Handling the IPR, contractual and regulatory dimensions for safer innovation in nanotechnology

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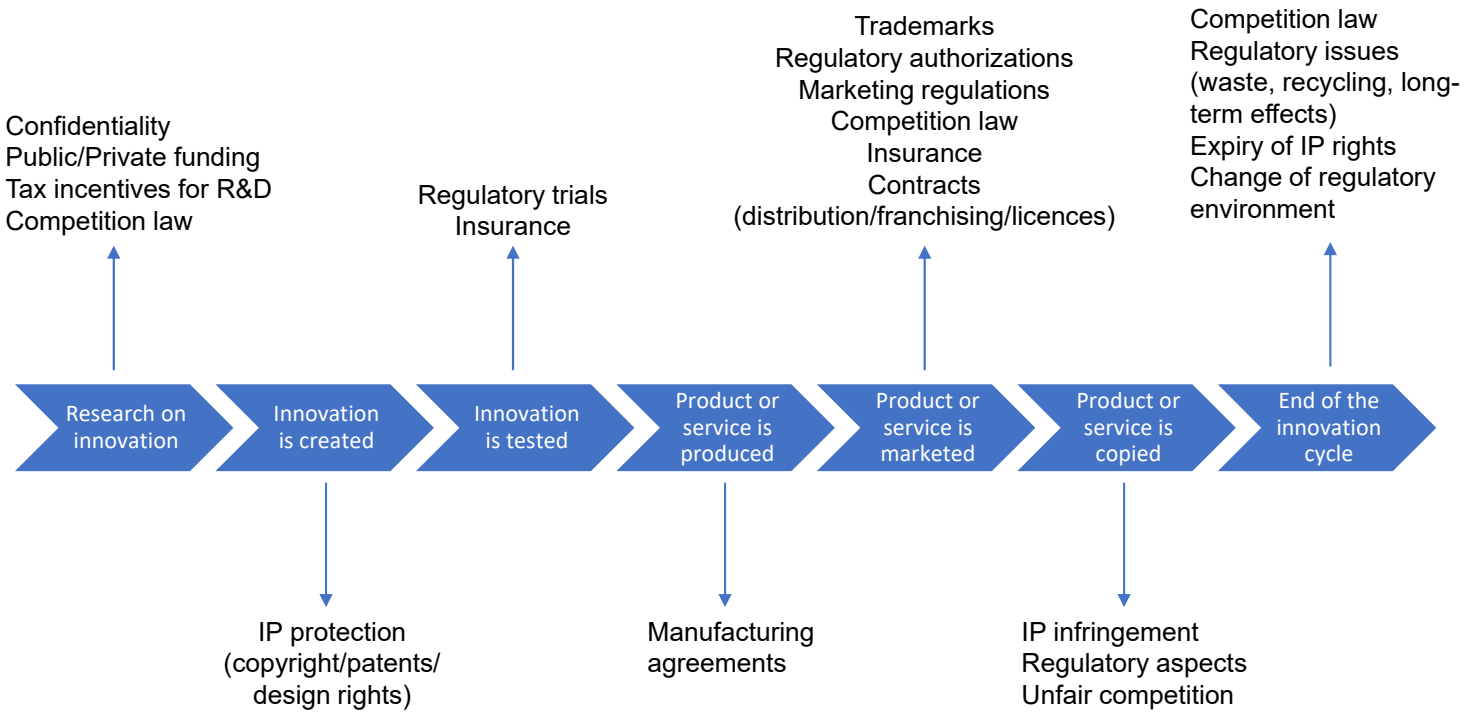
Introduction

- Safe innovation in nanotechnology goes beyond mere compliance with legally binding requirements : public trust is an objective
- Standards are better known by innovation actors than legal aspects : cooperation between lawyers/regulators and scientists is needed
- Integrating the different legal dimensions in the innovation cycles is a challenge for most innovation actors : lack of anticipation
- To go from lab to market, intellectual property rights (IPR), contractual and regulatory dimensions must be handled at the earliest stage possible to avoid legal barriers to innovation
- Safe by design is a good case study to understand how these legal dimensions should be handled

The legal aspects in the innovation cycle



I. The legal dimensions

IPR aspects in nanotechnology (1)

- There are no specific intellectual property rights for nanotechnology
- IPR are present at every stage of any cooperation project : background IP, foreground IP, sideground IP and postground IP
- Background IP has a limited legal status
  - For universities and public research organizations : *Commission Recommendation of 10 April 2008 on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations*
  - For other stakeholders : contractual solutions and the bargaining power of parties to any form of cooperation are key
- Background IP is sometimes insufficiently identified before the cooperation starts = issues during projects
- Background IP due diligence is recommended

IPR aspects in nanotechnology (2)

- Foreground IP legal issues are insufficiently anticipated
  - Joint ownership requires proper contractual framing
  - Taxation regimes of IP are often underestimated : better integration of taxation aspects in budget forecast of innovation revenue
- IPR costs are also underestimated
- Currently more focus on IP protection of innovation than on IP tools for certification on risk assessment
- Regulatory IP is an emerging topic : compulsory IP regimes and regulatory limits to IP protection

A complex regulatory environment

Legislation with specific provisions	Legislation with relevance for nanosafety issues
Food additives regulation	CLP Regulation
Active and intelligent materials food packaging regulation	RoHS directive
Plastic materials food packaging regulation	WEEE directive
Cosmetics Regulation	All occupational safety legislation
Food Information to Consumers Regulation	All product safety legislation
Foods for Specific Groups Regulations	All consumer information legislation
Biocidal Products Regulation	**Soft Law (non-binding)**
Novel Food Regulation	EU Code of conduct of 2008
Medical devices regulation	Recommendation of 18 October 2011 on the definition of nanomaterial
French nanoregister	**Standardisation**
Danish nanoregister	Role of ISO, CEN and national standards
Belgian nanoregister	**Regulatory guidance**
Swedish nanoregister	Guidance documents from regulators
REACH (as from January 2020)	Non-official guidance

Working in a complex regulatory environment

- Regulators at different levels (mostly EU and Member States levels)
- Regulatory guidance is better today than it used to be : keep in mind that guidance documents are not legally binding
- Legislation with specific provisions is easier to handle than legislation not specifically addressing risks with nanotechnology : need of interpretation methods of legislation and knowledge of the case law
- Dialogue with regulators is necessary to anticipate regulatory barriers to innovation
- Regulatory requirements are implicitly shape the IPR dimension

Understanding the contractual dimension

- Contractual governance must be tailor-made
- IPR do not protect everything : trade and technical secrets protection must be contractually anticipated
- To a certain extent, liability issues can be addressed in contracts
- Representations and warranties must be carefully written in technology transaction agreements
- Regulatory compliance and safe innovation principles/standards can be contractually implemented
- Non-technology regulatory requirements have an impact on contractual provisions (e.g. competition law and marketing authorisation regimes)

II. The legal dimensions of the « safe by design » concept

Safe by Design under EU law

- No legal definition of the Safe by Design concept under EU law = no regulatory certainty

- First occurrence of the concept in the European Commission's Communication on future networks and the internet (SEC(2008)2507)

  Paragraph 3.5 stating that *« it is clearly necessary to take steps now to make the internet of the future safe by design »*

- Second occurrence of the concept in the Commission decision of 7 March 2013 on the safety requirements to be met by European standards for certain seats for children pursuant to Directive 2001/95/EC on general product safety

  Annex – Section on « General Safety Requirements » : *« […] products need to be safe by design as far as possible, and therefore labels and warnings must not replace safety by design »*

Legal foundations of the Safe by Design concept

- In the field of environmental policy, article 191 (2) TFEU provides that the EU policy shall be based on the precautionary principle
- But the precautionary principle is not limited to protect the environment. Its scope is much wider and includes dangerous effects on human, animal or plant health – see the Commission Communication on the precautionary principle (COM (2000) 0001)
- Article 168 TFEU provides that a high level of human health protection shall be ensured
- Article 169 TFEU provides that a high level of consumer protection shall be ensured

Safe by Design and occupational safety

1989 Framework Directive on workers health and safety

- Among the principles of prevention every employer has to comply with, article 6 (2) (e) of the directive identifies *« adapting to technological progress »*
- Technological progress is not defined but it has been so far undisputed that introducing the use of nanomaterials would be considered as a technological progress
- Article 6 (3) (c) further obliges employers to *« ensure that the planning and introduction of new technologies are the subject of consultation with the workers and/ or their representatives, as regards the consequences of the choice of equipment, the working conditions and the working environment for the safety and health of workers »* - See also the Belgian nanoregister
- Article 12 also obliges employers to train workers when a new technology is introduced

But so far, how many employers did actually review their prevention measures, consulted their employees and trained them adequately ?

Safe by Design and consumer protection

2001 General Product Safety Directive

- Definition of « safe product » (art. 2 (b))

Any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

(i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

(ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;

(iv) the categories of consumers at risk when using the product, in particular children and the elderly.

- Obligation for producers to place only safe products on the market (art. 3.1)

- Quid over professional products that became consumer products: recital 10 of the directive provides that

Products which are designed exclusively for professional use but have subsequently migrated to the consumer market should be subject to the requirements of this Directive because they can pose risks to consumer health and safety when used under reasonably foreseeable conditions.

Safe by Design as an example of the need to handle IPR, regulatory and contractual dimensions at the same time

- Access to current knowledge : background IP is a challenge and questions to need for open innovation models
- Regulatory compliance is difficult : no legal regime of « safe by design » but the concept has been addressed in technology-neutral legal instruments
- Regulatory enforcement through contractual mechanisms : agreement of the meaning of « safe by design » in an innovation context
- Regulatory due diligence : is the innovation at stake capable of meeting the existing legal requirements and the agreed definition

Conclusion

- Need of better integration of the legal aspects is not only a matter of legal certainty but also of public trust for all stakeholders
- The « Fab Lab » model could be a solution to integrate lawyers and regulatory specialists at the earliest stage of the innovation cycles
- Standards are pre-normative requirements which can be further developped and implemented through contractual solutions
- More active role of citizens / consumers in the European Union both through legal enforcement mechanisms and consumer information tools : awareness of technological risks cannot be ignored and must receive credible answers

Thank you for your attention !

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