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International Biomedical Law in Search for Its Normative Status

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Summary: 1. Introduction. 2. International biomedical law in light of fragmentation of international law: a) Institutional proliferation of biomedical law; b) International biomedical law as a 'self-contained regime'? c) Relative normativity of international biomedical law? 3. International biomedical law in the context of global legal pluralism. 4. Conclusions: studies into global biomedical law?

Abstract: The broad and multifaceted problem of global health law and global health governance has been attracting increasing attention in the last few decades. The global community has failed to establish international legal regime that deals comprehensively with the 'technological revolution'. The latter has posed complex questions to regions of the world with widely differing cultural perspectives. At the same time, an increasing number of governmental and non-state actors have become significantly involved in the sector. They use legal, political, and other forms of decision-making that result in regulatory instruments of contrasting normative status. Law created in this heterogeneous environment has been said to be fragmented, inconsistent, and exacerbating uncertainties. Therefore, claims have been made that a centralised and institutionalised system would help address the problems of transparency, legitimacy and efficiency. Nevertheless, little scholarly consideration is paid to the normative status of international biomedical law. This paper explores whether formalisation and 'constitutionalisation' of biomedical law are indeed inevitable for its establishment as a separate regulatory regime. It does so by analysing the proliferation of biomedical law in light of two the theory of fragmentation and the theory of global legal pluralism. Investigating the problem in this way helps determine the theoretical framework and methodology of future studies of biomedical law at the international level. This in turn should help its future development in a more consistent and harmonised manner.

Keywords: Biomedical Law, Health Law, Public International Law, Genetics, Soft law, Globalisation, Fragmentation of International Law

‘There is no one issue or perspective that provides the path to the future. Rather we must seek new connections and new patterns (...) new possibilities.’¹

I. INTRODUCTION

The broad and multifaceted problem of global health law and global health governance has been attracting increasing attention in the last few decades.² Global health law is usually understood to regulate aspects of infectious and non-communicable diseases, international trade and control of safety of health services, food and pharmaceuticals, addictive substances such as tobacco and narcotics, as well as biomedical science.³ The regulation of biotechnology and

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¹ B. Bennett. 2008. *Health Law's Kaleidoscope: Health Law Rights in a Global Age*, Ashgate, 119.

² O. Aginam. 2005. *Global health governance: international law and public health in a divided world*, University of Toronto Press Inc.; L. O. Gostin and E. A. Mok, Grand challenges in global health governance, *British Medical Bulletin* 2009; 90: 7–18, DOI:10.1093/bmb/ldp014; J.Prah Ruger, Normative Foundations of Global Health Law, *Georgetown Law Journal*, 2008; 96:423. L.O. Gostin, A. L. Taylor, Global Health Law: A Definition and Grand Challenges, *Public Health Ethics* 2008; 1: 1: 53–63; B. Bennett. 2008. *Health Law's Kaleidoscope: Health Law Rights in a Global Age*, Ashgate.

³ See F. Grad. Public Health Law: Its Forms, Functions, Futures and Ethical Parameters, *International Digest of Health Legislation* 1998; 49: 19-40. This paper will often refer to global health law, and occasionally to environmental law. This is because the latter two fields have so far attracted much more academic attention; since they are overlapping analogies can be sought and conclusions can be drawn for international biomedical law.

biomedicine constitutes a special – extremely fast-changing and contentious – area within public health law. The application of new technologies in biomedicine has posed complex questions to regions of the world with widely differing cultural perspectives. Despite many attempts to regulate this area, the global community has failed to establish international legal regime that deals comprehensively with the ‘technological revolution’⁴. At the same time, an increasing number of governmental and non-state actors have become significantly involved in the sector. Non-state actors especially, including a wide range of nongovernmental organisations, agencies, foundations, research and other professional networks, religious groups, and for-profit organisations such as pharmaceutical industry, have had an increasingly powerful influence on international health policy and global lawmaking.⁵ The members of this complex network use legal, political, and various other forms of decision-making that result in regulatory instruments of contrasting normative status.

Law created in this heterogeneous environment has been said to be developing in a fragmented, uncoordinated, amorphous, hence inconsistent, inefficient, and incomplete manner.⁶ Such a fractured legal process exacerbates uncertainties about the legal regime that governs biotechnological developments. Therefore, proposals have been formulated for more effective separation⁷, coordination⁸, or subsumption⁹ of different regulatory remits. Indeed, claims have been

⁴ R. Brownsword. 2008. *Rights, Regulation and the Technological Revolution*, Oxford University Press.

⁵ K. Buse, G. Walt, Global public–private health partnerships: Part I — a new development in health? *Bulletin of the World Health Organization* 2000, 78: 549–561 and K. Buse, G. Walt, Global public–private health partnerships: Part II — what are the issues for global governance? *Bulletin of the World Health Organization* 2000, 78: 699–709.

⁶ A. Taylor. Governing Globalization of Public Health, *The Journal of Law, Medicine and Ethics* 2004, 500-508: 500, J.P Ruger, D. Yach. The Global Role of the World Health Organization, *Global Health Governance* 2008 /2009, 2:2.

⁷ J.Williams. UNESCO’s proposed declaration on bioethics and human rights. A bland compromise, *Developing World Bioethics. Special Issue: Reflections on the UNESCO Draft Declaration on Bioethics and Human Rights* 2005; 5: 210-5.

⁸ J.Prah Ruger, D. Yach. The Global Role of the World Health Organization, *Global Health Governance*. 2008 /2009, 2:2: 1-11; A.Taylor, Global governance, international health law and WHO: looking towards the future,

made that a formalised, centralised, and institutionalised system would help address the problems of transparency and legitimacy and deal with bioethical issues at the international level more effectively. These claims usually rest on an implicit assumption that international norms concerning biotechnology and biomedicine can be recognised as a new type of autonomous regulatory regime – *in statu nascendi* – that is on its way to its constitutionalisation.¹⁰ However, despite the growing belief that conventional international law can serve as a dynamic tool for multilateral health cooperation in an increasingly interdependent world, little scholarly consideration is paid to the institutional basis and the normative status of international biomedical law.

This paper aims to address this gap. In particular it explores whether formalisation, centralisation, and ‘constitutionalisation’ of biomedical law are indeed inevitable for its establishment as a separate regulatory regime. It does so by analysing the institutional and normative proliferation of biomedical law at the global level in light of two theories of public international law, namely the theory of fragmentation¹¹ and the theory of global legal pluralism¹². While the first addresses the recent developments in international law; the second offers an

Bulletin of the World Health Organization 2002, 80: 12; A.Taylor, Governing Globalization of Public Health, *The Journal of Law, Medicine and Ethics* 2004, 32: 3, 500-508: 500.

⁹ T.A. Faunce, Will International Human Rights Subsume Medical Ethics? Intersections in the UNESCO Universal Bioethics Declaration, *Journal of Medical Ethics* 2009, 31:173. Cf.: R. Ashcroft, Could Human Rights Supersede Bioethics?, *Human Rights Law Review* 2010, DOI: 10.1093/hrlr/ngq037.

¹⁰ R. Andorno, Dignity of the person in the light of international biomedical law, *Medicina e Morale* 2005; 1: 91-105. Also: F. Francioni, Genetic Resources, Biotechnology and Human Rights: The International Legal Framework, *EUI Working Paper LAW* 2006; 17, available at: <http://cadmus.eui.eu/handle/1814/6070>. Accessed on 25.10.2010. [Accessed on 1 Nov 2010]. The problem of regimes’ collision has been extensively analysed by A. Fischer-Lescano, G.Teubner, Regime collisions: the vain search for legal unity in the fragmentation of global law, *Michigan Journal of International Law* 2004; 25: 999-1045.

¹¹ M. Koskenniemi, P. Leino, Fragmentation of International Law? Postmodern Anxieties, *Leiden Journal of International Law* 2002; 15:3:553-579.

¹² A. Fischer-Lescano, G.Teubner, Regime collisions: the vain search for legal unity in the fragmentation of global law, *Michigan Journal of International Law* 2004; 25: 999-1045.

analysis of the developments of law in general in the era of globalisation. Although not without limitations, both provide a helpful tool in addressing the issue of biomedical law and its normative status at the global level. Analysis of the current status and scope of challenges in terms of conventional perspectives upon legal regulation is considered alongside attempt to theorise the fluidity and complexity of the reality of the modern global condition made by scholars such as Günter Teubner and Martti Koskenniemi. Investigating the problem in this way helps determine the theoretical framework and methodology of future studies of biomedical law at the international level. This in turn should help its future development in a more consistent and harmonised manner. As these issues exceed the limits of an academic article, the modest aim of this paper is to bring to light a new dimension of analyses and clarify the agenda for future research.

II. INTERNATIONAL BIOMEDICAL LAW IN LIGHT OF FRAGMENTATION OF INTERNATIONAL LAW

a) Institutional proliferation of biomedical law

The universal influence of new technologies has undermined conventional territorial boundaries and emerged as global and common objects of regulation. Consequently, parts of medical, health and environmental law are predominantly set at supranational, international and transnational institutional levels.¹³ This has determined further developments. Firstly, more and more governmental organisations have taken interest in issues of health and biomedicine. The UN Commission for Human Rights, UNESCO, WHO, WTO, UNEP, and recently also the OECD have all contributed to the elaboration of international instruments in the rapidly evolving field of biomedical science. While the UN Commission for Human Rights has adopted resolutions pertaining to human rights and bioethics with implications for public health and biomedicine¹⁴,

¹³ I-J. Sand. 2004. Polycontextuality as an Alternative to Constitutionalism. In: *Transnational Governance ad Constitutionalism*, Ch. Joerges, I-J. Sand, G. Teubner (eds), Hart Publishing: 55.

¹⁴ UN Commission for Human Rights, Resolution on Human Rights and Bioethics 2003/69, 2001/71, 1999/63, 1997/71, 1993/91, available at:

UNESCO was drafting the three major Declarations of 1997, 2003, and 2005.¹⁵ At the same time, in the years of the Human Genome Project (HGP), WHO started preparing separate, competing reports on genomics, health, and intellectual property rights.¹⁶ It was not until 2003 that the WHO and UNESCO established a special Inter-Agency Committee on Bioethics¹⁷ to address potential tensions and to facilitate dialogue and compliance between the documents issued by both organisations. Other conflicts, this time between the WTO and the WHO have been revealed in the context of disputes over access to medicines emerging in relation to the Doha Declaration¹⁸ on the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement¹⁹ and Public Health.²⁰

[http://www.unhchr.ch/huridocda/huridoca.nsf/\(Symbol\)/E.CN.4.RES.2001.71.En?Opendocument](http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.RES.2001.71.En?Opendocument). [Accessed 1 Nov 2010].

¹⁵ Universal Declaration on the Human Genome and Human Rights (unanimously and by acclamation on 11 Nov 1997), International Declaration on Human Genetic Data (16 Oct 2003), Universal Declaration on Bioethics and Human Rights (19 Oct 2005), available via: <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/about-bioethics/>. [Accessed 29 Oct 2010].

¹⁶ E.g. WHO. *Control of hereditary disorders: Report of WHO Scientific Meeting 1996*, World Health Assembly *Statement on "Cloning in Human Reproduction"* 1997, WHO, *Statement of the WHO Expert Consultation on New Developments in Human Genetics*, 21 Jul 2000, WHO/HGN/WG/00.3, available at: http://whqlibdoc.who.int/hq/2000/WHO_HGN_WG_00.3.pdf, Report of the Advisory Committee on Health Research: *Genomics and World Health 2002*, Review of Ethical Principles in Medical Genetics 2003; available via: <http://www.who.int/topics/genetics/en/>. [Accessed 29 Oct 2010].

¹⁷ Member organizations are listed at: www.who.int/ethics/about/unintercomm/en/

¹⁸ Doha Declaration on the TRIPS Agreement and Public Health, adopted in Doha, Qatar on 14 November 2001, WT/MIN(01)/DEC/2; available via: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. Accessed on 29.10.2010

¹⁹ The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco, 15 Apr 1994, available at: http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm. [Accessed 29 Oct 2010].

²⁰ A. Fischer-Lescano, G. Teubner. Regime collisions: the vain search for legal unity in the fragmentation of global law, *Michigan Journal of International Law* 2004, 25: 999-1045. For a detailed discussion on the medicines decision: F.M. Abbott. The WTO Medicines Decision: World Pharmaceutical Trade and the

These disputes serve as an example of tensions between different rationalities, intellectual traditions – and corporate logic – of different organisations within the ever expanding UN system, characterised by a multiplication of committees and sub-committees and new administrative structures such as programmes and funds.²¹ These complex structures are then supplemented by regional organisations, such as the Council of Europe and the European Union which so far have probably been the most active and influential regulators of biomedicine and biotechnology worldwide.²² However, this is only a part of the overall picture of the international governance of biomedicine.

The new emerging international health framework is no longer dominated by a few intergovernmental organisations, but consists of numerous global health actors; some with finance-policy-operational functions²³, and others with professional-standards-setting functions. Even business corporations seem to be accepting a more prominent role in international law.²⁴ Again,

Protection of Public Health, *American Journal of International Law* 2005, 99: 317-358; D. J. Gervais. Trips, Doha and Traditional Knowledge, *Journal of World International Property* 2003, 6: 403-419.

²¹ The latest example of this institutional incoherence is the fight against HIV/AIDS. The Joint UN Programme on HIV and AIDS, UNAIDS, which was recently established, has been given responsibilities which should normally fall within the framework of the WHO mandate. Subsequently, the Global Fund, dedicated to the same goals, has been recently created outside the UN. See: P. de Sanarclens. 2007. The United Nation as a social and economic regulator, In *Regulating Globalisation, Critical Approaches to Global Governance*, P. de Sanarclens, A. Kazancigli (eds), United Nations University: 8-35.

²² Their regulatory activities are discussed below.

²³ The World Economic Forum has sponsored deliberations about HIV/AIDS, tobacco control and vaccines to obesity. The UN Security Council has been involved in issues related to HIV/AIDS. Finally the private sector, for- and non-profit organisations developed as a force in international health as relatively new, yet important players. See: J.P Ruger, D. Yach. The Global Role of the World Health Organization, *Global Health Governance*, 2008 /2009, 2:2: 1-11.

²⁴ See: UN Sub-Commission on the Promotion and Protection of Human Rights with the adoption in 2003 of a set of norms of the responsibility of transnational corporations and other business enterprises with regard to human rights, 26 Aug 2003 (E/CN.4/Sub.2/2003/12/Rev.2), available at:

non-state actors are equally active at regional levels.²⁵ This complex network offers an institutional alternative which offsets the weight of states and intergovernmental organisations. Unfortunately, the proliferation of NGOs has increased the difficulty of achieving coherence and coordination in the social, economic, and humanitarian fields.²⁶ The appearance of standard-setting organizations raises closely related questions with regard the scope of regulatory authority, as well as the legitimacy of grounds and enforcement.²⁷ At the same time, rapid advances in science, coupled with strong promises of local medical and economic gains reveal competing ambitions between non-state actors.

Such competition is well reflected in the regulatory activities of several non-governmental organisations undertaken at the end of the 20th - and the beginning of the 21st century. For instance, the Council for International Organizations of Medical Sciences (CIOMS)²⁸ and the World Medical

[http://www.unhcr.ch/huridocda/huridoca.nsf/\(Symbol\)/E.CN.4.Sub.2.2003.12.Rev.2.En](http://www.unhcr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2003.12.Rev.2.En). [Accessed 25 Oct 2010].

²⁵ Eg. Regional non-state regulators in Europe include for instance: European Forum for Good Clinical Practice, European Medical Research Councils, European Society of Human Reproduction and Embryology, European Committee for Standardization.

²⁶ P. de Sanarclens. 2007. The United Nation as a social and economic regulator, In *Regulating Globalisation, Critical Approaches to Global Governance*, P. de Sanarclens, A. Kazancigli (eds), United Nations University: 8-35.

²⁷ N. Brunsson, B. Jacobsson 2000, *A World of Standards*, Oxford: Oxford University Press; H. Schepel, 2004, Constituting Private Governance Regimes: Standards Bodies in American Law, In: *Transnational Governance and Constitutionalism*, Joerges, Sand and Teubner (eds), Oxford: Hart Publishing: 161–88; P. Zumbasen. Transnational Law, *Comparative Research in Law and Political Economy*, Research Paper 2008; 2: 4 (originally in *Encyclopedia of Comparative Law* J. Smits (ed.) 2006).

²⁸ Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research involving human subjects* (2002) (enumerating a set of ethical guidelines for biomedical research dealing with topics like confidentiality, informed consent, and the duty to provide health services).

Association (WMA)²⁹, apart from adopting general rules concerning medical research involving human subjects, have both engaged with the developments in the science of genetics issuing respectively, the Declaration on Inuyama on Human Genome Mapping, Genetic Screening and Gene Therapy (1990), and the Statement on Genetics and Medicine (2005 and 2009).³⁰ At the same time, the Ethical, Legal and Social Issues Committee of the Human Genome Organisation (HUOGO) prepared the Statement on the principled conduct of genetics research (1996) which had also played a role in shaping the debate and research practices about genetics.³¹ Parallel to the multitude of actors, whose status can only inadequately be reassigned to well-known public/private distinctions, the biomedical world is witnessing the emergence of a large, decentralized and non-harmonized body of norms.

This proliferation of multilateral institutions with overlapping ambitions and legal authority has resulted in the serious criticism that the multitude of international organisations sharing lawmaking authority with other actors reflects an increasingly fragmented, and incongruent global health agenda.³² As rightly summarised by Alan Taylor: ‘dramatic advances in the field of biomedical

²⁹ World Medical Association *Ethical Principles for Medical Research Involving Human Subjects*, Declaration of Helsinki, Jun1964 (as amended by 59th WMA General Assembly, Seoul, October 2008)(providing guidelines for medical professionals around the world who conduct experimental research with human subjects), available at <http://www.wma.net/e/>. [Accessed 29 Oct 2010].

³⁰ WMA, *Statement on Genetics and Medicine*, Santiago, Chile, Oct 2005 and amended by the WMA General Assembly, New Delhi, India, Oct 2009, replaced the *Declaration on the Human Genome Project*, adopted by the 44th World Medical Assembly Marbella, Spain, Sep 1992; available at: <http://www.wma.net/en/30publications/10policies/g11/index.html>. [Accessed on 30 Oct 2010].

³¹ Human Genome Organisation; Ethical, Legal, and Social Issues Committee; *Statement on the Principled Conduct of Genetics Research 1996*, available at: <http://www1.umn.edu/humanrts/instree/geneticsresearch.html>. [Accessed 30 Oct 2010].

³² J.P Ruger, D. Yach, The Global Role of the World Health Organization, *Global Health Governance*, 2008 /2009, 2:2. L.O. Gostin, A. L. Taylor, Global Health Law: A Definition and Grand Challenges, *Public Health Ethics* 2008;1:1: 53–63; A. Taylor, Governing Globalization of Public Health, *The Journal of Law, Medicine and Ethics*, 2004; 500-508: 504.

science have recently triggered numerous, uncoordinated regional and global initiatives, which, while undertaken without meaningful consultation, coordination or planning, obscure rather than rationalised the global legal framework.³³ This development can be seen as an impediment rather than an incentive for international scientific co-operation, making it extremely difficult for doctors, researchers, and private companies to determine which governance regime is applicable in any particular case, and which prevails when conflicts occur. It may also become confusing for national legislators, who, when trying to regulate particular problems, look for clear and coherent international guidelines. Many differences in the legal requirements at the national level remain and militate against networking. Consequently, the proliferation and specialization of laws leads to a multiplication of standards and terminology.³⁴ Quite apart from the varying interests of different societies, there are often 'different starting points for the very idea of regulation'.³⁵ This criticism carries direct parallels with a critique of public international law. Institutional proliferation of biomedical law at the international level resulting in potential tensions between regulatory instruments can be seen, either as a reflection, or an element of a wider phenomenon of

³³ A. Taylor. Governing Globalization of Public Health, *The Journal of Law, Medicine and Ethics*, 2004, 500-508: 504. See also: J.P Ruger, D. Yach, The Global Role of the World Health Organization, *Global Health Governance*, 2008 /2009, 2:2. L.O. Gostin, A. L. Taylor, Global Health Law: A Definition and Grand Challenges, *Public Health Ethics* 2008;1:1: 53–63.

³⁴ B.M. Knoppers, M. H Abdul-Rahman, and K. Bédard, Genomic Databases and International Collaboration, *King's Law Journal* 2007; 18: 291–311; A. Cambon-Thomsen, C. Sallée, E. Rial-Sebbag and B.M. Knoppers, Populational Genetic Databases : Is a Specific Ethical and Legal Framework Necessary? *GenEdit* 2005; 3:1: 1-13; S. MC Gibbons, J. Kaye. Governing Genetic Databases: Collection, Storage and Use, *King's Law Journal* 2007; 18: 201–208.

³⁵ M.D. Kirby, 1999. *Human Freedom and Human Genome: The Ten Rules of Valencia*, cited by: R.Brownsword. 2008. *Rights, Regulation, and the Technological Revolution*, Oxford University Press: 295. Also: M.D. Kirby. The Human Genome Project – Promise and Problems, *Journal of Contemporary Health Law and Policy* 1994; 11:1.

'fragmentation of international law'.³⁶ The analysis of this phenomenon offers important insights into the development of the international biomedical law and its role within 'general' international law.

b) International biomedical law as a 'self-contained regime'?

According to the special Study Group of the UN International Law Commission (ILC) chaired by Martti Koskenniemi, the phenomenon of fragmentation of international law is related with the increasing specialization and related autonomization of parts of society, called by sociologists 'functional differentiation'.³⁷ Such differentiation has been accompanied by the emergence of specialized and (relatively) autonomous rules or rule-complexes, legal institutions, and spheres of legal practice that have no clear relationship to each other. From a tool dedicated to the regulation of formal diplomacy, international law has expanded to deal with the most varied kinds of international activity, from trade to environmental protection, from human rights to scientific and technological cooperation. This expansion has taken place in an uncoordinated fashion and resulted in diversity of international law both in substance and procedure.³⁸

In substance, international law is fragmented, firstly, along functionally defined issue-areas such as human rights law, trade law, environmental law, humanitarian law, criminal law and the law of the sea. These issue-areas, also referred to as '(self-contained) regimes', often correspond to functionally specialized international organizations such as the WTO, UNEP, WIPO, ILO and WHO. Fragmentation of, or between, those regimes becomes particularly contentious when such functionally specialized regimes claim autonomy either from each other (say, the WTO disregarding the WIPO), or from general international law. Secondly, international law can be fragmented along

³⁶ International Law Commission, Study Group on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law, 58th Session, Geneva May-Aug 2006, (A/CN.4/L.702), para. 483; available at: http://untreaty.un.org/ilc/guide/1_9.htm. [Accessed 5 Nov 2010]

³⁷ *Ibid.*

³⁸ J. Pauwelyn, 2009. Fragmentation of International Law, IN: *Max Planck Encyclopedia of Public International Law*, Heidelberg and Oxford University Press.

geographical or regional lines (EU, NAFTA). Finally, these two forms of fragmentation can lead to a third, when parallel or conflicting norms or obligations in the same issue-area such as trade or environmental protection apply to the same states or subjects of international law. Thereafter, fragmentation in procedure arises most prominently in the context of multiple international courts and tribunals.³⁹ The ILC Study Group acknowledged that the emergence of new and special types of law creates problems of coherence and consistency in the interpretation and development of international law; '[a]nswers to legal questions become dependent on whom you ask, what rule system is your focus on.'⁴⁰ Each rule-complex or 'regime' comes with its own principles, its own form of expertise and its own 'ethos', not necessarily identical to the ethos of neighboring specialization. Very often new rules or regimes develop precisely in order to deviate from what was earlier provided by the general law. When such deviations become general and frequent, the unity of the law suffers.⁴¹

However, the ILC concluded – echoing earlier works of Koskenniemi – that the emergence of special treaty-regimes has not seriously undermined legal security, predictability or the equality of legal subjects. International law is a decentralised system and as such has long had to face the problem of relating together a variety of rules derived from general treaties, specific treaties and customary law. What characterises international law is a strong presumption against normative conflict.⁴² It uses several generally accepted techniques of interpretation and conflict resolution

³⁹ A. Zimmermann, R. Hofmann (eds.) 2006. *Unity and Diversity in International Law*, Berlin: Duncker und Humblot.

⁴⁰ International Law Commission, Study Group on Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law, 58th Session, Geneva May-Aug 2006, (A/CN.4/L.702), para 365.

⁴¹ International Law Commission, Conclusions of the work of the Study Group on the Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law, 58th Session, Geneva May-Aug 2006, (A/61/10, para. 14 (1)), *Yearbook of the International Law Commission*, 2006; II: 2.

⁴² M.Koskenniemi, P.Leino. Fragmentation of International Law? Postmodern Anxieties, *Leiden Journal of International Law* 2002; 15: 553-579.

such as the maxim *lex specialis derogat legi generali* or *lex posterior derogate legi priori*.⁴³ Nevertheless, it has been noted that increasing attention is to be given to the collision of norms and regimes as well as the rules, methods and techniques for dealing with such collisions. These conclusions allow for some optimism as to the effects that the variety of legal rules may have on international biomedical law. However, they also shift the focus of attention onto 'self-contained regimes', for only such regimes, provided certain criteria are met, may seek precedence over general rules of international law. In light of these comments, it becomes crucial whether international biomedical law indeed constitutes a new 'self-contained' regime. A closer look at the definition of such regimes sheds doubt on any such assertion.

A 'self-contained regime', as understood by the ILC, is a group of rules and principles concerned with a particular subject matter that is applicable as *lex specialis*, i.e. that is able to seek precedence in regard to general international law.⁴⁴ Such special regimes often have their own institutions to administer the relevant rules. Firstly, they may be constituted by a special set of (secondary) rules concerning breach of a particular group of (primary) rules (e.g. diplomatic law).⁴⁵ Secondly, a special regime is formed by a set of special rules, including rights and obligations, relating to a special subject matter together with the rules for the creation, interpretation, application, modification, or termination of those rules. Such a special regime may emerge on the basis of a single treaty (e.g. a treaty on the regulation of the uses of a particular weapon or tobacco control), several treaties, or treaty plus non-treaty developments (such as subsequent practice or customary law). Thirdly, all the rules and principles that regulate a certain problem area may be

⁴³ These two Latin maxims translate to: law governing a specific subject matter overrides a law which only governs general matters and the later law replaces the earlier one.

⁴⁴ A definition of a 'self-contained regime' can be found in the Report of the Study Group of the International Law Commission finalized by Martti Koskenniemi, *Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law*, 13 Apr 2006 , UN Doc. A/CN.4/L.682 p. 1-256 and 18 July 2006, UN Doc. A/CN.4/L.702 1-25.

⁴⁵ J. Pauwelyn, 2009. *Fragmentation of International Law*, IN: *Max Planck Encyclopedia of Public International Law*, Heidelberg and Oxford University Press.

collected together and are referred to as 'branches of international law'. Such collations presume to function in the manner of self-contained regimes, claiming to be regulated by their own principles. Expressions such as 'law of the sea', 'humanitarian law', 'human rights law', 'environmental law' and 'trade law', are used for mainly didactic purposes.⁴⁶

It is clear from the foregoing that, at least at this point of time, it would be extremely difficult to argue that international biomedical law constitutes a 'self-contained regime'. First of all, it is neither founded on any specific treaty outlining rights and obligations relating to specific subject matter, nor does it have a body of rules for the administration of primary rules. The same refers to any adjudicative body that would seek to interpret such rules and provide some kind of dispute resolution. There is no clear central coordinating institution either. This is despite the claims that the WHO would act as an umbrella health agency coordinating and convening legal and non-legal activities of different organisations providing thereby a more effective collective management.⁴⁷ Such claims are brought into question by the fact that the WHO has long been reluctant to pursue international law approaches to public health issues⁴⁸ and that it was UNESCO who adopted the three most important international human rights acts in the area of biomedicine and bioethics.⁴⁹ Last but not least, one of the biggest problems faced by international biomedical law is the lack of

⁴⁶ A definition of a 'self-contained regime' can be found in the Report of the Study Group of the International Law Commission finalized by Martti Koskenniemi, *Fragmentation of International Law: Difficulties arising from the Diversification and Expansion of International Law*, 13 Apr 2006, UN Doc. A/CN.4/L.682 p. 1-256 and 18 July 2006, UN Doc. A/CN.4/L.702 1-25.

⁴⁷ K. Buse, G. Walt, Global public-private health partnerships: Part II — what are the issues for global governance?, *Bulletin of the World Health Organization* 2000; 78: 699-709. J.P Ruger, D. Yach, The Global Role of the World Health Organization, *Global Health Governance* 2008 /2009, 2:3.

⁴⁸ D. P. Fidler. *The Future of the World Health Organization: What Role for International Law?*, Vanderbilt Journal of Transnational Law 1998; 31:1079.

⁴⁹ R. Adorno, Global Bioethics at UNESCO: in defence of the Universal Declaration of Bioethics and Human Rights, *Journal of Medical Ethics* 2007; 33: 150-154.

legally binding norms, on which the whole ILC's Report seemed to be focused.⁵⁰ This last feature of biomedical law requires considerable attention.

c) Relative normativity⁵¹ of international biomedical law?

What characterises biomedical law at the international level is a general lack of legally binding norms – the so called hard law – alongside an overwhelming proliferation of soft law instruments. The term 'hard law' as used in this special issue refers to legally binding obligations which are precise and which delegate authority for interpreting and implementing the law.⁵² For the mainstream international (positivist) lawyer hard law includes rules that are both formal and *enforceable*. Reliance on coercion – understood as diplomatic measures, reprisals or dispute settlement – is crucial. In addition to requiring commitment to a background set of legal norms – including engagement in established legal processes and discourse – legalization provides actors with a means to instantiate normative values.⁵³ Treaties are by definition always hard law, because they are always binding, although an agreement involving states may still be binding in the absence

⁵⁰ That conceptual frame constituting a starting point for the ILC's Report was provided by the Vienna Convention on the Law of Treaties of 1969 (VCLT), signed at Vienna on 23 May 1969, entered into force on 27 Jan 1980, United Nations, *Treaty Series*, 1155: 331.

⁵¹ A graduate normative hierarchy developed in international law, i.e. normative gradations amongst rules of international law exemplified, in particular, by the concepts of *jus cogens* and soft law. See: P. Weil. Towards relative normativity in international law?, *The American journal of international law* 1983; 77, 413-442; U.Fastenrath. Relative Normativity in International Law, *European Journal International Law* 1993; 4: 305-340.

⁵² F. Snyder. 1993. Soft law and Institutional Practice in the European Community. In: *The Construction of Europe – Essays in honour of Emile Noel*, S. Martin (ed), Kluwer Academic Publishers: 197-225: 198.

⁵³ S. Spiliopoulou Åkermark 2004. Soft Law and International Financial Institutions – Issues of Hard and Soft Law from a Lawyer's Perspective, In: *Soft Law in Governance and Regulation– An Interdisciplinary Analysis*, U.Mörth (ed), Edward Elgar: 61-101: 77-78.

of a treaty, so the distinction between soft and hard law is not simply synonymous with the distinction between treaties and non-treaties.⁵⁴

The realm of 'soft law' is much more elusive as it begins once legal arrangements are weakened along *one or more* of the dimensions of obligation, precision, and delegation. This softening can occur in varying degrees along each dimension and in different combinations across dimensions.⁵⁵ Thus, the term 'soft law' can be ascribed different meanings. The most common distinction between hard and soft law norms is that soft law lacks the possibility of legal sanctions.⁵⁶ In this respect it could be summarized as: 'the rules of conduct that find themselves on the legally non-binding level (...), but which according to the intention of its authors indeed do possess legal scope, which has to be further defined in each case.'⁵⁷ Alternatively, however, rather than being simply non-binding, soft law can be viewed to include open-textured norms of general content and wording, i.e. 'principles', rather than specific commitments. In this sense treaties, regarded by Public International Law as binding, can be either soft or hard, or both, as exemplified by the EU Charter of Fundamental Rights.⁵⁸ The Charter used to lack legal force, and hence was seen as 'soft law' in the common sense of the term. However, it has recently been elevated to the same status as the EU treaties. Nevertheless, because its chapter on solidarity refers to principles and values

⁵⁴ A.E. Boyle. Some reflections on the relationship between treaties and soft law, *International Comparative Law Quarterly* 1999; 48: 901-913: 901.

⁵⁵ M. Aldestam, 2004. Soft Law in the State Aid Policy Area, In: *Soft Law in Governance and Regulation– An Interdisciplinary Analysis* U.Mörth (ed), Edward Elgar: 11-36: 12.

⁵⁶ U.Mörth, ed 2004. *Soft Law in Governance and Regulation– An Interdisciplinary Analysis*, Edward Elgar.

⁵⁷ K. C. Wellens, G. M. Borchardt. Soft Law in European Community Law', *European Law Review* 1989; 14: 267-321: 274.

⁵⁸ The normative tensions engendered within other EU instruments are well illustrated in Favale, M. and Plomer, A. (2009) Fundamental Disjunctions in the European Legal Order on Human Tissue, Cells and Regenerative Therapies', 16 *Maastricht Journal of European and Comparative Law* 1: 89-112.

rather than rights and duties, it might still be considered (at least partly) a soft law document.⁵⁹ Finally, another understanding of soft law can focus on the avoidance of compulsory adjudication or disputes. To sum up, soft law rules do not have in common a uniform standard of intensity as far as their legal scope is concerned, but they do share a desire to influence the practice of states, international organisations and individuals. They contain an element of law-making intention and progressive development, but without containing international legal rights and obligations.⁶⁰ It is clear from the above definition that the term soft law can, therefore, be used to distinguish a broad class of deviations from hard law on the one hand and, on the other hand, from purely political arrangements in which legalization is largely absent.

Using the above classification it becomes clear that only regional organizations such as the Council of Europe and the EU have been able to produce hard law instruments directly concerning biomedicine. While the Convention on Human Rights and Biomedicine together with its Additional Protocols remains the only international treaty in the field,⁶¹ the EU has incorporated explicit provisions concerning biomedicine into its primary and secondary law.⁶² The only other legally

⁵⁹ The Charter of Fundamental Rights of the European Union, adopted by the Presidents of the European Parliament, the Council and the Commission at the European Council meeting in Nice on 7 Dec 2000, OJ EU 2007/C 303/01.

⁶⁰ J. Sztucki. 1990. Reflections on international soft law, In: *Festschrift till Lars Hjermer*, L. Ramberg, O. Bring, S. Mahmoudi (eds), Norstedts: 549-575: 573. See also: Ch. Chinkin 2000. Normative Development in the International Legal System, In: *Commitment and Compliance: The Role of Non-Binding Norms in the International Legal System*, D.Shelton (ed), OUP: 21-42,

⁶¹ The Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine 4/4/1997 (ETS 164). Accompanied by Additional Protocols concerning: the Prohibition of Cloning of Human Beings, 1998 (ETS 168); concerning Transplantation of Organs and Tissues of Human Origin, 2002 (ETS 186); concerning Biomedical Research, 2005 (ETS 195); concerning Genetic Testing for Health Purposes, 2008 (ETS 203).

⁶² Primary law now includes the Charter of Fundamental Rights of the EU and directives binding as to the effect, e.g.: Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and

binding instruments that might have a bearing on the field of biomedicine are the TRIPS Agreement, the Convention on Biological Diversity⁶³ accompanied by the Cartagena Protocol on Biosafety⁶⁴, and the WHO International Health Regulations as well as, however indirectly, the Framework Convention on Tobacco Control⁶⁵ along with general human rights treaties, such as the International Covenants on Civil and Political Rights and Social Economic and Cultural Rights⁶⁶. And yet, even this limited group of legally binding instruments contains many open-textured, i.e. soft law provisions. For instance, the Framework Convention on Tobacco Control and other WHO instruments still neglect rights-based nomenclature.⁶⁷ These considerations suggest that the field of biomedical law at the global level is predominantly 'soft', in that it is dominated by declarations,

distribution of human tissues and cells; Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices; Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions; Directive 95/46/EC of the European Parliament and of the Council of 24 Oct 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

⁶³ The Convention on Biological Diversity (CBD) adopted 22 May 1992 at the Conference for the Adoption of the Convention on Biological Diversity, Nairobi, Kenya, entered into force on 29 Dec 1993.

⁶⁴ The Cartagena Protocol on Biosafety adopted at First Extraordinary Meeting of the Conference of the Parties, Cartagena, Colombia 22 - 23 Feb 1999 and Montreal, Canada, 24 - 28 Jan 2000, entered into force 11 Sep 2003.

⁶⁵ WHO Framework Convention on Tobacco Control (WHO FCTC) adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 Feb 2005.

⁶⁶ International Covenants on Civil and Political Rights and International Covenant on Social Economic and Cultural Rights, adopted by General Assembly resolution 2200A (XXI) of 16 Dec 1966, entered into force 3 Jan 1976.

⁶⁷ Ch. Kuppuswamy, 2009. *The International Legal Governance of the Human Genome*, Routledge.

communications, recommendations, resolutions, codes of practice, guidelines, notices, and positions.⁶⁸

Soft law has been widely criticized and even dismissed as a factor in international law. Prosper Weil, for example, argued as early as 1983 that increasing use of soft law 'might destabilize the whole international normative system and turn it into an instrument that can no longer serve its purpose.'⁶⁹ Critics usually focus on the absence of an independent judiciary with supporting enforcement powers, and the weaker credibility of their commitments.⁷⁰ In the field of biomedical law lack of legally binding international instruments enables interested parties such as tourists-scientists, patients and industries to 'pick and choose' from a patchwork of regulation containing a wide spectrum of possible options. Such freedom may contribute to the more efficient diffusion of controversial technologies and new regulatory regimes without conceding time for their cultural elaboration.⁷¹ Health risks and ethical problems are complex and the reaction to them may be culturally based. The result may be both a lack of constructive diversity and a lack of cultural and democratic legitimacy. It may also lead to larger inequalities and a kind of moral imperialism. Paradoxically, it might be easier to impose norms and values through ethical and professional codes of practice rather than through binding international treaties, which have to be negotiated in accordance with formal procedures and which treat all parties as sovereign equals.⁷²

To sum up, the multiplicity of political, legal and other forms of public decision-making, developed to address the complexities of specialised knowledge, tend to lack some of the qualities

⁶⁸ This proliferation is well illustrated, for instance, on the EU Science in Society Portal which enumerates only the legal instruments related to research involving medical intervention, available at: <http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1428>. [Accessed 10 Nov 2010].

⁶⁹ P. Weil. Towards relative normativity in international law?, *The American journal of international law* 1983; 77: 413-442: 423.

⁷⁰ Downs, Rocke, and Barsoom 1996, cited in: K.W.Abbott, D. Snidal, Hard and Soft Law in International Governance, *International Organization*, Summer 2000, 54: 3: 421–456.

⁷¹ T. Stoltzfus Jost, Comparative and International Health Law, *Health Matrix* 2004; 141:14.

⁷² Special thanks to Dr Christine Hauskeller for the discussion about this problem.

of democratic participation, transparency, stability, accountability and effectiveness. These values are justificatory grounds of formal procedural requirements in decision-making, and explain why so many lawyers feel extremely uneasy when confronted with the notion of soft law where it indicates a lack of institutionalized adoption procedures. Legal rules must also observe legitimacy. Legitimacy in a normative sense entails the coherence of the legal system; that the rule respects other fundamental rules and principles.⁷³ These are the main reasons for a structural and technical demand for harmonisation and compatibility.⁷⁴

Over the last decade a great deal of time has been devoted to finding adequate solutions to the above mentioned problems. Proposals, already mentioned in this paper include calls for harmonisation through international codes of practice⁷⁵, centralisation⁷⁶, and institutionalisation through new, formalised frameworks of international collaboration, institutions and legal practices, including codification and implementation of treaty law.⁷⁷ Other scholars, such as Thomas Faunce, called for subsumption of medical ethics under international human rights law. He argued that '[the] human rights system is established to generate globally top-down normative guidelines and therefore, is more effective and more legitimate than reliance on the professional standards

⁷³S. Spiliopoulou Åkermark 2004. Soft Law and International Financial Institutions – Issues of Hard and Soft Law from a Lawyer's Perspective, In: *Soft Law in Governance and Regulation– An Interdisciplinary Analysis*, U.Mörth (ed), Edward Elgar: 61-101: 77-78.

⁷⁴ I-J. Sand, 2004. Polycontextuality as an Alternative to Constitutionalism, In: *Transnational Governance and Constitutionalism*, Ch. Joerges, I-J. Sand, G. Teubner (eds), Hart Publishing: 55.

⁷⁵ B.M. Knoppers, M. H Abdul-Rahman, and K. Bédard, Genomic Databases and International Collaboration, *King's Law Journal* 2007; 18: 291–311.

⁷⁶ D. P. Fidler, The Future of the World Health Organization: What Role for International Law? *Vanderbit Journal of Transnational Law* 1998; 31:1079.

⁷⁷ L.O. Gostin, A. L. Taylor, Global Health Law: A Definition and Grand Challenges *Public Health Ethics* 2008; 1:1: 53–63.

departments of national medical associations or even the WMA.⁷⁸ As medicine is globalised, and as medical research in particular is globalised, there is strong pressure for universal norms both to allow practices to be evaluated transnationally and to allow for cross-border treatment, multinational clinical trials, trade in goods and services and so on.⁷⁹ Although this argument rests on a false assumption that human rights law has clear implementation and enforcement mechanisms, it reflects the more widely held view, that not only biomedical governance requires legalisation, but also that the current domination of soft law instruments is just an interim phase in the development of customary and then conventional international law. Francesco Francioni's words constitute a good example of the latter argumentation:

'[The Universal Declaration on Human Genome] is not a binding treaty. Its text can at best be understood to reflect emerging principles of international law which, expressed in the soft-law form of the Declaration, are designed to model the evolution of customary law and to eventually harden into more detailed and exacting standards. In any event, it is difficult to deny that the Declaration has already affected the *opinion iuris* of the international community.'⁸⁰

In line with those arguments is the view that we are witnessing the emergence of a new regime of international biomedical law. According to Roberto Andorno 'the main distinguishing feature of this new emerging field of international law is *the very central role it gives to the notion of human*

⁷⁸ R. Ashcroft, Could Human Rights Supersede Bioethics?, *Human Rights Law Review* 2010, DOI: 10.1093/hrlr/ngq037, commenting on: T. Faunce, Will International Human Rights Subsume Medical Ethics? Intersections in the UNESCO Universal Bioethics Declaration, *Journal of Medical Ethics* 2009; 31: 173.

⁷⁹ T.A. Faunce, H. Nasu, Normative Foundations of Technology Transfer and Transnational Benefit Principles in the UNESCO Declaration on Bioethics and Human Rights, *Journal of Medicine and Philosophy* 2009; 34: 296.

⁸⁰ F. Francioni, Genetic Resources, Biotechnology and Human Rights: The International Legal Framework, EUI Working Paper LAW No. 2006/17, available at: <http://cadmus.eui.eu/handle/1814/6070>. [Accessed on 25 Oct 2010].

dignity.⁸¹ Such assertions are very rarely explicitly expressed by legal scholars, but they often constitute either an implicit assumption concerning the status quo, or a prescriptive statement for the future development of international biomedical law.⁸² However, such interpretations still stay within the classic conceptions of international law and seem not to take into consideration the complexities of the contemporary globalised world. Soft law may be identified not only as a phase in the process of legalisation, but also as an alternative, to more formal sets of law.⁸³ It may be in the interests of the parties to keep to a less legalized relationship, providing for the possibility of compromise in terms of cost-effectiveness, pluralism and flexibility.⁸⁴ One theory that takes into account these complexities is the theory of global legal pluralism, inspired by the sociological theory of Niklas Luhmann, and developed by Günter Teubner.

III. INTERNATIONAL BIOMEDICAL LAW IN THE CONTEXT OF GLOBAL LEGAL PLURALISM

According to Luhmann, modern societies are seen as emerging via generalised functional and communicative systems which traverse society – irrespective of territorial and institutional boundaries – such as economics, politics, law, sciences, religion, art, etc. None of the

⁸¹ R. Andorno, Dignity of the person in the light of international biomedical law, *Medicina e Morale* 2005; 1: 91-105.

⁸² R. Ashcroft, Could Human Rights Supersede Bioethics?, *Human Rights Law Review* 2010, DOI: 10.1093/hrlr/ngq037. Also: R. Ida, What Ethics Framework for Global Governance of Biomedical Research - from Japanese and Asian Perspective, presentation at the conference *International Dialogue on Bioethics: The role of ethics in the international biomedical research*, Madrid 4-5 Mar 2010, available at: http://ec.europa.eu/european_group_ethics/docs/JP_Ryuichi%20IDA.ppt#1. [Accessed on 1 Nov 2010].

⁸³ J. Goldstein, M. Kahler, A-M. Keohane, R.O. Slaughter, Legalization and World of Politics, *International Organization* 2000; 54: 3: 385-400.

⁸⁴ K.W.Abbott, D. Sindal, Hard and Soft Law in International Governance, *International Organization* 3, Summer 2000; 54: 421–456.

communicative systems are privileged or seen as the centre of society.⁸⁵ They are simultaneously characterised by both normative autonomy and complex relations and their interdependencies. At the global level, the combination of the globalisation of markets, international treaties, and new technologies (e.g. telecommunication and genetics) may lead to more comprehensive global dynamics in several fields than previously existed. Science and knowledge and the discourses related to these are part of what might be called 'transnational dynamics'.⁸⁶ Teubner's idea is that 'an autonomous network of legal communications has arisen that produces its inventory of norms primarily from a plurality of transnational processes of rule-making'.⁸⁷ Therefore, Teubner rejects the constitutional response to fragmentation taken by the ILC. In his view, legal fragmentation is only a legal reproduction of collisions between the diverse rationalities within global society itself. Global pluralism is not simply a result of political pluralism, but is instead the expression of deep contradictions between colliding sectors of global society. Thus, any aspirations to a normative unity of a global law are doomed from the outset.⁸⁸

There is an assumption that law has established itself globally as a unitary social system beyond national laws. However, the unity of global law is not based on consistency of legal norms, structurally secured by the hierarchy of courts.⁸⁹ The notion of legal system refers to various processes of self-organisation and self-coordination on the global level: a) the incremental forming

⁸⁵ N.Luhmann 1982. *The Differentiation of Society*, Columbia University Press; N.Luhmann 1997. *Gesellschaft der Gesellschaft*, Suhrkamp.

⁸⁶ U.Beck. 2000. *What is globalism*, Cambridge, Polity Press.

⁸⁷ T.Vesting. 2004. Constitutionalism or Legal Theory: Comments on Gunter Teubner, In *Transnational Governance and Constitutionalism*, Ch. Joerges, I-J. Sand, G. Teubner (eds), Hart Publishing: 30.

⁸⁸ A. Fischer-Lescano, G.Teubner, Regime collisions: the vain search for legal unity in the fragmentation of global law, *Michigan Journal of International Law* 2004; 25: 999-1045.

⁸⁹ A. D'Amato. 2005. International Law as an Autopoietic System, In: *Developments of International Treaty Making*, R.Wolfrum, V.Roeben (ed), Springer: 335. See also: A. Fischer-Lescano, G.Teubner, Regime collisions: the vain search for legal unity in the fragmentation of global law, *Michigan Journal of International Law* 2004; 25: 999-1045.

of conventions (e.g. *lex mercatoria*⁹⁰), b) the reception of internal standards set by networks of companies, organisations and regulatory agencies (e.g. world-wide standardisation processes), c) rules emerging from market relations (e.g. contracts between global players) and so on. 'The relations between international, supranational and transnational levels are varied, and can be described by interdependence and combinations, rather than hierarchical orders. This can be seen as a new poly-centricity and poly-contextuality in law, where unity in the old sense does not exist, and where interdependence, diversity, fragmentation and legal conflicts have emerged more clearly as qualities of legal regimes.'⁹¹ Therefore, Inger-Johanne Sand – a follower of Teubner – argues that 'instead of the observation of the formal procedures, we must explore diverse approaches to contextualized legitimation of transnational regimes through techniques, such as deliberative supranationalism and democratic experimentalism'.⁹² In Teubner's world of global legal pluralism we must grapple with laws that do not give rise to a single 'ultimate rule of recognition' and 'decisions [which] are only "final" within the meaning of each specific system'.⁹³

To explain his vision of global law populated by interrelated autonomous regimes, Teubner uses the example of *lex mercatoria*. However, his analysis seems incredibly applicable to international biomedical law. According to Teubner, *lex mercatoria* consists of broad principles that change in their application from case to case. This is one of the reasons why some lawyers reject its existence as law altogether. This rejection is ill-founded; it seeks a body of rules as the 'essence' of an autonomous legal order, instead of looking for a communicative process that moves the symbol of validity according to the binary code. It is more a law of values and principles than a law of structures and rules. Teubner argues that its softness should not be seen as a deficiency, but as a typical characteristic of global law. It compensates for the lack of global enforceability, rendering it

⁹⁰ Lex mercatoria is a term used to describe the transnational law of economic transactions.

⁹¹ I-J. Sand. 2004. Polycontextuality as an Alternative to Constitutionalism, In: *Transnational Governance and Constitutionalism*, Ch. Joerges, I-J. Sand, G. Teubner (eds), Hart Publishing.

⁹² *Ibid.*

⁹³ A. Fischer-Lescano, G. Teubner, Regime collisions: the vain search for legal unity in the fragmentation of global law, *Michigan Journal of International Law* 2004; 25: 999-1045: 1008.

suitable to a global unification of law, remaining at the same time relatively resistant to symbolic destruction in the case of deviance.⁹⁴ In this respect, it should not come as a surprise that the area of medical treatment and research that has evolved both internationally and transnationally has been recognised by Sand as a transnational regulatory system of its own.⁹⁵ The theory of global legal pluralism allows for a much wider, complex and comprehensive conceptualisation of biomedical law at the international, transnational and national level; a conceptualisation that allows for a more systematic acknowledgement of the prominence of soft law and non-law rules. This new all-embracing concept should be called 'global biomedical law'.

IV. CONCLUSIONS: STUDIES INTO GLOBAL BIOMEDICAL LAW?

Contemporary society is increasingly viewed as a network rather than a structure and an 'infinite volume of permanent permutations'.⁹⁶ It is governed by a multitude of normative layers. Consequently, our definitions of governance are changing. There is an increased focus on the variety of techniques of governance being extended from law and politics to include economic, scientific, technological and ethical techniques, among others, which illustrates the change of focus from politico-legal institutions to the increasing significance of a variety of communicative functions or techniques.⁹⁷ In fact, the creation of new knowledge can be seen as a *de facto* form of governance and regulation in itself. It may be argued that knowledge and scientifically-based

⁹⁴ G. Teubner, P. Korth 2009. Two Kinds of Legal Pluralism: Collision of Laws in the Double Fragmentation of World Society. In *Regime Interaction in International Law: Theoretical and Practical Challenges*, M. Young (ed),; available at: SSRN: <http://ssrn.com/abstract=1416041>. [Accessed on 5 Nov 2010].

⁹⁵ Such claim is justified simply by the fact that the World Medical Association has developed the Helsinki Declaration on ethical principles of medical research, which is widely used by all authorities in the field. See: I.-J. Sand. 2004. 'Polycontextuality as an Alternative to Constitutionalism', in: *Transnational Governance and Constitutionalism*, Ch. Joerges, I.-J. Sand, G. Teubner (eds), Hart Publishing: 76.

⁹⁶ Z. Bauman. 2007. *Liquid Times. Living in an Age of Uncertainty*, Polity Press: 12.

⁹⁷ N. Luhmann 1982. *The Differentiation of Society*, Columbia University Press; N. Luhmann 1997. *Gesellschaft der Gesellschaft*, Suhrkamp.

discourses are taking over parts of the normative functions of law.⁹⁸ Although international governance has become increasingly legalized throughout the 20th century, legalization is not binary. That is, international law is not simply present or absent in a given issue area. The situation is much more complex, as legalization is seen more as a continuum, moving from “soft” law to “hard” law. Finally there is the increasing diversity and differentiation of types of actors involved in governance.⁹⁹ The emphasis is on co-ordination, collaboration, and networks among several actors, as well as on seeing decision-making as part of a more comprehensive and varied process.

At the same time, the question inevitably presents itself as to how we ought to draw the line between official law and non-official law, between hard and soft law, ultimately between law and non-law.¹⁰⁰ Should we accept that in the place of universalist presumptions and procedures aiming at consensus, there are learning processes, collaborations, comparisons and an acceptance for disagreements and ambiguity where ‘meaning’ is attempted in complex areas.¹⁰¹ However, such conceptualisation of global biomedical law still leaves us with the issue of who and how takes the ultimate decision about what is right or/and legal in the particular case. Drafting translegal perspectives such as those of Teubner onto the biomedical arena helps to re-imagine the challenge. Arguably such a view is more particularly relevant to a field so sensitive to issues of culture, faith, and the very generation of humanity itself. Here theoretical constructs reach the limits of their abilities, leaving space for social scientific investigation. It would be interesting and productive to explore the ways in which different actors construct the relationship between different

⁹⁸ N.Luhmann, 1993. Demands on Politics. In: *Risk: A Sociological Theory*, N.Luhmann (ed.), de Gruyter. Also: L. Lessing 1999. *Code and Other Laws of Cyberspace*, New York: 53-4; R.Brownsword. 2008. *Rights, Regulation, and the Technological Revolution*, Oxford University Press, 295.

⁹⁹ Ch.Joerges, Deliberative Supranationalism – Two Defences, 8 *European Law Journal* 2002, 133.

¹⁰⁰ P. Zumbasen, Transnational Law, *Comparative Research in Law and Political Economy*, Research Paper 2008; 2: 4 (originally in *Encyclopedia of Comparative Law* J. Smits (ed.) 2006).

¹⁰¹ G.Teubner, P.Korth 2009. Two Kinds of Legal Pluralism: Collision of Laws in the Double Fragmentation of World Society. In *Regime Interaction in International Law: Theoretical and Practical Challenges*, M.Young (ed),; available at: SSRN: <http://ssrn.com/abstract=1416041>. [Accessed on 5 Nov 2010].

normative instruments, and the ways various kinds of professional and civil servant use the different 'languages' and rationalities for different purposes in different contexts. What causes one norm to be followed rather than another? What impact do soft law norms created by international governmental and non-governmental organisations have on the scientific community and national regulators? Francis Fukuyama aptly pointed out that: '[a]ll international institutions face the same design tradeoffs...: institutions that are regarded as legitimate... are not terribly effective, while those that are effective are not regarded as legitimate'.¹⁰² Such research should hopefully help resolve this paradox and allow for a more coherent development of the global biomedical law in the future.

¹⁰² F.Fukuyama. 2007. *After the Neocons*, Profile Books: 163.