

Preface

As a Ph.D. Professor of Law, my opinion of this book has to be seen as that of a “non-expert” in the medical field. Nevertheless, I can surely testify to the absolute relevance of the theme to today’s perception of legal issues that arise from an interdisciplinary¹ approach of bioethical discussions regarding patenting nanomedicines.² Indeed, as the presentation states, “the multidisciplinary aspect of nanomedicine provides a unique opportunity for patenting the innovations. But at the same time it poses several challenges also.”

1. In 1959, Richard Feynman in Pasadena, told the world “[T]here is *plenty of room in the bottom*”. He continued: “What I want to talk about is the problem of manipulating and controlling things in a small scale ... What I have demonstrated is that there is room—that you can decrease the size of things in a practical way. I now want to show that there is plenty of room. I will not discuss how we are going to do it, but only what is possible in principle ... We are not doing it because we haven’t yet gotten around to it”.³

But it is important to stress that “the positive attitude to nanotechnology is based not on knowledge but on hope and fascination. The perceived risk is low because of a lack of vivid and frightening images of possible hazards. If new flashes were to link nanotechnology to concrete hazards or actual harm to people, attitudes might suddenly change”.⁴

¹ On this multidisciplinary context, SARGENT, Ted, *The Dance of Molecules How Nanotechnology is Changing our Lives*, New York: Thunder’s Mouse Press, 2006, p. xiii.

² About the emerging threats, FIOLHAIS, Carlos, “Nanotecnologia: o Futuro Vem Aí” in *Biologias na Noite* (coord: Amadeu Soares), Porto: Edições Afrontamento, 2007.

³ *Apud* ROUKES, Michael L. “Plenty of Room, Indeed” in *Understanding Nanotechnology* (coord: Sandy Fritz), New York: Warner Books, 2002, p. 18.

⁴ SIMONS, Johannes, ZIMMER, René, VIERBOOM, Carl, HÄRLEN, Ingo, HERTEL, Rolf, e BÖL, Gaby-Fleur, “The Slings and Arrows of Communication on Nanotechnology, *Journal of Nanoparticle Research*, 2009, n. 11, pp. 1555 e ss.

From this perspective, it is both a privilege and responsibility to be able to contribute to an objective review of this book, from a legal perspective.

2. The first guarantee of quality arises from the biosketch of the Editor. Presenting a brilliant *curriculum vitae* as a researcher, Eliana B. Souto also has a most singular interest in law regulation, which grants the scope of the book an in-depth and thorough text dissection and conceptual reasoning even from a comprehensive legal perspective. That circumstance ensures the high quality and commitment of the result to be presented.
3. It is stated that the book “is primarily addressed to professionals from the field of patent examiners, academics, researchers and scientists, as well as post graduating students, developing their research in the area of nanomedicines in general, and intellectual property in particular” and that “pharmaceutical companies are also potential targets since the book will also be a guideline in the design and process development of novel drug delivery systems, dealing with ethics, socio-political policies and regulatory aspects”. And it is also relevant that the target market is expected to be broad because of further recommendations and search for potential market players and stakeholders such as professional associations working in nanomedicines.
4. The “emerging threats” and “grant opportunities” of the nanomedicines are well explained in the scheme into which the book is divided. Not only is the *summa division* between Parts I and II,⁵ clear and helpful, but the scope of the chapters is also clearly pointed out.

Thus, from a legal perspective, the book seems to be a relevant collection of cases regarding the most recent developments in the nanomarket, which requires reflective attention from the legislative authorities and administrative and judicial bodies.

In all chapters the so-called ELSI (ethical, legal and social issues) to which bioethics must adjust are self explanatory.⁶

In fact, and again from a legal point of view, it is most essential to address questions that deal with the ethical fundamentals of legal rights, such as “protection of identity, privacy, obtaining informed consent and communicating benefits and risks”. Given the scenario of limited information being available, we must question the validity of some medical uses and patenting.⁷

⁵ Regarding this issue, OSTROWSKI, Alexis D., MARTIN, Tyronne, CONTI, Joseph, HURT, Indy, e HARTHORN, Barbara Herr, “Nanotoxicology: Characterizing the Scientific Literature, 2000–2007”, *Journal of Nanoparticle Research*, 2009, n. 11, p. 255 and SAWANT, Rishikesh M., SAWANT, Rupa R., GULTEPE, Evin, NAGESHA, Dattatri, PAPAHADJOPOULOS-STERNBERG, Brigitte, SRIDHAR, Srinivas, e TORCHILIN, Vladimir P., “Nanosized Cancer Cell-target Polymeric Immunomicelles Loaded with Superparamagnetic Iron Oxide Nanoparticles”, *Journal of Nanoparticle Research*, 2009, n. 11, pp. 1777 e ss.

⁶ CORMICK, Craig, “Why Do We Need to Know What the Public Thinks About Nanotechnology?”, *Nanoethics*, 2009, n. 3, p. 167.

⁷ MEILI, Christoph, “The ‘Nano Information Pyramid’ Could Help to Solve the ‘No Data—no Market’—Problem of Nanotechnologies”, in “No Data, no Market?” Challenges to Nano-Information and Nano-Communication Along the Value Chain, 5th International “NanoRegulation” Conference 25–26 November 2009, Rapperswil (Switzerland) Conference Report (coord: Stephan Knébel e Christoph Meili), Switzerland: The Innovation Society, 2010, p. 2.

Furthermore, it is important to question the relationship between intellectual property⁸ and the limits to science activity (Part I, Chaps. 1 and 2). In fact, it is not only a question of deciding the regulatory framework (Part I, Chap. 3⁹) but also, more thoroughly, questioning its ethical roots.

5. In addition to the consideration of health and safety precautions¹⁰ in the Chap. 3 of Part I, it would also be important to address the issues of consumer safety,¹¹ particularly when we are considering synthetic nanoparticles (as “engineered or manufactured nanoparticles”) or buckyballs (as buckminsterfullerenes).

The application and lessons that arise from the precautionary principle must also be brought into light.¹²

⁸ KOEPESELL, David, “Let’s Get Small: An Introduction to Transitional Issues in Nanotech and Intellectual Property”, *Nanoethics*, 2009, 3, pp. 157 e ss., and SEEMAN, Nadrian C., “Nanotechnology and the Double Helix”, *Scientific American*, June 2004, pp.35 e ss.

⁹ About this issue LEE, Robert, and STOKES, Elen, “Twenty-FirstCentury Novel: Regulating Nanotechnologies”, *Journal of Environmental Law*, 2009, vol. 21, n. 3, pp. 469 e ss.; CALSTER, Geert van, “Regulating Nanotechnology in the European Union”, *European Law Review*, Agosto – Setembro de 2006, pp. 238 e ss and JOHNSON, Robbin, “Emerging Technologies Oversight: Research, Regulation, and Commercialization”, *Journal of Medical Ethics*, vol. 37, n. 4, Inverno de 2009, pp. 587 e ss.

One of the most important legal instruments applicable to nanomaterials is Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). REACH provides a general framework of the manufacture, marketing and use of chemicals within the European Union.

¹⁰ HOWARD, John, and Murashov, Vladimis, “National Nanotechnology Partnership to Protect Workers”, *Journal of Nanoparticle Research*, 2009, n. 11, p. 1674. Also confront Working Conditions Committee of the Social and Economic Council of the Netherlands, *Nanoparticles in the Workplace: Health and Safety Precautions*, 2008.

¹¹ “Nanomaterials in Consumer Products, Availability on the European Market and Adequacy of the Regulatory Framework”, RIVM/SIR Advisory Report 11014, European Parliament, Policy Department Economic and Scientific Policy (April 2007), p. iii.

¹² About this specific issue, Agência Europeia do Ambiente, *Late Lessons from Early Warnings: the Precautionary Principle 1896–2000*, Copenhagen, 2001; CASTAING, Cécile, “La mise en œuvre du principe de précaution dans le cadre du référé suspension”, in: *Actualité Juridique Droit Administratif*, n 43, 15 de Décembre de 2003; DOVERS, Stephen, “Precautionary policy assessment for sustainability”, in: *Implementing the Precautionary Principle. Perspectives and Prospects*, Edward Elgar, Cheltenham, 2008; FISHER, Elisabeth, Judith Jones, René von Schomberg, “Implementing the Precautionary Principle. Perspectives and Prospects”, Edward Elgar, Cheltenham, 2008; O’RIORDAN, Timothy e James Cameron, “Interpreting the Precautionary Principle”, *Earthscan*, 1994; SUNSTEIN, Cass R., “Beyond the Precautionary Principle”, *University of Pennsylvania Law Review*, Janeiro de 2003, p. 1004 and SUNSTEIN, Cass R. (2005), *Laws of Fear Beyond the Precautionary Principle*, Cambridge: Cambridge University Press, pp. 36 e ss.

The investment policies and the patenting of nanomedicines in underdeveloped countries¹³ must also be addressed, particularly when related to the issue of nano-waste.¹⁴

It is clear that all those issues mentioned here are central and not merely peripheral to the objective(s) of the study, hence the usefulness of this book to a legal professional who needs to master the ultimate subject of legal reasoning and expertise.¹⁵

Porto, Portugal, 2012

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¹³ FOLADORI, Guillermo, INVERNIZZI, Noela and ZÀYAGO, Edgar, “Two Dimensions of the Ethical Problems Related to Nanotechnology”, *Nanoethics*, 2009, n. 3, p. 123; JAMISON, Andrew, “Can Nanotechnology Be Just? On Nanotechnology and the Emerging Movement for Global Justice”, *Nanoethics*, 2009, n. 3, pp. 129; KISS, Alexandre, “L’Irreversibilité et le Droit des Generations Futures”, in: *Révue Juridique de l’Environnement*, numéro spécial, 1998 and NISSEN, Ulrik B., “Justice in Nanotechnological Development (Symposium Introduction)”, *Nanoethics*, 2009, n. 3, p. 119.

¹⁴ BUTTI, Luciano, “Harzardous Waste Manegement and the Precautionary Principle”, *Waste Management*, 29 (2009), pp. 2415–2416 and TELLENBACH, Mathias, “How to Treat Nano-Waste: Challenges and Information Needs along the Value Chain” in “No Data, no Market?” Challenges to Nano-Information and Nano-Communication Along the Value Chain, 5th International “NanoRegulation” Conference 25–26 November 2009, Rapperswil (Switzerland) Conference Report (coord: Stephan Knébel e Christoph Meili), Switzerland: The Innovation Society, 2010, p. 32.

¹⁵ WILLIAMS, Linda and ADAMS, Wade, “Nanotechnology Demystified”, New York: McGraw-Hill, pp. 3 e ss.

Patenting Nanomedicines
Legal Aspects, Intellectual Property and Grant
Opportunities

Souto, E.B. (Ed.)

2012, XXIV, 460 p., Hardcover

ISBN: 978-3-642-29264-4