

Future Challenges Regarding the International Regulation of IPRs and Biotechnology: The future of TRIPS

Symposium on Future Challenges of International Law:

The Way Forward in Patenting Biotechnology.

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WIPO, in cooperation with University of Berne and WTI

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outline

- The exceptions to patentability under TRIPS
 - A sounder, more representative empirical base: notifications and information gathering
- The 27.3b review process under TRIPS
 - Lessons from actual practice, and diversity of policy choices
 - The broadening focus of IP policymaking
- A change of emphasis in Doha
 - A new mandate on CBD/TK/‘relevant new developments’
- Current state of play
- Future directions

charting the trajectory

- The issue of biotechnology patentability under TRIPS presaged wider trends in IP law and policy in recent years
 - Early expectations about the 27.3b exceptions were that exceptions to patentability of certain life sciences inventions could be narrowed further or removed as part of the review process
 - This was the original rationale for the inclusion of a review process in the TRIPS text

charting the trajectory

- But the direction, tenor and content of the process have evolved considerably since then
 - Less emphasis on a linear scale – ‘stronger’ or ‘weaker’ protection – or ever-higher levels of protection
 - More emphasis on the broader policy context, on a wider array of interests and a wider normative perspective
 - e.g. the 27.3b ‘built-in’ mandate was one element referred to in the Doha Declaration mandate for TRIPS Council work on
 - TRIPS and the Convention on Biological Diversity
 - protection of traditional knowledge and folklore
 - these are not only *substantive issues* but also a *normative context* that go well beyond the relatively narrow confines of setting the scope of patentability of certain areas of subject matter (important though that question may be)

Looking again at 27.3b

Article 27 Patentable Subject Matter

3. Members may also exclude from patentability: ...
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Looking again at 27.3b

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- Entry into force: January 1, 1995
- Four-year trigger: January 1, 1999

Given the shift in focus under 27.3b, it is in this period, historically, that international IP policy making can be said to have taken a distinctive move towards

- a wider normative context
- a wider understanding of the policy role of the IP system
- a more active assertion of positive developing country interests (as compared with defensive interests)

Looking again at 27.3b

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Looking again at 27.3b

TRIPS Council work has produced a unique body of information as a reference for policymakers on biotech patentability issues:

- national laws and regulations notified under art 63.2 (IP/N/....)
- TRIPS Council review of notified materials (IP/Q...)
- questionnaire on implementation of 27.3b (IP/C/W/273)

Art. 27.3(b) in practice....

- IP/C/W/273/Rev.1 on patentability of biotech inventions and protection of plant varieties
- a record of TRIPS flexibilities in practice
 - and a policymaker's resource
- scope of patentable subject matter shaped by:
 - specific exclusions of subject matter (27.3b)
 - regional convergence (EPC)
 - morality and public policy exceptions (human body)
 - definition of 'invention' – e.g. excluding 'discoveries'
 - exclusions of double protection of plant varieties
 - diverse conceptions of morality and *ordre public*

The 'triplets'

A wider policy agenda since Doha:

- review of the provisions of Article 27.3 (b) in IP/C/W/369;
- relationship between TRIPS and the CBD in IP/C/W/368;
- the protection of traditional knowledge and folklore
 - In practice, policy debate has led to a convergence of these issues

The 'triplets':

presaging a wider policy perspective

- review of the provisions of Article 27.3 (b)
 - Biotech patentability and plant variety protection
- relationship between TRIPS and the CBD in IP/C/W/368;
 - Interface between IP law and policy, and broader public international law/public policy
- protection of traditional knowledge and folklore
 - A broader conceptual base, scope of interests and stakeholders, for the protection of IP

Doha and 'implementation'

- The Doha mandate and the trajectory of the disclosure issue
 - from questions over TRIPS consistency of an optional measure ...
 - ... to proposals for a mandatory requirement
- Broadening the equitable basis of the entitlement to apply for a patent?
- Integrating the patent system with public international law?
- An 'implementation' agenda and a recasting of the legal framework for the patent system

conclusion

- Biotech patentability under TRIPS has illustrated:
 - A broadening of focus in international IP policymaking from a linear debate of ‘stronger’ vs ‘weaker’ protection, to a richer policy context
 - The call for greater coherence with public policy areas such as biodiversity and food security
 - A ‘back to basics’ call for a return to the policy roots of the IP system, in this case looking at the essential principles and policy rationale of the patent system

conclusion

- Future directions:
 - Harvesting the lessons of 15 years of practical implementation of TRIPS
 - A richer, more geographically representative, better grounded empirical basis for policy discussion
 - Contextualizing the core principles of the patent system within a broader policy framework
 - A broader conception of the equitable basis of the patent and wider IP system, keying into...
 - ... a stronger conceptual foundation for protection of traditional knowledge systems through IP mechanisms