American College of Veterinary Pathologists (ACVP), a landscape assessment informed by member and external stakeholder surveys revealed that computer technology and molecular medicine are significant disruptive forces for the future of veterinary pathology. Yet artificial intelligence and advanced molecular tools are driving the movement toward precision medicine, which tailors treatment to the individual characteristics of patients, both human and animal, based on classification into subpopulations that differ in disease susceptibility,

pathogenesis, morphology, response to treatment, and/or prognostic outcomes (La Perle ٢٠١٩).

In deep learning, a subset of machine learning, deep neural networks are developed so computers can map information and predict classification of new inputs. Even though computer algorithms can extrapolate patterns and expose correlations that suggest causality, they must be trained and are unable to identify causal links. Once machine learning models are trained, they work in tandem with pathologists to provide improved diagnostic results with increased efficiency and accuracy (Djuric et al., ٢٠١٧)

However, the resultant predictive data provided by machines through deep neural networks are only as valuable as the input data they receive. The review herein by (Awaysheh et al.,٢٠١٩) of variables that affect machine learning processes is widely applicable to veterinary pathologists, especially those dipping their toes in the machine learning pond.

Feature selection should invariably involve a pathologist at some point; pathologists must consider the number of features for machine learning just as they contemplate severity levels when creating or adapting grading schemes, because more is not always better. Performing annotations at lower magnifications can also have variable effects on the prevalence of false positives or false negatives. In addition, variability in routine hematoxylin and eosin staining as well as immunohistochemical staining can affect machine learning through incorrect classifications. Pathologists are, understandably, more sensitive to manipulations in color, whereas imaging scientists are more sensitive to image noise, which can be introduced at the time of image acquisition or transmission and can undergo preprocessing (Platisˇa et al., ٢٠١٧)

**IPRs protection and veterinary digital pathology**

Patents represent a form of intellectual property. Understanding the patent system is crucial for the protection of intellectual property and to help overcome related infringements. Patent landscapes have in fact been successfully used to identify and study-specific scientific and technological trends. A similar evaluation of digital pathology patents may help summarize emerging technology trends, identify technology gaps, and possibly provide some insight into the future direction of this field. Colling et al., ٢٠١٩.

Niazi et al., ٢٠١٩ stated that the integration of digital pathology (DP) with artificial intelligence (AI) enables faster, more accurate, and thorough diagnoses, leading to more precise personalized treatment. As technology is advancing rapidly, it is critical to understand the current state of AI

applications in DP. Therefore, a patent analysis of AI in DP is required to assess the application and publication trends, major assignees, and leaders in the field.

Inventions in digital pathology can be protected using either patents or trade secrets, but each of these provide different advantages and disadvantages. A fundamental difference between these two is that a patent relies on mandatory public disclosure whereas a trade secret relies on guarded secrecy from the public. From the perspective of public policy, a patent is granted with exclusive rights for a limited time when an inventor provides sufficient disclosure of their invention which can benefit the public. Patent protection lasts ٢٠ years from the filing and trade secret protection can be perpetual, if one is able to keep its secrecy. However, trade secret protection is lost if someone reverse engineers the invention whereas a patented invention is protected against reverse engineering. Thus, it is important to carefully consider which type of IPRs protection is optimal for an invention Aeffner et al., (٢٠١٩). Hence, it is important for inventors in this field to understand the patent system that enables them to protect their IPRs. The most requested patents in digital pathology are utility and design patents. For digital pathology most patents requested or granted can be broadly classified into the following technological categories: digital scanners, pathology consultation/diagnostic networks, digital image analysis, and computer-aided diagnosis tools Ferreira et al., (٢٠١٩).

**Ethical considerations associated with IPRs protection in veterinary digital pathology**

The ethical considerations associated with Intellectual Property Rights (IPRs) protection in veterinary digital pathology in the era of artificial intelligence (AI) revolve around balancing the rights of creators and innovators with the broader societal interests, including access to knowledge, collaboration, and animal welfare (Chauhan and Gullapalli). Here are some key ethical considerations:

١. Access to Knowledge: IPRs protection, particularly through patents and copyrights, may restrict access to certain technologies, algorithms, or data associated with veterinary digital pathology. This can hinder the dissemination of knowledge and impede the progress of research and development. Striking a balance between protecting intellectual property and ensuring access to knowledge is crucial for the advancement of veterinary medicine and the welfare of animals.

٢. Collaboration and Innovation: Collaboration and sharing of information are essential for scientific and technological progress. Excessive IPR protection may discourage collaboration among researchers, pathologists, and veterinarians. Encouraging open collaboration and the sharing of ideas, data, and methodologies can foster innovation, accelerate advancements, and improve the overall quality of veterinary digital pathology.

٣. Animal Welfare: The primary focus of veterinary medicine is to promote the health and well-being of animals. Ethical considerations arise when IPRs hinder the development or accessibility of veterinary digital pathology technologies that could improve diagnostics, treatment options, or overall animal care. Balancing IPR protection with the ethical responsibility to prioritize animal welfare is crucial in this context.

٤. Fair Use and Fair Access: Fair use provisions in intellectual property laws allow for limited use of copyrighted material without permission, particularly for purposes such as education, research, and criticism. Ensuring that fair use provisions are upheld in the context of veterinary digital pathology can enable researchers, educators, and veterinarians to utilize and build upon existing knowledge and technologies to benefit animal health.

٥. Responsible AI Development: Ethical considerations also arise in the development and deployment of AI algorithms in veterinary digital pathology. AI systems should be developed and validated using diverse and representative datasets to avoid biases and ensure fairness. Transparency and interpretability of AI algorithms are important to understand how decisions are made and to ensure accountability.

٦. Balancing Commercial Interests: IPRs protection is often associated with commercial interests and profit-making. While it is important to incentivize innovation and rewarding creators, striking a balance between commercial interests and the public good is crucial.

Implementing licensing agreements, open-source initiatives, or alternative business models can help ensure that veterinary digital pathology technologies remain accessible and affordable while still protecting the rights of innovators.

**Limitations to veterinary digital pathology**

There are, of course, currently some limitations to digital pathology. There is requirement at the pathologist's end for high-speed internet, the ability to store or download large files and the need for one or more large high-resolution monitors. Additionally, the image resolution may limit the ability to identify some very small structures (e.g. bacterial organisms) and assess tissue structures for refractile/birerefringent qualities. The digital images are by definition strictly two dimensional whereas microscopic evaluations of glass slides allow for focusing in different planes. Inspection of tissues at magnifications greater than ٤٠x requires oil immersion and this cannot be done on scanned slides (Niazi et al., ٢٠١٩).

By nature of their precision and sensitivity, the scanners can also be prone to technical and mechanical malfunction—such as lens contamination with wet coverslip mounting media, which may contribute to scanner downtime and require reverting to the use of glass slides (Jones-Hall et al., ٢٠٢١).

The costs (typically borne by the laboratory) of scanners, technicians, scanner maintenance, digital storage, computer software and

hardware are also significant and may be the limiting factor for some small laboratories. Regardless, this is outweighed by the ability to utilise pathologists working remotely and helps with staff retention.

Veterinary digital pathology also provides the ability to offer second opinions on cases and can be utilised in training pathologists, both locally and remotely. Interesting cases can be flagged and stored in personal files for studies or publication, and experts can be consulted on cases even if they are overseas.

Veterinary digital pathology is here to stay and although there remains some limitations, this utility continues to make great improvements, and has become a routine method used by pathologists around the world.

## Conclusion

Intellectual Property Rights (IPRs) play a vital role in the protection of veterinary digital pathology. While IPRs provide incentives for innovation and protect the rights of creators and innovators, their implementation should be balanced with ethical considerations to ensure broader societal interests, access to knowledge, collaboration, and animal welfare. IPRs protection in veterinary digital pathology can encourage investment in research and development, driving advancements in diagnostic accuracy, treatment effectiveness, and

overall animal care. It incentivizes the creation of new technologies, algorithms, and methodologies that contribute to the improvement of veterinary medicine. However, striking the right balance is crucial. Excessive IPRs protection can hinder the dissemination of knowledge, hinder collaboration, and impede progress. Ethical considerations call for fair access to knowledge, encouraging open collaboration, and fostering innovation through responsible sharing of ideas, data, and methodologies.

Furthermore, animal welfare should be a central consideration. IPRs should not impede the development or accessibility of veterinary digital pathology technologies that can enhance diagnostics, treatment options, and overall animal care. Balancing IPR protection with the ethical responsibility to prioritize animal welfare is essential.

The implementing of the initiatives and measures, the field of veterinary digital pathology aims to standardize practices, ensure quality assurance, and promote consistent and reliable diagnostic outcomes. These efforts contribute to the overall improvement of animal healthcare and support the integration of digital pathology into routine veterinary practice.

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