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主　論　文　の　要　旨

論文題目	Technological Advances in Plant Innovation and the Dynamics of Intellectual Property Law　（植物分野のイノベーションにおける技術的進歩と知的財産法を動かすダイナミクス）
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論　文　内　容　の　要　旨

Increasingly in recent decades national patent laws have undergone significant changes with respect to plant biotechnology in some states as a result of legislative changes and in others due to groundbreaking case law. The potential of plants as a technology platform is increasingly being explored as are the socio-ecological impacts. However, the implications of these changes on existing intellectual property law frameworks remain largely unexplored. Plant variety protection in particular is one of the least studied forms of intellectual property protection. Even though there has been very little direct engagement in plant variety protection and existing literature has largely focused on the geo-political implications, it remains a productive area for exploring the interplay between technological change and the evolution of intellectual property law.

This is because, much uncertainty remains about the possibility to adopt the existing intellectual property frameworks to changed circumstances since the 20th century. This uncertainty raises questions regarding both the limitations of the technology-neutral principles of the patent system and the effectiveness of industry-specific modifications. The advent of new technologies, such as information

technologies and biotechnology in particular, pose significant challenges to existing norms. Unlike mechanical inventions of the 19th century, cutting edge technologies of today are producing intellectual property as their manufactured product and embodying them in the metabolic process of plants. In addition, unlike other innovative technologies that produce self-replicating products such as electronic code replication, human ingenuity alone is not the sole inventor in the context of self-replicating plants.

The notion that plant innovation did not seem to fit the standard instruments of intellectual property (IP) protection initially led to the designing of *sui generis* plant variety protection. Plant Variety Protection (PVP) system and its industry-specific deviations from the patent system have been tailored around the difficulties and contentious aspects of plant innovation. However, today patents are increasingly applied to protect plant genomes, technological tools used in plant development and transformation methods. Furthermore, in some jurisdictions, the scope of patentable subject matter gradually expanded until it covered all plant genetic resources.

In addition, despite the initial rationale to address the limitations of patent protection through PVP, policy makers are considering changes to PVP that will bring it into closer proximity to patent protection. Hence, the question of exclusive, alternative, cumulative protection or overlap of IP rights in plants arises.

To date, existing literature has been mostly restricted to either patent protection or plant variety protection while some provided limited comparisons of the both systems. In light of the increasing patent protection, the interfaces between the two systems merit more detailed treatment. The intellectual merit of this thesis rests in the fact that we know little about technological advances

in plant innovation and the changing aspects of the IP law framework, particularly the interfaces between patent protection and PVP and whether and which system is better suited for plant innovation. This indicates the need for a systematic account that includes both the current trends in IP protection and most recent advances in plant biotechnology as well as simultaneous exploration of the future implications.

In order to capture different dimensions of the issues at hand, this thesis employs combination of methods and triangulation of data that centers on comparative legal analysis. This unique study examines a level of IP law framework for plant innovation never before studied in this regard. The analysis presented in this thesis consists of (a) in depth historical review of technological developments in plant innovation and corresponding developments in IP protection, (b) comparative analysis of existing IP law framework for plant innovation in eleven countries, (c) analysis of trends in patent protection through examination of patent statistics and empirical literature on global patenting activity covering plant innovation and (d) analysis of trends in PVP through WIPO statistics database, (e) in depth review of existing empirical studies on incentive effects of IP protection, (f) comparative analysis of patentability of naturally occurring substances, (g) comparative analysis of farmer's seed saving exemption, (h) comparative analysis of research exemption for plant inventions, (i) analysis of market concentration in plant biotechnology and its implications and (j) a case study on biofuels.

The combination of findings suggests that patents either have become, or are becoming, the main form of protection for plant genetic resources in those jurisdictions that allow the issuance of patents. These results also suggest that increasing patent protection often covering fundamental

research tools may result in higher costs for acquiring knowledge. This in turn may slow the total pace of innovation and likely lock out crucial innovations to which it is difficult to attach an economic value such as agro-biodiversity, since private sector innovate only if their payoffs exceed their R&D costs. Patent protection is not adequately flexible to incorporate the most pertinent aspects, and results in prohibitive conditions for small and medium sized enterprises and the public sector research institutions. This is evident from the high industry concentration in plant biotechnology sector. High levels of industry concentrations erect barriers to the participation of new firms and researchers. In the event of less competition, there is less incentive to further R&D to produce new technology. In fact, higher market concentration is not necessarily associated with higher R&D investment in plant biotechnology.

Comparative review of research exemption for plant related inventions demonstrates that contrary to the common belief in the scientific community, there is no explicit safe harbor from patent infringement for research and experimental use. Thus, the absence of a robust breeder's exemption is commonly referred to as a major influence upon the increasing interest in patent protection for plant innovation as opposed to PVP. In contrast, the 'breeder's exemption' provided in the UPOV model PVP system is not only compulsory, but also very specific and tailored exclusively for the unique necessities of plant development.

In light of the findings of this thesis, it is hard to argue that the existing patent system is serving its purpose to advance R&D. On the other hand, outright exclusion of plant innovation from patentable subject matter would be choosing an easy escape from solving a difficult problem, since the exclusion of subject matter often leads to skillful claim drafting around the eligibility constrictions. This in return leads the focus on the form of the claims rather than the policy considerations. Addressing the concerns

through carefully crafted exceptions such as explicit statutory recognition of a more liberal research exemption may serve balancing the issues to finely tuned conditions. Even though most national patent systems provide for research or experimental use exception, the scope of these exemptions are generally not well defined. This exemption is crucial for plant innovation because public sector still carries out the great majority of the R&D efforts in plant innovation and research heavily depends on access to necessary data or resource inputs. In addition, availability of IP protection can influence the kind of research that is done.

As the comparative analysis of existing IP law framework demonstrates, developed and developing countries not only followed different paths in their legal evolution, but also have contrasting approaches to the IP protection of plant genetic resources. Although the trend in developed countries is not uniform, they follow a parallel approach to the IP protection of plant genetic resources, which is more permissive than the majority of the developing countries. The majority of developing countries on the other hand appear to follow a restrictive approach towards IP protection for plant genetic resources. The comparative review of farm-saved seed exemption points out the importance of tailoring the IP laws according to each state's development goals. It appears that even in a highly harmonized IP system as in UPOV, this review revealed that member states are tailoring the optional farm saved exemption according to their national interests. However, access to the plant genetic resources is governed by complex and evolving web of international agreements. This means fine-tuning national laws cannot be made in isolation from the international systems. In addition, since the adoption of the TRIPs Agreement, several FTAs and EPAs include clauses that require patent protection or ratification and accession of UPOV Convention as the legal framework to protect plant breeders' rights. These agreements further limit the

level of discretion for tailoring national laws.

Overall, the findings of this thesis suggest that PVP system's checks and balances are better suited to plant innovation challenges. This is because the PVP system creates a proper balance between breeders' and farmers' interests. However, unless the hard questions of the overlap between patent protection and PVP are addressed, this less robust form of IP protection will remain as a supplemental form of protection as opposed to an exclusive alternative to patent protection. This in turn reduces the PVP system's social utility because allowing dual protection of the same subject matter tips the balance towards overprotecting to the detriment of spillovers from disclosure. Thus, addressing the problem of co-existence between PVP and patent protection through refined and clear demarcation lines for the scope of the protected subject matter is crucial for balancing the policy goals and effectiveness of PVP. This in turn requires limiting the scope of patent protection to only the results of modern biotechnology and requiring more stringent requirements for patent protection. Therefore, the scope of PVP should be limited solely to new plant varieties that are the result of the application of traditional breeding techniques. In terms of adapting to technological changes, it can be argued that the difference between the narrowly tailored PVP system and the technology neutral patent protection is simply a matter of degree. In fact, in terms of addressing the industry and technology specific challenges, PVP system is superior to a one-size-fits-all regime of patents. This in turn suggests that the focus should be on each system's checks and balances, rather than their pace of adapting to changes in technology.

The analysis presented in this thesis not only reveals the unique challenges of plant innovation but also displays the widening gap between technology in the constant state of evolution on one hand and traditional concepts of patent law on the other. A deeper understanding of these challenges may aid

bringing plant innovation debates in line with the realities of scientific research, and might even help making the doctrinal conundrum more traceable.

Several broader impacts results from this research. First, research findings inform debates over how the existing IP framework has adapted to advances in plant related technology. Second, findings in this thesis provide a new understanding of the relationship between patent and PVP systems, as well as the two systems' strengths and limitations in terms of their implications on innovative activity. The case study on biofuels contributes additional evidence to existing literature and suggests that patent protection is not adequately flexible to incorporate most pertinent aspects of plant breeding. The findings of the study further indicate that plant innovation appears to be prone to suffer from patent thickets in the near future. Finally, this thesis' findings provide legal scholars, attorneys, industry representatives, law reformers, and legislative advocates with a more nuanced and comprehensive understanding of the IP law framework for plant innovation.