



GRUR Workshop: "New Genomic Techniques and Patents in Plant Innovation"

Reflections on various
proposals

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Regulatory and IP aspects relating to NGT plant innovations

- The current scene relating to both the regulatory framework and the IP aspects of NGT based plant innovations requires a nuanced approach
- In light of climate change and sustainability challenges, and the increasing use and decreasing efficacy of (bio)pesticides, innovation in plants is crucial, definitely when taking a global perspective
- Innovation requires a number of parameters to be fulfilled in order to thrive:
 - Legal certainty
 - Clear regulatory frameworks
 - Innovation incentives broadly defined
 - Money

Legal certainty and clear regulatory frameworks

- Multi-layered:
 - Laws that are clear and/or with limited potential to be contested
 - Breeders must also be capable of knowing what are their rights and limitations thereto
 - Innovation requires regulatory certainty
 - Protracted political debates where (too) many issues are superimposed are counterproductive

Innovation incentives challenges

- Developing NGT technologies and plant innovations using the same is a rather expensive affair
- Inevitably, for research intensive technologies, and in view of the cost, proprietary positions will be taken (e.g., patents, PBRs, trade secrets, etc.)
- SMEs must, however, also be in a position to innovate.
- One of the (many) negative side effects of proprietary positions is that research intensive large companies have oftentimes a comparative advantage, as they are more likely able to develop such proprietary positions, or acquire the necessary licences.
- In the NGT era, that implies many proprietary rights to navigate (platform technology, parts of platform technology, (polygenic) traits, etc.)
- That becomes increasingly difficult for follow-on innovators or even for breeders in general
- Some breeders might even inadvertently infringe those exclusive rights

Innovation incentives challenges

- However, NGT is not the only area where SMEs get confronted with large sets of patents (patent clusters, patent thickets, etc.)
 - Look at for instance SEPs
- Hence, NGT patent situation is not necessarily unique
- One could argue against the above that in the SEP “world”, implementing SEPs is different than using patented subject matter for breeding purposes.
 - There is some merit, but only some
- One could also argue that SEPs are different, because for plant innovations, there are two different IP rights (patents and PBRs, the latter having a qualified full breeders’ exemption)
- In the SEP context, many other problems arise which are dissimilar to plant innovations
 - Nevertheless, the choice in that area of technology has not been to exclude patents or make them unenforceable, but to ensure access

Solutions

- Regulatory clarity is key, as it is likely a prime driver of innovation
- That makes that trying to insert patent exclusions and/or limitations in regulatory frameworks is not a good idea
 - It delays negotiations, makes them very complex, and creates a lot of legal uncertainty
- Solution: keep the two apart
 - My view on the amendments by EP and other proposals floating: see above
 - My view on the Council negotiation position: see above

Solutions

- Assuming that IP rights are at least also in part a function of innovation, excluding NGT plant innovations from IP protection, making those rights unenforceable against follow-up innovation (e.g., full breeders' exemption) or limiting the scope of such innovations to the extent that the patent has no practical use might lead to less innovation
- The above must be put in context, however, because SMEs are also major innovators in this area of technology, and they are exactly the ones who face most of the drawbacks of those IP rights, in the absence of which they might thrive more and innovate more
- Regulatory and IP uncertainty might have made Europe less innovative in NGT innovations, compared to for instance the US and China
- Europe does not want to become a technology taker, as we then have to hope that we can gain access to the "right" innovation (biotic and antibiotic stresses of relevance for Europe)

Solutions

- How to solve this conundrum of stimulating innovation, without drastic and likely unproductive measures such as exclusions from patentability, or unenforceable patents, whilst at the same time allowing SMEs to thrive and innovate?
- A list of solutions in the short, medium and long term:
- ALLEA STATEMENT ON MEASURES TO EASE THE IMPACT OF THE IP SYSTEM ON NEW GENOMIC TECHNIQUES FOR CROP DEVELOPMENT:
<https://allea.org/portfolio-item/allea-statement-on-measures-to-ease-the-impact-of-the-ip-system-on-new-genomic-techniques-for-crop-development/>

Solutions

- Proposals to make patents non-enforceable by for instance introduction of full breeders' exemption and limiting scope of plant innovations will likely create much legal uncertainty, as they might conflict with TRIPS and/or the Biotech Directive 98/44/EC
- Patent exclusion and scope limitations require re-opening of the Biotech Directive, which will equally cause much legal uncertainty, and likely for many years to come
 - -> Furthermore, see what I said earlier re innovation incentives

Solutions

- The key word is ACCESS to the technology. If everyone can gain access to proprietary technology, then everyone can innovate
- How?
 - Transparency in terms of registration of proprietary positions (difficulty remains trade secrets)
 - Licensing (voluntary, mandatory licence of dependency, compulsory licensing)
 - Voluntary schemes have the disadvantage that limitations or other restrictions might “creep” into the system, and there is always risk of creating “barriers” for certain categories of licensees
 - Declare NGT technology as an essential technology, which could then trigger a FRAND style system, forcing all IP right holders to licence their proprietary technologies under fair and reasonable terms

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