In particular, Article 31(3)(c) of the VCLT would require a panel to consider, together with their context, any relevant rules of international law applicable to the relations between the parties. If one understands 'parties' as parties to the dispute and not all WTO Members,[55] the rules of the FCTC will become relevant for the majority of WTO Members. Last but not least, even if one subscribes to the narrow position taken by the *Biotech* panel, the FCTC and its guidelines could assist WTO dispute settlement bodies in ascertaining the ordinary meaning of terms (e.g. what should be regarded as necessary when it comes to tobacco control measures). In other words, they may be used not so much as a source of binding law but as a kind of legal dictionary which reveals the internationally agreed-upon meanings and ramifications.[56]

Explicit acceptance of the above mechanisms by the dispute settlement bodies, when confronted with tobacco control measures, could help to reduce the margin of uncertainty as to the scope of WTO obligations and would encourage Members actively to pursue their anti-tobacco policies.

[55] *Contra*, Panel Report, *EC – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, Add.1 to Add.9, and Corr.1, adopted 21 November 2006, para. 7.70.

[56] *E.g.*, Appellate Body Report, *US – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998.

IS TRIPS INNOVATIVE ENOUGH? HOW TO RECONCILE IP, INNOVATION AND HEALTH

Daniel Kraus*

1. Introduction

During his entire career, Professor Petersmann has always put the human being at the centre of his focus, be it in his numerous writings, but just as well as a highly appreciated employer and Ph.D. supervisor. Ernst-Ulrich Petersmann has not only been – and still is – a most productive author, but also a very creative and innovative one. Those characteristics, we believe, justify the choice of a theme linking creativity, innovation and human rights.

Rightly so, the human being must be at the centre of any rule of law in conformity with principles of justice, human rights and fundamental freedoms. This is particularly true in the field of international intellectual property law, and, more generally speaking, in the field of innovation.[1] Innovation can put the human being under a tremendous amount of pressure, not only when it comes to producing the latest technologies, which too often take place without respecting basic human rights, but also when it comes to consuming them. Even if it is true that many of these technological innovations have increased in a significant manner our quality of life, consumers are submerged with invitations to consume more every day. This pressure leads to a vicious circle of production – consumption – elimination, which, even in a short-term perspective, is not sustainable.

But innovation is not available to all. This is particularly true in the field of health technologies, of utmost important for the human being. As an example of a field of technology where human rights and fundamental freedoms play a central role *par excellence*, health innovation will be the focus of the present contribution. Innovation in health is confronted to important challenges, which will increase in the near future (2). After providing our definition of innovation (3), we shall analyse the existing legal framework (4) and end by drawing a general canvas in which solutions can be found.

* Professor at the University of Neuchâtel Law Faculty, Counsel, Umbricht Attorneys, Part-time Judge at the Swiss Federal Patent Court. Many thanks to Mr. Jean Perrenoud, collaborator at the Institute of Health Law, Neuchâtel, for his precious help with the documentary research.

[1] See e.g. E.-U. Petersmann, 'Constitutional Problems of Multilevel Judicial Governance in Trade and Investment Regulation', *EUI Working Papers LAW* No. 2012/08. p. 8.

2. Current Challenges

The first challenge that must be addressed is the development of new medicines and pharmaceutical products. As formulated by some authors, "although investment in pharmaceutical R&D has increased substantially in recent decades, the lack of corresponding increase in the output of new drugs being approved indicates that therapeutic innovation has become more challenging. This decline is associated with an increasing concentration of R&D investments in areas in which the risk of failure is high, corresponding to unmet therapeutic needs and unexploited biological mechanisms".[2]

Other challenges range from ever increasing costs of R&D, escalating problems of drug failures and adverse drug reactions. Meanwhile, many increasingly prevalent diseases, such as Alzheimer's disease, diabetes, many cancers, and stroke, remain without adequate treatments. The major reason evoked for the rising cost of new drugs is the fact that more than 90% of them fail in clinical trials.[3] Companies need to recoup the cost of development not only for the drug that succeeds, but also for all others that do not reach the stage of market approval.

Other scholars have observed that more breakthrough therapeutics will reach patients only if the industry ceases to pursue "safe" incremental innovation, reengages in high-risk discovery research, and adopts collaborative innovation models that allow sharing of knowledge and costs among collaborators.[4]

Challenges that the health sector faces are numerous and represent a serious risk for the public. But beyond these issues, not only diseases encountered in industrialized countries and for which markets are available need to be addressed; health problems of the developing world also need to be so. Countries hosting research-based industry have an important role to play in that field, as they benefit from the know-how for the development of new, promising biomedical products. As such, they must take an active part in addressing the health problems of the developing world.

In order for those challenges to be taken up by researchers, whether publicly or privately funded, a predictable, legally secure system is necessary, which on the one hand stimulates quality innovation, whilst on the other addresses health issues that primarily affect developing countries, including access. Industrialized countries can contribute to take up those challenges on the one hand by contributing to the maintenance and development of an efficient, balanced

[2] F. Pammolli, L. Magazzin and M. Riccaboni, 'The productivity crisis in pharmaceutical R&D', 10 *Nature Reviews Drug Discovery* June 2011, pp. 428 ff.

[3] K. Archibald, R. Coleman, Ch. Foster, 'Open letter to UK Prime Minister David Cameron and Health Secretary Andrew Lansley on safety of medicines', 377 *The Lancet*, Issue 9781, p. 1915, 4 June 2011.

[4] B.H. Munos, W.W. Chin, 'How to Revive Breakthrough Innovation in the Pharmaceutical Industry', *Sci. Transl. Med.* 3, (89): 89:cm16.

framework which stimulates innovation (including the IP and marketing approval legal systems); but on top of that, they need to actively participate and show flexibility in finding solutions for the stimulation of R&D into diseases that (mainly) affect the developing world. The solution will lie in a system which does not affect the balance in the IP system, whilst improving it in order to stimulate innovation in and for developing countries.

3. What is Innovation and What Are Its Needs?

3.1. *Innovation*

Innovation goes well beyond the pure product innovation. In the words of Schumpeter, innovation also relates to the adoption of new processes, unreleased technologies, and the use of new raw materials as well as the opening of new markets.[5] Innovation is not just about science and technology but also about art. It is not just a result but a process, a behaviour. It is not just about products with high but also those with a lower added value. Innovation is also an action – risky, but prone to a result. In the words of the French sociologist Gérald Gaglio, "innovation is not only associated with technology, business competitiveness and growth of gross domestic product",[6] rather, it is intrinsically linked to human beings. The focus must not be on technology, but on human beings.

Innovation is inherently interdisciplinary. It constitutes the daily bread, the motivation, even the essence to scientists, be they involved in fundamental or applied research, be it at university or in industry. It also closely concerns economists seeking to understand and improve innovation administration processes both from a macro and micro-economic perspective; political scientists assessing the utility and impact of public policies around innovation as well as anthropologists, ethnologists and psychologists studying and developing "creative methods to stimulate new ideas." Any legal framework that is developed must take those characteristics in consideration, in order not to slow down innovation.

3.2. *Innovation's Needs*

So what is the role of law as regards innovation? Should one totally exclude the law from regulating innovation, so that this total freedom may bring forth the greatest of creations and innovations? If only it were that simple. Innovation is expensive, risky, and the industry does not venture on such an undertaking without a safety net. This safety net is woven by the general framework in which a State develops itself economically as well as socially. The rule of law is called upon to create,

[5] J.A. Schumpeter, *Théorie de l'évolution économique*, (Paris Dalloz [1911] 1999), p. 319.

[6] G. Gaglio, *Sociologie de l'innovation,* (Presses universitaires de France, 2011), p. 100.

maintain and ensure this general framework – a space of freedom and creativity surrounded by a fence of legal certainty.

Beyond the general framework relating to education, to taxation, or to migration, the law must also establish a framework which provides the impetus for creativity and which stimulates innovation. To do this, the law must establish minimum standards in which the human being can flourish. This is where a fundamental aspect of the law of innovation, the intellectual property law and particularly patent law, comes into play. By giving the holder an exclusivity on his invention – some would (more often than not wrongly) call it a monopoly – the possibility of obtaining a patent will encourage the entrepreneur to engage into innovation, especially because he will feel protected against counterfeiting and see a chance to obtain capital investment.

However, it is well known that too many patents can also block innovation.[7] Access also needs to be given to competing researchers. The system must ensure that innovation is accessible to those who want to contribute to technological development, within the broader aim of increasing social welfare. The law must strike a balance between the instruments that drive innovation and those that provide access to it. Although innovative when it was adopted, the balance of rights, exemptions and exceptions emerging from the TRIPS agreement may still be fine-tuned.

4. The Existing Legal Framework: TRIPS and Health

Health has been at the centre of a constitutional and human rights approach for more than 60 years now, starting with the inclusion of the attainment by all peoples of the highest possible level of health as the – one and only – objective of the World Health Organization in its Constitution.[8] The respect of the right to a healthy standard of living was then also proclaimed by the Universal Declaration of Human Rights of 1948.[9] The right to the enjoyment of the highest attainable standard of health was again recognized as a human right in the 1966 International Covenant on Economic, Social and Cultural Rights (the Covenant), according to which States Parties to the Covenant must recognize that right to each and every

[7] See e.g. F. Abbott, 'Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health', *ICTSD Issue Paper No. 24*, p. 9.

[8] Art. 1 WHO Constitution, see www.apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf.

[9] Its art. 25 provides that "(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
(2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection".

person.[10] At the same time, the Covenant acknowledges the right of everyone to enjoy the benefits of scientific progress and its applications as well as to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.[11] How can these rights be reconciled? Although some authors discussed for a long time which of these rights has priority on the other, it has also been said that human health rights and human economic rights ought to be considered as mutually supportive.[12]

The international community has tried to deal with the relationship between innovation and health for the last 20 years, starting with the inclusion of two specific provisions in the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1995, which, although they could have been used at least as a means of interpretation of other provisions of the TRIPS agreement[13] have, in our view, been underutilized until now: whereas article 7 TRIPS foresees that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations, article 8 TRIPS in particular allows WTO Member States to adopt measures necessary to protect public health and to promote the public interest in sectors of vital importance to their socio-economic and technological development whilst formulating or amending their laws and regulations, provided that such measures are consistent with the TRIPS provisions (paragraph 1). The text of the TRIPS Agreement also recognizes that appropriate measures, provided that they are consistent with the provisions of said Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

These objectives and principles are realized up to a certain point in the exceptions provided for by article 30 TRIPS. Alongside with the non-discriminatory conditions of patentability (art. 27.1 and 28 TRIPS) and exemptions to patent protection which are open to Member States (art. 27.2 and 27.3 b TRIPS), the general idea of foreseeing exceptions included in article 30 TRIPS provides for the

[10] Office of the United Nation High Commissioner for Human Rights/World Health Organization, The Right to Health, Factsheet No. 31, Geneva 2008.

[11] Art. 15 of the Covenant.

[12] For a good overview of the issues and discussions, see L.R. Helfer, 'Human Rights and Intellectual Property, Conflict or Coexistence?', 5 *Minnesota Intellectual Property Review* 2003, pp. 47–61.

[13] Vienna Convention on the Law of Treaties articles 31 and 32.

necessary balance between principles and exceptions, rights and obligations, and the interests of intellectual property right holders and of users.

But, in order to address the challenges awaiting the field of health, more fine-tuning is requested: the quality of granted patents needs to be increased; access to information needs to be improved; and research into neglected diseases of the developing world needs to be better addressed.

4.1. *Improvement of the Quality of Patents Granted*

In theory, the improvement of the quality of patents granted could be achieved by a more thorough examination of applications as regards novelty and inventive step.[14] Although these conditions are already examined in some of the main patent offices of the world – in particular the United States Patent and Trademark office (USPTO), the European Patent Office (EPO) and the Japan Patent Office (JPO), they are not in other countries.[15] Such a thorough examination would however require too many resources, be they financial or human, which neither industrialized nor developing country applicants would be ready to, nor could, support.

But the quality of patents granted can be improved by a better delimitation between mere discoveries and inventions. Such delimitation has been established in the European Union (EU) or in Switzerland. In the EU Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, the difference between discoveries and inventions is clearly established.[16] That is also the case in Switzerland, where, in particular, a naturally occurring sequence or partial sequence of a gene is not patentable as such. Only sequences that are derived from a naturally occurring sequence or partial sequence of a gene may be patented as an invention, if they are produced by a technical process, their function is specifically indicated, and the further conditions of patentability are fulfilled.[17] Such a clear distinction could not been seen in the United States until recently, where the principles of the "Chakrabarty doctrine"[18] has been prevailing for over 30 years, including in the field of gene patenting, the argument being that the mere intervention of man is sufficient to consider that one is not dealing with a mere – not patentable – discovery but with an invention. This has however recently changed with the Myriad case which recently reached the Supreme Court of the United States.[19]

[14] Art. 27.1 TRIPS.

[15] Such is for example the case of Switzerland.

[16] *Official Journal* L. 213, 30/07/1998 p. 0013 – 0021, recital13 and 16 ; art. 5.

[17] Federal Law on Patents, article 1b.

[18] U.S. Supreme Court, *Diamond V. Chakrabarty*, 447 U.S. 303 (1980). *See* M. Rimmer, *Intellectual Property and Biotechnology: Biological Inventions* (2011), p. 26; M. Temmerman, *Intellectual Property and Biodiversity, Rights to Animal Genetic Resources* (2012), p. 48 ff.

[19] *See* A.S. Kesselheim, and M.M. Mello, 'Gene Patenting — Is the Pendulum Swinging Back?', 362 *N Engl J Med* 2010, pp. 1855–1858.

In the court of first instance, the New York district court recognized that product and process patents on the human BRCA genes that were held by *Myriad Genetics* were not valid because these genes existed in nature and represented nothing more than a mere discovery. On appeal, the U.S. Court of Appeals for the Federal Circuit partly reversed this decision regarding the product patent, but not on the process of comparing the analyses of the genes. The case has reached the United States Supreme Court, which has sent it back to the U.S. Court of Appeals for the Federal Circuit for a new decision.[20] The issue of the case is not yet certain, but a wind (or at least a little breeze) of change might be blowing in the direction of what seems to be a will to limit the extent of patentability of biotechnological inventions on the territory of the United States. This is also the direction in which *Mayo Collaborative Services v. Prometheus Laboratories* is going in relation with combination of natural processes,[21] or *Bilski* in the field of business methods.[22]

Although the decisions have been taken by American courts, it is to be expected that they will influence patent offices and judges in other industrialized countries – in particular in Europe – and are certainly well accepted in developing countries. An increase in the quality of patents granted in the field of health is certainly be welcome as it provides for more legal security at the international level, leaves room for more competition, whilst not limiting in an unfair manner of the patent role as stimulator of innovation.

4.2. *Improvement of Access to Information*

An increase in the quality of patents granted and of legal security is also in favour of research, as much as ever necessary in the field of health, as the patent thicket has been recognized to have a negative effect on the research and development.[23] In parallel, access to information also needs to be improved, notably by a more generally adopted research exemption. It is usually accepted by authors that the research exemption is based on the general exception of article 30 TRIPS.[24] However, the TRIPS agreement does not expressly foresee it, and the exception has not clearly arisen from the WTO dispute settlement.[25] A clear legal formulation has been elaborated in the recently modified Swiss patent law, which provides for a limited research exemption for research on patented inventions and a legal

[20] U.S. Supreme Court, *Molecular Pathology v. Myriad*, No. 11–725.

[21] U.S. Supreme Court, 566 U. S. ___ (2012).

[22] 545 F.3d 943 Fed. Cir. 2008; 130 S. Ct. 3218, 561 US, 177 L.Ed. 2d 792 (2010).

[23] M.A. Heller, R.S. Eisenberg, (1998), 'Can Patents Deter Innovation? The Anticommons in Biomedical Research', *Science*, 280: 698–701 (1998).

[24] *See* e.g. J.M. Mueller, 'The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development', 56 *Baylor Law Review* 2004, p. 971.

[25] Although the Bolar exception has expressly been accepted in WT/DS114/R, *Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States*, Decision of 17 March 2000.

(compulsory) license for research tools.[26] Such an exception has proved to provide a good balance between the interests of researchers, patent holders and of the general public. The research exemption provides a good instrument that helps patent serve their primary goal, which is to stimulate innovation rather than block competitors. In that spirit, a clear and general acceptation of that exception at the international level would be more than welcome.

4.3. *Encouragement of R&D into Neglected Diseases*

Neglected diseases account for more than 530.000 deaths annually.[27] Although low cost and easy to use treatments do exist and are embedded in national and international control programs against some diseases prevailing in developing countries, other diseases lack safe, affordable, and modern effective health tools.[28] The needs of developing countries for new products, including medicines, vaccines and diagnostics has already been recognized in 2003 with the establishment of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). That Commission and the Consultative Expert Working Group on Research and Development that was set up in order to deepen the analysis of proposals that had been made by the Expert Working Group on innovative sources of financing has concluded that the market failure which intellectual property rights try to correct in developing countries is compounded by a lack of reliable demand for the products generated by research and development. The Consultative Expert Working group concludes that there is an economic case for public action, which also amounts to a human rights matter.[29]

5. Possible Solutions

Innovation is a process moved by creativity which, by definition, requires a level of regulation which is as low as possible in order for creativity not to be hampered, and just as high as necessary to prevent parasitism. For this reason, minimum standards as established by the TRIPS agreement[30] seem to provide a sufficient framework, be it regarding rights, obligations, exemptions or exceptions.

[26] Réf. Art. 9 et 34.

[27] P.J Hotez., D.H Molyneux., J. Kumaresan, S. Ehrlich Sachs, J.D. Sachs, L. Savioli, 'Control of Neglected Tropical Diseases', 357 *N Engl J Med* (*10*), September 2007, pp. 1019, 1021.

[28] Such as African trypanosomiasis, Dengue fever, or Chagas disease. *See* B. Stirner, *Research and Development of Pharmaceutical Products for Neglected Diseases: Legal Means for Stimulation in Switzerland* (2010), p. 35.

[29] Report of the Consultative Expert Working Group on Research and Development: 'Financing and Coordination, Research and Development to Meet Health Needs in Developing countries: Strengthening Global Financing and Coordination', World Health Organization, April 2012, p. 1.

[30] Art. 1.1. TRIPS.

Nevertheless, increasing the quality of patents granted, increasing the flow of information in particular through a more general acceptation of the research exemption will foster innovation in the health sector and contribute to the reconciliation of intellectual property, innovation and health.

R&D into neglected diseases therefore requires solutions outside the intellectual property system, in particular through further financing as well as better coordination, priority setting, coherence and efficiency.[31] One keyword here may be *delinking* the price of medicines with the cost of research and development, allowing at the same time a better access to products that have been developed. If taxation can be considered as one possible instrument here, further instruments must also be examined, such as (pre-) competitive research and development platforms, equitable licensing and necessary coordination within existing structures and frameworks and building on existing institutional structures will be necessary in order to avoid unnecessary duplications.[32]

6. Conclusion

The TRIPS agreement has been considered as a modern instrument in order to attract and protect investments in innovative products and processes. In some cases however, and in particular where no market is available for innovative products or processes, it has been recognized that the intellectual property system, including TRIPS, has failed to provide the necessary stimulation for innovation. In those cases, another system, completing but not replacing the IP system, and not hampering innovation, needs to be elaborated. That is in particular the case with neglected diseases.

Now that preliminary steps for a possible future research and development treaty have been taken at the World Health Organization,[33] it is important to focus again on the human being rather than to get dispersed in hidden agendas. Negotiating parties will have to concentrate on the best possible instruments favouring creativity and innovation. Intellectual property is certainly one of those instruments, in particular if a fine balance is ensured between the rights of researchers as patent holders or patent users. For the rest, negotiators will have to concentrate on instruments outside the intellectual property system which will

[31] Ibid, p. 8–9.

[32] Ibid, p. 10–13; see also T.K. Mackey, B.A. Liang, 'Promoting global health: utilizing WHO to integrate public health, innovation and intellectual property', *Drug Discovery Today* (2010), doi:10.1016/j.drudis.2012.06.012, p. 6–10.

[33] World Health Assembly (WHA) Resolution 65.22, Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination.

ensure financing and coordination of research in health issues, without destroying the fine tuning that has been elaborated over decades in the patent system. The negotiating process is still at its beginning and there seems to be a general agreement in that direction. Let us hope it remains along the long and windy road to come.

THE FUTURE OF INTERNATIONAL INVESTMENT PROTECTION LAW: THE PROMOTION OF SUSTAINABLE (ECONOMIC) DEVELOPMENT AS A PUBLIC GOOD

Ilze Dubava*

1. Introduction

For many decades international investment protection law struggled with the issue of finding a balance between a host state's interest in retaining its regulatory flexibility and investor protection. This issue is particularly noticeable in connection with the standard of 'indirect expropriation', which investors often invoked to challenge *bona fide* regulatory measures which have a detrimental effect on foreign investment. Various methods used by adjudicators in determining the scope of the loosely drafted indirect expropriation standard are followed by concerns about how much regulatory space and flexibility is left for the host state to protect legitimate public welfare objectives. For some decades dating back to the period of decolonization and the New International Economic Order this has been the key matter of concern in international investment protection law.[1]

Currently, one may shape the issue so as to reflect the wider discourse on the protection of public goods, namely national and international goods, *"which in contrast to private goods, must be collectively supplied by government"*, e.g., the protection of the global environment and transnational rule of law, human rights, an efficient common market, democratic peace and sustainable development.[2] Hence, this study confronts Petersmann's concern about the ineffective protection of public goods, to which he has devoted many of his academic contributions in calling for a paradigm shift in international economic law.[3] Petersmann calls for the application and interpretation of international economic law *"in conformity with principles of justice' and the human rights obligations of states* (Preamble and

* Ph.D. Researcher, European University Institute (EUI), Florence.

[1] T. M. Frank, *Fairness in International Law and Institutions* (Oxford University Press, 2002), pp. 23, 441, 473.

[2] E.U. Petersmann, 'International Economic Law, 'Public Reason', and 'Multilevel Governance of Interdependent Public Goods', 14 *JIEL* 2011, p. 1, at p. 24, footnote 1; E.U. Petersmann, 'The Future of International Economic Law: A Research Agenda', *EUI Working Papers*, Law 2010/06, pp. 23, 25.

[3] E.U. Petersmann, 'International Economic Law, 'Public Reason', and Multilevel Governance of Interdependent Public Goods', 14 *JIEL* 2011, pp. 34, 23–76; E.-U. Petersmann, 'Introduction and Summary: 'Administration of Justice' in International Investment Law and Adjudication?', in P.M. Dupuy, F. Francioni, E.-U. Petersmann (eds.), *Human Rights in International Investment Law and Arbitration*, (Oxford University Press) 2009, pp. 1–45.