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SEEDS REGULATION, FOOD SECURITY AND SUSTAINABLE DEVELOPMENT

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Seeds Regulation, Food Security and Sustainable Development

Thus far, debates relating to the adoption of the proposed amendments to the Patents Act 1970 have focused overwhelmingly on its consequences for the pharmaceutical sector. However, the Act is only one among several other legal instruments expected to have a significant impact on the future development of agriculture. This article argues for the widening of the patents debate to include agriculture, which under the current WTO regime, is now bound to its regulations relating to trade and intellectual property. It also looks at several legal instruments, already in place or in the offing, examining them together in the light of the linkages and overlaps between them. At the same time, these instruments need to be examined in context of the international framework, for increasingly, international treaties and conventions have come to exercise some influence at the national level.

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In recent months, there have been renewed debates concerning the implementation of WTO treaties, in particular in the field of patents. Debates concerning the Patents (Amendment) Act, 2005 have focused overwhelmingly on medical patents and questions of access to drugs because this happens to be one of the most visible impacts of the introduction of product patents. Nevertheless, other areas, in particular agriculture, are also affected by the Patents (Amendment) Act, 2005 and further attention needs to be given to the implications of the amendments on food security. This is important in general but also more specifically because the minister for commerce and industry conceded that there was scope for further debating questions related to flexibility or safeguards concerning new chemical entities and micro-organisms and introduce changes in the legislation at a later date.[1] A technical expert group was accordingly set up on April 5, to determine whether it would be possible to limit the scope of patentability to new chemical entities and to exclude micro-organisms from patenting.

Despite the importance of patents in recent debates, the Patents (Amendment) Act, 2005 is only one among several legal instruments that have or will have significant impact on the development of agriculture in years and decades to come. In particular, Parliament is now considering a proposal for a new Seeds Act which has the potential to indirectly bring substantial changes to the existing intellectual property protection regime in agriculture. Further, while the question of plant variety protection and farmers' rights was comprehensively addressed in the Protection of Plant Varieties and Farmers' Rights Act, 2001 (Plant Variety Act), the fact that the Act is yet to be notified must be read in the context of the proposed new Seeds Act.

This article examines various issues arising in the context of adoption of the Patents (Amendment) Act, 2005, the possible further amendments to the Patents Act, the Seeds Bill, 2004, the Plant Variety Act and other relevant instruments such as the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells, 1989 (Biosafety Rules) and the Biological Diversity Act, 2002. Despite the fact that these legal instruments cover distinct issues, they need to be examined together because there are a number of links as well as overlaps which must be taken into account. Further, each of these instruments must be analysed in view of the existing and evolving international law framework given that international treaties play an increasingly important role in influencing developments at the national level.

I
Existing Legal Framework

Seeds constitute only one input among a host of factors that contribute on the whole to ensuring agriculture's contribution to food security, to the realisation of the right to food and to sustainable use and conservation of environmental resources. Seeds nevertheless constitute one of the focal points of debates at present.

From a legal point of view, seeds are regulated from at least three different perspectives. First, the quality of seeds is regulated to ensure that seeds purchased conform to the characteristics that have been advertised. Second, the safety of seeds is regulated through biosafety measures to ensure that new or imported seeds do not create unwanted environmental harm. Third, in recent years, the intellectual property protection regime has rapidly expanded to include new seeds or new micro-organisms inserted in seeds as products which can be protected under different types of intellectual property rights.

The regulation of seeds has been and remains of tremendous importance because of the direct implications that it has on the majority of the population engaged in agriculture as well as on the fulfilment of basic food needs. Until a decade ago, the various legal instruments governing seeds remained relatively unintrusive insofar as they were by and large limited to ensuring seed quality and did not intrude into farmers' and researchers' ability to freely exchange and change seeds. This situation has dramatically changed in the recent past. Changes have largely first taken place at the international level and have been progressively integrated into domestic law. This section therefore explores both the international and national dimensions of seed-related regulatory frameworks.

The International Context

The international legal framework concerning seeds has rapidly evolved over the past couple of decades. This can be divided into three broad categories. First, there are instruments which are

concerned in direct or indirect ways with sustainable agriculture, the quality of seeds and the environmental impact of agricultural practices. Second, there are instruments which focus mostly on the social and human aspects of agriculture such as human rights treaties. Third, there are instruments which focus less on the food security aspect of agriculture and more on its economic aspects by emphasising trade in agricultural products and promoting the development of commercially valuable new crops. These include trade treaties and intellectual property rights instruments.

In the first category, the most relevant treaty is the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA treaty) which provides the main legal framework concerning international cooperation for agricultural research.[2] The PGRFA treaty focuses on the exchange, use and conservation of germplasm, one of the most important sources of new plant varieties in the formal sector. The treaty seeks to maintain some aspects of the broad system of free exchange of germplasm that provided the basis for the advances that led to the development of varieties ushering the green revolution.[3] The promotion of free exchange is, however, heavily qualified by the (re)assertion by source countries of their sovereign rights over seeds and biodiversity. As a result, the compromise which has been found is that states maintain sovereignty over their germplasm but agree to 'facilitate' access in the case of a limited number of crops.

Another important treaty is the Biodiversity Convention. In general, it provides for the conservation and sustainable use of all biological resources, including agricultural biodiversity. Further, it includes a special programme of activities on agricultural biodiversity which seeks to promote agricultural practices that minimise the negative impacts on agro-biodiversity and foster the conservation and sustainable use of genetic resources of actual or potential value for food and agriculture.[4] Its importance stems from the fact that it is one of the main treaties concerned with environmental protection where the link with agriculture has been clearly made. Further, the Biosafety Protocol which has been adopted within the context of the Biodiversity Convention fosters further links with agriculture since some of the main issues with regard to genetically modified organisms arise in the context of their deliberate release into the environment as seeds.

In the second category of instruments focusing on social and human rights aspects, the International Covenant on Economic, Social and Cultural Rights is one of the most relevant instruments. It recognises, for instance, the human right to food which directly links food security and human rights. The core elements of the right include requirements of availability as well as accessibility of food.[5] This includes a number of direct and indirect links with the control and rights that farmers have over seeds, the price of seeds which affect farmers directly and consumers indirectly as well as seed quality from a health and nutritional point of view.

In the third category focusing on the promotion of more commercially-oriented agriculture, there has been a spurt of legal instruments introducing intellectual property rights standards starting in the 1960s and rapidly evolving in the past couple of decades, partly as a result of new economic opportunities offered by genetic engineering. The two main instruments in this field are the TRIPS Agreement and the UPOV Convention. The former is a broad-ranging treaty which has had impact at various levels. In the context of agriculture, two main aspects can be highlighted. Firstly, the TRIPS Agreement provides for the introduction of life patenting, such as patents on micro-organisms, in all WTO member states. Secondly, it specifically mandates the introduction of a form of intellectual property protection for plant varieties. This has made intellectual property protection a central concern of agricultural policy in the context of the implementation of TRIPS commitments. The UPOV Convention has a much narrower focus and specifically introduces a form of intellectual property rights known as plant breeders' rights which largely protect commercial breeders of conventional seeds.[6] In other words, the UPOV Convention and the TRIPS Agreement are largely complementary because the former does not provide specific protection for genetically modified seeds. This does not imply that the two treaties necessarily address separate situations since a plant variety protected through plant breeders' rights may also include a patented micro-organism. In other words, unless double protection is specifically prohibited, plant breeders' rights and patents can coexist in a specific case.

Intellectual Property Protection

Agricultural policy has been continuously evolving since independence. Nevertheless, some recent trends may be seen as especially momentous for the future of agriculture and for the majority of the population for whom agriculture is a livelihood. Among the various changes that have been and are taking place, one of the most significant ones is the increasing focus on agriculture as a commercial activity that also contributes to the goals of food security from the individual to the national level rather than an activity providing employment to a majority of the population. In legal terms, this is visible in the context of the progressive introduction of intellectual property rights in agriculture and in the proposed Seeds Bill.

(i) The Patents Act

Historically, the Patents Act, 1970 singled out agriculture for specific restrictions with regard to patentability as well as limitations on the scope of the rights granted to patent holders.[7] The national consensus on this issue does not seem to have significantly evolved between 1970 and the adoption of the TRIPS negotiations. It is therefore only after the ratification of the TRIPS Agreement that substantive changes to the Act have been made in this area.

A number of changes that have been introduced as part of the three amendments to the Patents Act in the past decade will have direct impact on agriculture. The single most important change in this area is the elimination of the prohibition of product patents, which was introduced in 2005.[8] Other changes include the removal of the shortened duration period for food-related patents and the elimination of the automatic endorsement of food-related patents with the mention 'licenses of right'.[9] They also include a revised definition of the term inventive step.[10] This introduces a controversial new method of assessment of inventiveness which includes the 'economic significance' of an invention. This seems to imply that a genetically modified micro-organism could be patented in cases where it constitutes a genuine technological advance as well as in situations where it is only deemed to be economically beneficial.

Some limitations on the scope of patentability in agriculture have been retained. This includes the prohibition of patentability of plants in whole or in part, of plant varieties and of seeds. These new provisions require significant attention as the different interpretations that can be given will lead to different outcomes. In principle, the Patents Act seems to provide a number of clear exclusions. It adopts two of the exceptions allowed under the TRIPS Agreement by rejecting the patentability of plants and plant varieties. The inclusion of seeds in the prohibition

reinforces the message that patentability is denied to any part of a plant.

This does not provide a comprehensive picture of the scope of patentability in agriculture. In fact, while the introduction of patents on micro-organisms may be restricted in principle by the exceptions just mentioned, the case law in other jurisdictions points to the fact that courts may indirectly provide patent protection to seeds or plants. This is due to the fact that holders of patents on micro-organisms would argue that their rights should be upheld regardless of whether the protected micro-organism has been used in isolation or has been inserted into another organism. In traditional patent law, it has usually been accepted that patent protection is not lost in a situation where a patented device is used inside another device which may or may not be patented. Before the introduction of life patents, this principle of patent law would only have applied to human-made devices. In the case of micro-organisms inserted in seeds, the adoption of the same principle is problematic. The patented micro-organism inserted into a seed has the unique ability to be found not only in the seed sold by a licenced dealer but also in the progeny of this seed. In other words, while there is no input from the patent holder into 'making' the second generation of the seed, the patented micro-organism can still be identified in the latter. This calls for a separate treatment of life patents altogether. However, it cannot be assumed that courts in India would necessarily treat micro-organisms any differently than they would treat any patented mechanical device. This is of concern because other courts have already taken decisions where they determined that even where plants are not patentable, they may be indirectly protected in situations where they contain a patented micro-organism. One of the landmark cases in this area is the case of *Monsanto v Schmeiser* decided by the Canadian Supreme Court.[11] The court ruled that Schmeiser had used canola containing a patented cell and gene without obtaining licence or permission and had therefore infringed the patent act.[12] This was the result despite the fact that the Supreme Court had ruled two years earlier that plant patents are prohibited under Canadian law.[13]

This discussion of the interrelationship between different life patents indicates that a simple reading of the limitations on the scope of patentability in the Patents Act is not sufficient to fully grasp the specific scope of protection in the future. This is one of the reasons why the expert committee has been asked to (re)consider the issue of micro-organism patentability. Should the committee and the government want to ensure that there can be no extensive interpretation of patent protection for micro-organisms, two solutions are available. Firstly, the committee could recommend the inclusion of a specific provision indicating that micro-organisms are only protected in isolation and not where they are inserted into another organism which is itself not patentable under the Patents Act. Secondly, the committee could recommend restrictions on the patentability of micro-organisms based on Articles 7 and 8 of the TRIPS Agreement, the precautionary principle and the fact that Article 27(3)b, which mandates their protection, is still under review.

(ii) Plant Variety Protection Act

The exclusion of plant varieties from the scope of patentability under the Patents Act, 1970 is related to the introduction of a separate plant variety protection regime as part of the commitments taken under Article 27(3)b of the TRIPS Agreement. A decision was taken to adopt separate legislation, a solution adopted by a majority of WTO member states. The resulting Plant Variety Act introduces two new forms of protection for plant varieties.

First, the Plant Variety Act introduces plant breeders' rights modelled after the UPOV Convention. Plant breeders' rights constitute historically the compromise response of European states to the call for intellectual property protection in agriculture by the seed industry compounded with a widespread unwillingness to introduce life patents. Plant breeders' rights are thus a form of intellectual protection meant to provide incentives to commercial breeders. They are conceptually close to patent rights but differ insofar as the rights granted to commercial plant breeders are more circumscribed than under patent laws. Moreover, the Plant Variety Act also introduces farmers' rights. These are rights which allow farmers to register their varieties, largely in the same manner that is provided for commercial plant breeders.

The overall impact of the Plant Variety Act is to engineer a significant shift of policy towards intellectual property protection in agriculture even though patents are generally not welcomed at this stage as indicated above. This can be compared to the pre-existing system where no intellectual property protection was available in the field of agriculture and where the predominant paradigm was free exchange of germplasm and knowledge among all concerned actors from local to international levels.

II
Proposed Regime under Seeds Bill

Changes that have taken place over the past decade with the adoption of the Plant Variety Act, amendments to the Patents Act and the adoption of the Biodiversity Act which also contribute to fostering intellectual property protection in biodiversity-related activities are at the very least momentous. Their progressive implementation in coming years is likely to foster major changes in agriculture. While the three acts just mentioned have either not yet been implemented or are at best on the threshold of effective implementation, with the introduction of the Seeds Bill, 2004 the government has initiated a new process that may undo a number of rules and principles set out in existing legislation.

The Seeds Bill, 2004 is generally proposed as a replacement for the existing Seeds Act, 1966.[14] The rationale for a new act can be traced back to the relatively rapid changes that have been taking place in the seed sector in the past couple of decades. These include in particular the growing, yet still relatively marginal, role of private seed companies and the progressive introduction of transgenic seeds.

Seed Registration

Under the Seeds Act, 1966 the government can determine that the quality of certain varieties of seed need to be regulated. In such cases, certain conditions are laid down for anyone wishing to barter or sell any notified seed. The Seeds Bill, 2004 follows the same general principle but extends the regulation of seed quality to any seed sold for purposes of sowing or planting.[15] If passed as introduced in Parliament, the Seeds Bill would modify the legal regime for seed quality from one focusing on a small number of varieties to one which covers the overwhelming majority of local farmer varieties of seeds. This is a major step which seems to be largely out of line with the evolution of agriculture in the past couple of decades. This is not to deny that changes have taken place. Thus, the private sector seed industry's role has significantly increased in some specific crops. This warrants the extension of quality control

to all seeds traded by commercial seed sector actors. However, there is no rationale for extending registration obligations to individual farmers bartering or selling seeds to each other. The Seeds Bill goes one step further insofar as it not only imposes that all sold or bartered seeds should be registered but also imposes the registration of all seed producers and seed dealers. Under the Bill, a seed dealer includes anyone who supplies seed by himself or on someone else's behalf and includes anyone, including someone who simply desires to barter seeds.[16]

The registration system proposed in the Bill deserves several comments. First, it is largely for the proposed registration sub-committee to determine whether claims related to the efficacy of the seed and its safety to human beings and animals warrant its registration. Second, the Bill fails to specify most of the actual criteria for registration and determines, for instance, that the manner of registration or the period for multi-locational trials can be determined by the central government.[17] Third, the Bill specifies that registration is to be undertaken on the basis of information furnished by the producer rather than by independent verification. This system is lacking because important aspects of seed registration such as environmental impacts and risks to human health are not specified, because it leaves too much power to the government to determine the conditions of registration, and because the trials should ideally be effected by an independent or public sector body such as the Indian Council of Agricultural Research.

The Bill provides two main exemptions to compulsory registration; (i) Section 43 asserts that the rights of farmers to save, use, exchange, share or sell their farm seeds and planting material are not restricted. This exemption does not apply to farmers who want to sell seeds under a brand name and the exemption is further limited by the fact that farmer seeds must still conform to the minimum limits of germination, physical purity and genetic purity that may be prescribed by the Central Seed Committee; (ii) scientific and research organisations may be exempted from complying with the provisions. The Bill also provides that certain varieties cannot be registered. Section 18 which defines these exclusions is directly copied from similar clauses in the Plant Variety Act, itself modelled after Article 27(2) of the TRIPS Agreement. The Bill also follows the Plant Variety Act in providing that seeds containing genetic use restriction technologies cannot be registered.

One of the main issues with regard to the registration system under the Seeds Bill is the extent to which it will affect farmers and farmer seed-related practices of seed exchange, barter and inter-farmer seed sales. As provided under section 43, farmers are in principle exempted from the compulsory registration as long as they do not sell under a brand name. This, however, sits uneasily with section 22 which indicates that every person that wants, for instance, to 'barter' or 'supply any seed' must obtain a registration certificate. In effect, while sections 43 and 22 seem to provide a coherent system of activities that are covered or exempted, this is unlikely to be the case in practice. Where section 22 speaks of 'bartering', Section 43 speaks of 'exchange'. Barter is clearly defined in the dictionary as a form of exchange. In practice, the following is likely to take place under the existing wording. The principle established in the Bill is that all seeds must be registered. Some exclusions related to the nature of the seeds are provided for in section 18. Further, the central government has the power to grant certain exemptions. These exemptions, of which the farmer exemption is one, are clearly subsidiary and to be interpreted narrowly.[18] In other words, it is unlikely that the concession offered to farmers in section 43 will do more than allow them to maintain the right to save and use their seeds. With regard to exchanging, sharing and selling, since this contradicts section 22, it will likely be up to the registration sub-committee to determine which section should prevail. Further, in practice, it is likely that farmers will face another difficulty in situations where they sell or exchange seeds under the exemption of section 43. Since even these transactions are subject to the conditions of section 6 concerning genetic purity, for instance, this opens the door to an indirect system of registration. This is due to the fact that the only way to ascertain whether seeds sold under section 43 conform to the conditions laid down in section 6 will be to allow some agency to determine whether farmers are entitled to sell or barter these specific seeds.

Should registration be required in a majority of cases, this will probably have the impact of limiting small farmers' ability to rely on farm-saved seeds. Once this is taken away because it has been made illegal, farmers will increasingly rely on commercial seeds. This has direct economic consequences for small farmers as well as significant consequences from the point of view of agro-biodiversity conservation since this will lead to the disappearance of a number of local varieties.

Genetically Modified Seeds

The compulsory registration system introduced by the Seeds Bill may induce an uninformed reader in believing that the aim would be to introduce stringent quality standards for all seeds. In fact, one of the very controversial aspects of the Seeds Bill is section 15 which provides in effect for genetically modified seeds that registration under the Seeds Bill can trump existing biosafety regulations for a whole two years. More specifically, the Seeds Bill provides that the registration sub-committee is authorised to grant provisional registration to transgenic seeds for a period of two years. This is to be undertaken on the basis of multi-locational trials and other conditions which are the same as in the case of non-transgenic varieties.

This proposed system has significant implications for the future of agriculture: (i) Firstly, the conditions under which provisional registration can be obtained do not conform to the Biosafety Rules adopted to regulate the introduction of genetically modified organisms into the environment. This runs counter to the existing biosafety regulations as well as the precautionary principle which constitutes the basic regulatory principle for genetically modified organisms in India like in an overwhelming majority of countries around the world; (ii) the provisional registration of transgenic seeds will in effect negate the existence of the intricate biosafety regime in place at present. The 'provisional' registration is in the overwhelming majority of cases likely to remain unchallenged once it goes through the clearance required under the Environment (Protection) Act, 1986. This is due in part to the fact that there would likely be significant pressure on the regulatory authorities not to withdraw a registration already granted. This is also more importantly linked to the fact that provisional registration will play the same role that the illegal introduction of genetically modified seeds plays at present. The regulatory authorities will largely be forced to regularise a situation of fact which cannot be modified any more since genetically modified seeds can in general not be removed from the environment once they have been introduced. The alternative will be to withdraw registration and require a clean-up of the environment, a situation which would prove difficult to address in practice and one for which the legal system is not ready since there is yet no liability regime concerning genetically modified organisms.

The Seeds Bill is not the only initiative that would undermine the existing biosafety regulatory framework. The proposed National Biotechnology Development Strategy, 2005 proposes as one of its strategic actions, the establishment of a 'single National Biotechnology Regulatory Authority'. This is in line with the recommendations of the Swaminathan Report recommending a 'reduction in the levels and number of steps required in evaluation and environmental clearance of GM products/transgenics'.[19] In other words, the Seeds Bill must be analysed as one element of a broader process of change which is being initiated following what seemed to be the end of a process of regulatory changes undertaken mainly to ensure compliance with WTO treaties, the TRIPS Agreement in particular.

Monitoring, Enforcement and Liability

With regard to monitoring, the Seeds Bill does little more than copy relevant sections of the Seeds Act, 1966. Thus, like the existing Act, it provides that seed inspectors appointed by state governments can take a sample of any seed from anyone, at any time and from any location.[20] These are extensive powers but not new. What is, however, new and significant is the fact that the powers of the seed inspectors will not extend any more only to the relatively low number of seeds covered under the existing Seeds Act but will extend to all varieties except the ones protected by exemption clauses under Section 43.

The effect of the implementation of the Seeds Bill would be to dramatically increase the role of the state in monitoring and enforcing the act. This must be read in the context of the overall withdrawal of the state from its traditional roles in many areas. It appears that while the state withdraws from some of its welfare functions, it is willing to increase its policing role, increasingly on behalf of other actors rather than itself. On the one hand, the Seeds Bill proposes to strengthen the regulation of seeds by introducing compulsory registration and giving the state an important role in policing the provisions for registration. On the other hand, the Seeds Bill is clearly aimed at fostering a greater role for the private sector and in the case of genetically modified seeds, for instance, directly contributes to undermining the existing biosafety regulatory regime.

The question of liability is also noteworthy in the context of the Seeds Bill. The Bill provides that seeds sold must provide an indication of the expected performance under specific conditions. In situations where seeds fail to perform as expected, farmers are given the right to seek compensation from the producer or vendor but only through channels offered under the Consumer Protection Act, 1986. One of the consequences of this narrow regime is that there is neither a specific liability regime nor a crop insurance scheme. This is of significant concern in view of the fact that the sale of spurious seeds is not an unknown phenomenon. Further, a liability regime is of necessity in the context of the Seeds Bill which proposes to introduce genetically modified seeds without requiring the fulfilment of the conditions imposed under the Environment Protection Act. This is in fact acknowledged in the Swaminathan Report which specifically calls for the adoption of a strong liability regime and the introduction of a special insurance scheme for genetically modified crops.[21]

Intellectual Property Protection

The Seeds Bill is in principle an instrument which has no impact on the intellectual property rights regime put in place in the past few years. There are nevertheless a number of links and consequent impact which can be identified.

As noted above the Seeds Bill introduces a system of compulsory registration. Nevertheless, it does not specifically indicate that registration by one actor precludes another from also registering the same variety.[22] Indeed, it does not indicate any way in which the first application for registration is to be distinguished from any subsequent applications, thereby possibly opening the door to multiple registrations. This may open the way to a competitive system where different actors in different parts of the country are allowed to register the same variety without infringing on each other's rights. In this sense, the Seeds Bill may be seen as undermining the intellectual property rights regime and making a concession to farmers who would be able to register similar varieties independently of each other.

This does not appear to be a likely interpretation of the Bill for several reasons. First, Section 13(6) clearly indicates that the registration sub-committee can protect the interests of the producer even before registration is granted. This seems to indicate that there is little scope for a given variety to be registered by more than one person. Second, multiple registration, even if allowed, is unlikely to take place in any situation where a producer needs to have access to parental lines since this would be in most likelihood only available to the producer that developed the variety. Thirdly, even if small farmer producers can theoretically register their varieties, the proposed system is heavily biased against them by requiring, for instance, multi-locational trials for the registration of all seeds.

If the Seeds Bill is understood as providing a system which only allows registration by one producer, this appears closely related to the intellectual property rights system already put in place earlier. This is at first sight surprising and upon further analysis seems to imply that the Seeds Bill may constitute an attempt to undermine the existing legal regime, in particular, the Plant Variety Act. The major difference between a legislative instrument like the Seeds Bill and an intellectual property act like the Plant Variety Act is that the latter is based upon the recognition that there must be a balance between the rights granted to the intellectual property holder and society at large. Further, most intellectual property laws around the world recognise that the grant of an intellectual property right must be based upon a specific contribution made by an individual.

This basic difference has a number of implications. Firstly, the rights granted under an intellectual property law like the Plant Variety Act are limited in duration. This is linked to the recognition that the ultimate goal of intellectual property protection is innovation that must be of benefit to the broader society. Exclusive rights granted to commercial plant breeders constitute an incentive for innovation but are seen as being by definition temporary. The Seeds Bill does not follow this principle in any way. While it seems to follow the Plant Variety Act in providing that registration of varieties is to be valid for the same amount of time (15 years for most annual crops and 18 years for trees and other long duration perennials), this is deceptive because section 13(5) specifically allows the re-registration for another 15/18 years. In theory, there is no limit to the number of times that the re-registration can be granted, therefore implying that rights granted under the Seeds Bill may be of unlimited duration.

Secondly, the conditions for registration under the Seeds Bill are lax compared to the Plant Variety Act. The Seeds Bill fails, for instance, to include the Plant Variety Act requirement that the applicant should disclose the 'complete passport data of the parental lines from which the variety has been derived along with

the geographical location in India from where the genetic material has been taken'.[23] This constitutes a significant shortcoming from the point of view of access to information and information disclosure. Indeed, under intellectual property laws, one of the basic requirements that applicants must fulfil is the disclosure of all information related to the novel product. This information is then made available to the public. This is necessary for two reasons. It contributes to the diffusion of innovation and allows interested parties to have access to the information necessary to oppose the rights granted should this turn out to be necessary. The Seeds Bill does not provide for any publication of the information provided and is thus far less open than the most secretive intellectual property laws.

Thirdly, the conditions for registration under the Seeds Bill leave the door open to the registration of any variety. This is not completely surprising given that the Bill seeks to impose the registration of all seed varieties. This is nevertheless very problematic because it is likely to lead to the registration of farmer varieties by private companies while restricting farmers' opportunities to register their varieties. Under existing intellectual property laws such as the Plant Variety Act, applicants must always demonstrate that they have made a contribution which warrants the grant of exclusive or monopoly rights. Under the Plant Variety Act, breeders must thus demonstrate the characteristics of novelty, distinctiveness, uniformity and stability of the variety whose registration they are seeking. Where these conditions are not met, registration is not available and the variety remains in the public domain. Under the Seeds Bill, it appears that any variety at all could be registered apart from varieties specifically excluded at Section 18. In practice, this will mean that companies that conduct multi-locational trials will be able to register farmer varieties since farmers will not be able to oppose the registration. Further, farmers who cannot conduct multi-locational trials will not be able to register their varieties.

Fourthly, intellectual property laws provide mechanisms to ensure that the rights granted are not abused. Thus, the Plant Variety Act provides that where the reasonable requirements of the public for seed have not been satisfied or that protected seeds are not available at a reasonable price, anyone can request the grant of a compulsory licence from the Protection of Plant Varieties and Farmers' Rights Authority.[24] This constitutes the usual mechanism introduced in many intellectual property laws around the world to ensure that the rights granted by the state are not abused by the rights holder and that the public benefits from technological innovation. In other words, the possibility to grant compulsory licences provides a mechanism through which pressure can be put on the rights holder to increase production and/or reduce prices as appropriate. There is no similar mechanism under the Seeds Bill.[25] This would tend to imply that a company that registers a variety potentially has market exclusivity which is neither limited in time since re-registration is possible nor limited in scope since there are few opportunities for interfering with the registration. Conceptually, this is due to the fact that the Seeds Bill does not provide any 'exclusive marketing rights' or other related rights. Nevertheless, it appears that in practice, registration is likely to be akin to an exclusive marketing right which should therefore be subjected to the same conditions as other intellectual property rights.

Fifthly, the Seeds Bill considerably restricts the import of farmers' rights under the Plant Variety Act. This is linked to several factors already identified. Since the Seeds Bill does not require the disclosure of the complete passport data of parental lines, this drastically reduces farmers' ability to claim benefit sharing since they may never even know that their varieties have been used. With regard to the registration of varieties, the Plant Variety Act makes a special effort to accommodate farmers and to ensure that their varieties can also be registered. In contrast, the Seeds Bill with requirements such as multi-locational trials and genetic purity ensures that even farmers who wish to get their varieties registered will not be able to do so. Further, whereas the Plant Variety Act considers the contribution of farmers as farmer-breeders and as farmer-conservers of agricultural biodiversity, the Seeds Bill only exempts farmers from compulsory registration under certain conditions but does not offer them any incentives or rewards.

Overall, it is apparent that if the Seeds Bill was adopted in its present form, it would dramatically undermine the Plant Variety Act while creating a legal regime lacking clarity. Should the two acts be made to co-exist side by side, a number of additional provisions would need to be added to ensure that the two registration systems work in tandem and that the different types of rights offered are actually compatible. The rationale for the introduction of the Seeds Bill remains unclear. The Plant Variety Act was already introduced to 'facilitate the growth of the seed industry in the country'.[26] There is no apparent reason why another instrument should be introduced even before the first one has been effectively implemented.

III
Towards Seed Regulation

Today, the quality of seeds sold commercially is under-regulated because the Seeds Act, 1966 provides a limited framework for seed quality regulation. The changes that have taken place and are ongoing in agriculture require a new seeds law. This new law should take into account the increasingly rapid development of a private commercial seed sector, the increasing role of foreign companies in the seed market, the changing policy environment under which national and international public agricultural research takes place and the introduction of genetically modified crops.

The necessity for increasing seed regulation must be seen in the context of the rapid development of intellectual property protection standards in agriculture. The introduction of patents on micro-organisms and plant breeders' rights in the Patents Act and Plant Variety Act respectively can be analysed from two different perspectives. On the one hand, intellectual property protection in agriculture can be seen as a negative development which restricts current free flows of knowledge and seeds among farmers, research institutions and private companies. On the other hand, the introduction of intellectual property protection provides a basic regulatory framework which balances the rights offered to intellectual property holders with society's broader interests. This includes the various conditions which must be fulfilled for the grant of an intellectual property right and the mechanisms such as compulsory licences that are available to restrict the enjoyment of the rights granted in the interest of the broader public.

The Seeds Bill takes a completely different, yet closely related route to seed quality regulation. Instead of limiting the possibilities for registration to the relatively small number of actors who can fulfil the criteria for obtaining intellectual property rights, it provides that all sold or exchanged seeds must be registered. This constitutes a step forward insofar as it requires that all commercially available seeds are subjected to a minimum set of conditions before they can be allowed on the market. This

is, however, insufficient to ensure the orderly development of agriculture in general. Firstly, the Seeds Bill should exclude in much clearer terms than it does all farmer varieties and all non-commercial small-scale activities that constitute the bulk of inter-farmer seed transactions. Secondly, the Seeds Bill should ensure that farmer varieties cannot be registered by other actors. It appears unfair and unproductive to restrict small farmers that sell seeds from registering their varieties if they wish to do so because they cannot fulfil the criteria for registration while allowing other actors such as bigger seed companies to register any seed without any regard to the person(s) having originally developed the variety. Thirdly, the Seeds Bill should not only provide stricter quality tests for all commercially available seeds but also refrain from undermining the existing biosafety regulatory framework concerning transgenic seeds. Fourthly, if the Seeds Bill is to be understood as allowing only one person to register a given variety, it should defer to the existing Plant Variety Act which already provides a mechanism for determining who can register which varieties. The present uncertainty is likely to be extremely unfavourable to farmers whose varieties may be registered without their knowledge and without any form of benefit sharing. Fifthly, the Seeds Bill should either defer to the Plant Variety Act or introduce similar mechanisms to ensure that seed prices can be regulated and that producers and sellers are held liable wherever seeds fail to perform according to the specified standards.

Overall, the compulsory registration of all seeds sold to farmers is a welcome initiative and one which has, for instance, been endorsed by the Swaminathan Report.[27] This should, however, take place in a regulatory context which provides a fully-fledged quality control system, which does not undermine existing laws such as the Plant Variety Act and which includes certain elements such as a liability regime.

Seed regulation in the 21st century will be increasingly important and changes to the existing regulatory framework are probably unavoidable. However, the changes that are needed are likely to be at variance with the proposed Seeds Bill. Changes are required to ensure that small-scale and subsistence farmers who constitute the bulk of the agricultural work-force are not harmed by the various measures being introduced for compliance with WTO treaties. In this regard, the Plant Variety Act's introduction of a fully-fledged system of farmers' rights is noteworthy as it constitutes an attempt to reconcile the imperative of TRIPS compliance with social equity and food security. Further changes are required in view of the rapidly changing technological scenario. The introduction of genetically modified seeds, and maybe in the future the introduction of nano-technology, necessitates the maintenance of the existing biosafety regulations and the introduction of new measures, for instance, with regard to labelling and liability. These are debates which do not belong exclusively to the area of seed regulation but must nevertheless also be addressed in the context of agriculture. At the very least, proposed regulatory measures in agriculture should explicitly recognise these needs and should avoid undermining existing frameworks that contribute to environmental conservation.

Debates concerning the adoption of the third set of amendments to the Patents Act, 1970 have been extensive and have provided the basis for in-depth discussions of the issues involved. These have focused overwhelmingly on the consequences of the introduction of product patents for the pharmaceutical industry. This was largely to be expected because there is today a vibrant domestic pharmaceutical industry while there is no equivalent industry in agriculture. Nevertheless, the debate must be broadened to include agriculture for several important reasons. Firstly, agriculture is as important as health from the point of view of basic needs and human rights. Secondly, agriculture is also facing the full onslaught of the WTO regime both with regard to trade aspects and intellectual property protection aspects. Thirdly, the country has already moved towards the introduction of some form of intellectual property protection in agriculture with the adoption of the Plant Variety Act and the implications of the introduction of product patents, for instance, on micro-organisms deserve much more attention. EPW

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Notes

1 The minister of commerce and industry, Kamal Nath, replying to the discussion on the Patents (Amendment) Bill, 2005, in Lok Sabha, Synopsis of Debates (Proceedings other than Questions and Answers), March 22, 2005. Note that the minister was exclusively referring to the pharmaceutical industry.
2 International Treaty on Plant Genetic Resources for Food and Agriculture, Rome, November 3, 2001.
3 This system was, for instance, reflected in the International Undertaking on Plant Genetic Resources, Resolution 8/83, Report of the Conference of FAO, 22nd Session, Rome, November 5-23, 1983, Doc C83/REP.
4 Decision III/11, 'Conservation and Sustainable Use of Agricultural Biological Diversity' in Report of the Third Meeting of Conference of the Parties to the Convention on Biological Diversity, UN Doc UNEP/CBD/COP/3/38 (1996).
5 Paragraph 8, Committee on Economic, Social and Cultural Rights, General Comment No 12 – The Right to Adequate Food (Art 11), UN Doc E/C12/1999/5 (1999).
6 International Convention for the Protection of New Varieties of Plants, Paris, December 2, 1961, as revised at Geneva on March 19, 1991 (UPOV Doc 221(E), 1996).
7 Sections 3(h), 5, 53, 87, Patents Act, 1970 (as originally adopted).
8 Section 4, Patents (Amendment) Act, 2005 providing for the omission of Section 5 of the Act.
9 Section 39, Patents (Amendment) Act, 2002 providing for the substitution of new Chapter for Chapter XVI.
10 Section 2(ja), Patents Act, 1970 (as amended in 2005).
11 Monsanto Canada Inc vs Schmeiser, Supreme Court of Canada, Judgment of May 21, 2004, 2004 SCC 34.
12 Ibid, at paragraph 97.
13 Harvard College vs Canada (Commissioner of Patents), December 5, 2002, Supreme Court of Canada [2002] 4 SCR 45, 2002 SCC 76.
14 Section 49, Seeds Bill, 2004.
15 Section 13(1), Seeds Bill, 2004.
16 Sections 21, 22, Seeds Bill, 2004.
17 Section 46, Seeds Bill, 2004.
18 The place of the farmer exemption at Section 43, Seeds Bill, 2004 in Chapter IX dealing with the 'Power of Central Government' provides an indication of hierarchical order in which it is placed in the Bill.
19 Section 12, Report of the Task Force on Application of Agricultural Biotechnology chaired by M S Swaminathan (ministry of agriculture, May 2004).
20 Compare Sections 34, 35, Seeds Bill, 2004 and Sections 13, 14, Seeds Act, 1966.
21 Section 23, M S Swaminathan Report, Note 19 above.
22 Cf S Bala Ravi, 'Seeds of Trouble', *The Hindu*, March 8, 2005.
23 Section 18(e), Protection of Plant Varieties and Farmers' Rights Act, 2001, Act No 53 of 2001.
24 Ibid, Section 47.
25 Section 16 only provides that the registration sub-committee may, at its own discretion, cancel a registration where the variety is not performing according to the registration data.
26 Ibid, Preamble.
27 Section 22, M S Swaminathan Report, Note 19 above.