veloped nations should support the design and creation of patent pools and cross-licensing schemes to encourage the dissemination of climate technologies in developing countries. These patent pools could be used to support small and medium enterprises in the emerging markets in exchange for a low royalty fee[23]. This much hoped for approach would be similar to the "humanitarian licensing" scheme proposed earlier in the medical and agricultural fields[24].

Encouraging signals have been given recently. In one case the mercantilist condition stated in Section 204 of the Bayh-Dole Act was waived by the US government, i.e. the waiver by the US National Institutes of Health Office of Technology Transfer with reference to licencing tropical disease technologies to developing countries[25].

International organizations such as the World Intellectual Property Organization (WIPO) should also use their influence. As has been proposed[26], it would be advisable to set up global databases on licensing and cross-licensing patent pools on climate technologies. Such databases could support the establishment of benchmarks and determination of best practice in patent licensing negotiations between private companies or in public-private partnerships. WIPO in particular, and other organizations dealing with IPRs, should request patent owners to register their licensing deals within a certain time period to protect their latest commercial interests on a voluntary basis. The result of all this could be that these best practices in innovation and diffusion of climate technology might be shared in a way that both encourages innovation and complies with patentees' rights. This could also be a way for enterprises and other entities to present their latest inventions available for licensing.

It has also been argued that a Declaration on IPRs and Climate Change would be needed, as this would reinforce the trend toward finding a balance between innovation and the transfer of climate technologies at international level[27]. This declaration would be similar and comparable to the Doha Declaration on the TRIPs Agreement and Public Health, adopted by the WTO Conference in 2001, and should affirm the availability of flexible arrangements offered by the TRIPs Agreement for pursuing the dissemination and use of patented ESTs and climate technologies (such as compulsory and government-use patent licensing, limited exceptions to patent rights, variability in patentability standards, and potential for liability regimes).

Finally, what is the most suitable solution for addressing the issue of time-consuming and costly litigation in connection with patented climate technologies? One proposal could be the provision of heavy penalties against the plaintiff in cases where it can be established that a frivolous lawsuit has been brought with the sole purpose of frightening a competitor wishing to distribute similar technologies. This would discourage any such frivolous lawsuits and promote the availability of ESTs and climate technologies on the international markets.

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Regulatory Impact Assessment

This section regularly examines Regulatory Impact Assessment (IA) at three levels: the EU, the Member States and internationally. Contributions aim to cover aspects such as the interface between IA and risk analysis, looking at methodologies as well as legal and political science-related issues. Contributions are meant to report and critically assess recent developments in the field, develop strategic thinking, and make constructive recommendations for improving performance in IA processes.

Keeping the Centre of Gravity Work: Impact Assessment, Scientific Advice and Regulatory Reform

I. Introduction

Impact Assessment (IA) is a tool that assists regulators in their efforts to structure decision-making and increase the effectiveness of regulatory outcomes. As such, it reduces the risk of regulatory failure. If

23 Lee/Iliev/Preston, *Who Owns Our Low Carbon Future?*, *supra* note 3, at p. 60.

24 Brewster, Amanda/Chapman, Audrey and Hansen, Stephen, "Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation", *Innovation Strategy Today* (2005), pp. 203 et sqq., at p. 205.

25 Barton, *Intellectual Property and Access to Clean Energy Technology in Developing Countries*, *supra* note 18, at p. 8.

26 Lee/Iliev/Preston, *Who Owns Our Low Carbon Future?*, *supra* note 3, at p. 59.

27 Abbott, *Innovation and Technology Transfer to Address Climate Change*, *supra* note 18, at p. 26.

https://doi.org/10.1017/S1867299X00009X Published online by Cambridge University Press

used well, IA is particularly relevant to risk regulation. It promotes greater use of modern approaches to assess options for managing risks to human and animal health and to the environment. At the same time, it limits substantial negative unintended consequences.

This particular contribution seeks to be descriptive, analytical and programmatic at the same time. It recaps recent developments related to the IA system in Europe, suggests a possible method of interpretation, and briefly sketches the purpose of the future EJRR section dedicated to the topic. In other words, this is just the poster inviting the audience either to contribute or enjoy a forthcoming movie. Hopefully, the poster will be attractive enough. The movie certainly promises to be a blockbuster.

II. The pivotal role of Impact Assessment for launching reform

Some years ago, a senior official of the European Commission referred to the then recently introduced integrated IA system as "the crown jewel" of the EU's Better Regulation agenda. Rightly so. From the outset, the Commission has always been committed to develop and implement a comprehensive tool that would replace the old, partial and fragile system of assessments. In the 1990s, many of the Directorates-General (DG) developed its own sectoral instruments, resulting in a patchwork of good intentions overshadowed by silo practices and missed synergies. The idea was clearly to use IA as the centre of gravity around which a larger reform programme should pivot.

The 2002 Action Plan for Better Regulation was indeed accompanied by some eight ancillary communications (on minimum standards for consultation; the use of scientific advice; the reform of comitology, etc)[1]. IA was explicitly recognised as the element that linked the "governance" agenda of the Commission to its internal management reform and to the new planning and programming[2]. In those early years (2001-2003), the Secretariat-General (SecGen) was struggling to emerge as the new "kid on the block" in the agenda. It did so notably by leading the process of drafting the new IA guidelines, coordinating the machinery of inter-service consultation and managing the work programme of the institution. But in essence, however, the cards were actually held elsewhere. The big players were the DGs for Enterprise and Industry (DG ENTR), for Environment (DG ENV), to some extent the DG for Economic and Financial Affairs (DG ECFIN) and, to a lesser extent, the DG for Internal Market and Services, and DG Budget.

Over the years, the Better Regulation agenda has undergone a series of minor reforms and more in-depth refinements, the most evident and important of which was the shift from a "governance-driven" towards a "competitiveness-oriented" approach in 2005. The languishing status of the Lisbon Strategy, brought to light by its mid-term review, prompted the Barroso I Commission to re-direct efforts towards a "Better Regulation for Growth and Jobs"[3]. As a result, the Commission launched a more convincing simplification rolling programme[4], and accepted to embark on measuring administrative burdens on business.[5] In terms of IA development, it began by considering that – to paraphrase George Orwell – the economic and competitiveness impacts of a proposal were somehow "more equal" than the other two categories to be assessed, namely the social and environmental impacts.

Organisationally, DG ENTR was clearly the driving force behind that evolution, not least thanks to the prominent role played by its Commissioner, who had been appointed Vice-President with the additional special portfolio for Better Regulation. This certainly obfuscated the control that DG ENV initially shared over the reform agenda. While after 2005 IA never became a pure Cost-Benefit Analysis (CBA) of EU regulatory costs, DG ENV's original idea of using the integrated IA as a tool eventually to achieve greater policy integration in support of a sustainable strategy was partly side-lined[6].

A number of elements, however, made observers recently catch a glimpse of a sort of re-balancing.

1 European Commission (2002a), *Communication on European Governance: Better Lawmaking*, COM(2002) 275 final of 5 June 2002.

2 European Commission (2000), *White Paper on Reforming the Commission – Part I and II (Action Plan)*, COM(2000) 200 final of 1 March 2000 (as amended by COM(2000) 200 final/2 of 5 April 2000).

3 European Commission (2005), *Better Regulation for Growth and Jobs in the European Union*, COM(2005) 97 final of 16 March 2005.

4 See http://ec.europa.eu/governance/better_regulation/simplification_en.htm (last accessed on 3 February 2010).

5 See http://ec.europa.eu/governance/better_regulation/admin_costs_en.htm (last accessed on 3 February 2010).

6 Allio, L., The Emergence of Better Regulation in the European Union, King's College London, London 2009.

https://doi.org/10.1017/S1867299X00009X Published online by Cambridge University Press

Firstly, DG for Employment, Social Affairs and Equal opportunities started paying increasing attention to the internal implementation of the IA system, some calls for more consideration of the social implications of EU initiatives emerged from a number of external reviews and some stakeholders. As a matter of fact, responding to real or perceived unbalances, the Commission eventually issued additional guidelines on assessing social impacts,[7] which complement the central guiding tool[8].

Secondly, the establishment in 2006 of a central Impact Assessment Board (IAB) considerably strengthened the position of the SecGen *vis-à-vis* the operational DGs. The IAB controls the quality of draft IAs and supports the DGs in their daily work on IA. That step was in line with a progressive centralisation of the design and management of evaluation (in 2007 followed the inclusion of the Evaluation Unit from DG BUDG into the SecGen). It also represented a major departure from the role historically played by a traditionally small secretariat within the Commission[9].

More recently, a further advisory body was created in relation to the administrative burden reduction programme of the Commission. The High-Level Group of Independent Stakeholders on Administrative Burdens (the so-called "Stoiber Group")[10] is a further innovation in the *modus operandi* of the Commission. It fulfils its mandate autonomously, its members represent stakeholders and are not officials of any EU institution, and it is considered to be external to the Commission.[11]

In addition, the Commission has embarked on reforming the way scientific advice is collected, validated and used throughout the decision-making process. From the related 2002 Communication[12] to the Decision to reform the mandate and function of its scientific committees[13], the Commission has worked towards streamlining its interface with the regulatory agencies (such as EFSA, EMEA, ECHA, etc), the scientific community, and the stakeholders. These efforts have found their way also into the 2009 revised IA Guidelines, which both reinforce the requirement for desk-officers to rely on data that is of high quality and reliable and explicitly recognise the public management of risks as an important area of policy action at EU level. This formalises the link between IA and the practice of assessing, managing and communicating risk in the regulatory activity – an area that will be particularly explored in this section of the journal.

All these examples demonstrate that many Better Regulation fronts are influenced, triggered and supported by the various facets of IA. IA is understood here as a wide-ranging "process" structuring and closing the policy-making cycle. In a way, the Commission is thus following the international best practices promoted by the OECD and mainstream academia on designing, managing and revising regulatory reform.

III. Still no grounds for unconditional enthusiasm

The landscape is not without shadows, however. Considerable potential still remains, for instance in connection with IA as it is used by the other two vertices of the EU institutional triangle. Despite the 2003 inter-institutional agreement on Better Lawmaking,[14] neither the European Parliament nor – even less – the Council of the European Union has complied with the obligation of having their "major amendments" systematically assessed. The Council has limited itself to a couple of pilot projects, and issued an internal note addressed to its Working Groups on how to use the IA reports received from the Commission. Yet the Parliament has showed more interest in the agenda, and adopted a number of reports and opinions. Some budget has been allocated for "evaluation studies" to be carried out at

7 See http://ec.europa.eu/social/main.jsp?catId=760&langId=en&preview=cHJldmlld0VtcGxQb3J0YWwh (last accessed on 3 February 2010).

8 European Commission (2009a), *Impact Assessment Guidelines*, SEC(2009) 92 of 15 January 2009.

9 Kassim, H., "The Secretariat General of the European Commission, 1958–2003. A singular institution", in Smith, A. (ed.), *Politics and the European Commission. Actors, Interdependence, Legitimacy*, 2004, pp.47–66.

10 See http://ec.europa.eu/enterprise/policies/better-regulation/administrative-burdens/high-level-group/index_en.htm (last accessed on 3 February 2010).

11 *De facto*, however, the Stoiber Group currently does not have a budget of its own, its secretariat sits within the Commission's SecGen, and it is not entitled to determine its own agenda (which proposals to review).

12 European Commission (2002b), *"Improving the Knowledge Base for Better Policies." Communication on the Collection and Use of Expertise by the Commission: Principles and Guidelines*, COM(2002) 713 final of 11 December 2002.

13 European Commission (2008), Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, in OJ L 241 of 10 September 2008, pp.21-30.

14 See OJ C 321 of 31 December 2003, p. 1.

https://doi.org/10.1017/S1867299X00009X Published online by Cambridge University Press

the demand of the rapporteurs – but we are still far from mainstreaming IA in the European legislature. Maybe this is asking too much. But the impression is that a true debate has not yet fully taken place about the desired role that IA should play in EU policy-making.[15]

Similarly, the Lisbon agenda has not delivered as expected. The "Better Regulation for Growth and Jobs" approach does not seem to have produced many more results than in the previous five years of reforms. Indeed, EU Member States have remained very cautious about embarking on radical and sustained Better Regulation strategies at home. Academic research on IA suggests that there has been diffusion but not necessarily convergence. Progress has been sporadic and has occurred relatively late. The fact that most European countries nowadays claim to have some forms of RIA in place does not mean that they all have fully-fledged RIA systems, or that RIA serves the same function in their national decision-making. Not all impacts are given equal priority, and when governments speak of RIA, they may mean quite different things[16]. This has recently been confirmed by the OECD indicators[17] and analyses.[18] On its side, the Commission has not managed to exert sufficient pressure for upgrading IA practices across the EU – neither as a catalyst nor as an anchor. Generally speaking, apart from a few exceptional individual initiatives, in the capitals there is usually insufficient political leadership, general understanding or discipline for significant advances to be made. This holds particularly true if we consider how Member States address risks in their decision-making process.

From these admissions, some may raise questions about the true added-value of introducing fully-fledged IAs. They wonder whether too high expectations have been placed on this tool. IA cannot change the way decision-making unfolds. Nor is it able eventually to bring about the famous new "regulatory culture". Reformers should perhaps just focus on a "light version" of IA. This criticism is right, in the sense that IA alone is powerless. IA is definitely not Harry Potter's magic wand. But as a "process", it naturally spills over into the development of other equally crucial elements of regulatory reform, such as enhanced planning and programming; systematic and timely consultation practices, a smoother implementation and enforcement of legislation, and enhanced transparency and accountability.

IV. What comfort is there in looking into the future of IA?

It is therefore not only opportune but indeed vital to keep investing in a better understanding and diffusion of comprehensive IA processes. A number of factors will provide us with a sufficient amount of reassurance. Let's name just a few.

At the start of his second mandate, Commission President Barroso expressed his intention to take direct political leadership and responsibility for the reform programme even further.[19] By re-labelling the strategy "Smart Regulation", the President insisted on a small number of concrete priority actions. While keeping momentum with cutting red tape, efforts will be devoted to "joining up" the policy cycle's extremes: more attention to *ex post* evaluation and outcomes, also in relation to a further enhanced *ex ante* assessment system. The Commission is currently thinking of channelling its administrative burden reduction programme into the IA structure; enhancing the assessment and consideration of social impacts, and extending the consultation period beyond the current standard eight weeks. This may imply shifting away from a procedure-driven approach in order to follow a more outcome-driven line. In other words, Smart Regulation would re-define regulatory quality as what it really is: a means towards an end, namely more effective, efficient and participatory public policies. The goal is to further pursue policy integration, and convey the message that the exercise may lead also to – but not be driven by – de-regulation. The questions remains as to how far the Smart Regulation agenda will fit and find support in the EU 2020 Strategy.

15 Meuwese, A.C.M., *Impact Assessment in EU Lawmaking* (Kluwer Law International 2008), The Hague.

16 Radaelli, C.M., "Diffusion without convergence: How political context shapes the adoption of regulatory impact assessment", in *Journal of European Public Policy*, Vol.12/5, 2005, pp.924–943; Radaelli, C.M., "Desperately seeking Regulatory Impact Assessment: Diary of a reflective researcher", in *Evaluation*, Vol.15/1, 2009, pp.31-48.

17 OECD (2009), *Indicators of Regulatory Management Systems. 2009 Report*, Paris.

18 The OECD, in partnership with the European Commission, is carrying out a project reviewing regulatory reform in fifteen EU Member States. For more information, see http://www.oecd.org/document/24/0,3343,en_2649_34141_41909720_1_1_1_37421,00.html (last accessed on 3 February 2010).

19 See http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/09/400&format=HTML&aged=0&language= EN&gui Language=en (last accessed on 3 February 2010); and President Barroso's *Political Guidelines for the Next Commission*, 2009.

https://doi.org/10.1017/S1867299X00009X Published online by Cambridge University Press

In the European Parliament, increasing attention is being given to evaluation. *Ex post* evaluation features much more prominently in the political debate, and the vast circles in the House have repeatedly pleaded for improvements in the EU institution's performance in this respect. Whether by enhancing its own means, or by calling upon the Commission to be more active, the Parliament has certainly an important role to play. *Ex ante* analyses are also being taken increasingly seriously by MEPs. The recent initiative by the Chairman of the Internal Market and Consumer Protection Committee not to start committee debates without a preliminary presentation by the Commission of the proposal and the related IA is a powerful leverage to increase the relevance of the IA tool. Ongoing discussions will extend that practice to other parliamentary committees. That would certainly be a welcome development, for again it would raise decision-makers' awareness of the true added value of evidence-based decision-making, and prompt a more balanced consideration of the overall impacts to be assessed.

At the national level, interesting developments have taken place. While there is no space here to review them thoroughly, it will just suffice to mention a few illustrative examples. France has adopted an organic law providing a stronger legal basis for IA. A number of countries, including Germany and Austria, are considering diffusing the practice of sustainability assessments. The Dutch and Spanish governments are also engaged in upgrading their existing IA procedures. In many countries (in both Western and Eastern Europe), IA is still relatively in its infancy but progress is being made. Many oversight bodies have also emerged in the recent years and their mandate is evolving[20]. Across the Atlantic, a new understanding of regulatory IA appears to be coming to light. As one of his first decisions after taking office, US President Obama instructed the Office of Management and Budget (OMB) to produce recommendations for a new Executive Order on regulatory review[21]. The new US OMB/OIRA Administrator is committed to strengthen the application of behavioural economics in the traditionally strict US CBA approach. Arguably, redistributive aspects will also be considered with greater attention, so that reference will now be made to a "warm" or "humanised" CBA. This might seem to be a possible European contribution to the regulatory quality debate in the US. Certainly, there appears to be a certain cross-fertilisation of approaches between the two continents[22].

These examples could multiply. To sum them up: IA will only fulfil expectations and prove to be a credible and effective investment in regulatory quality if all those involved are committed to it, and if they deliver. Fixing the "process" is a shared responsibility and it is an indispensible pre-condition. Let us consider the level of the EU: the SecGen needs to show that it is mature enough not only to coordinate but also to lead and drive the reform policy. This would be a positive shift, since it would make Smart Regulation a more horizontal and potentially less biased endeavour, thereby increasing its acceptance and spreading the sense of ownership among the stakeholders. The challenge will then be to keep it close to reality and to the needs of organised interests and of EU citizens, a task typically left in the hands of operational DGs.

On their side, policy-makers must truly mean what they say. Time will prove whether the tone set for a "partnership for progress"[23] is credible and strong enough. the President of the Commission, all the Commissioners, and also MEPs and ministers must stand firmly behind the agenda and find ways to implement the 2003 inter-institutional agreement. The three EU institutions are moreover discussing the extension and revision of the "Common Approach" on IA signed in 2005. In addition, further to the entry into force of the Treaty of Lisbon, ideas have also been voiced on the development of forms of further inter-institutional cooperation related to decision-making and which could encompass regulatory quality aspects. These are all opportunities for strengthening the reform agenda. The Member States bear the responsibility for making the multi-level regulatory governance work. The machinery must work not only smoothly but also in a manner that will provide added-value for EU decision-making. This means investing in capacity-building at the national and sub-national level. The

20 Wiener, J.B./Alemanno, A., "Comparing regulatory oversight bodies across the Atlantic: US OMB/OIRA and the EU IAB", in Rose-Ackerman, S./Lindseth, P.L. (eds), *Comparative Administrative Law* (Yale University Press 2010).

21 Obama B., *Memorandum of January 30, 2009 – Regulatory Review*, 74 Fed. Reg. 5977 (published on 3 February 2009).

22 Wiener, J.B., *Better Regulation in Europe*, Paper 06-26, AEI-Brookings Joint Center for Regulatory Studies, Washington D.C., 2006.

23 See http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1272&format=HTML&aged=0&language=EN&guiLanguage=fr (last accessed on 3 February 2010).

https://doi.org/10.1017/S1867299X00009X Published online by Cambridge University Press

entry into force of the new Parliament and Commission, the enhanced roles entrusted to the Committee of the Regions and the European Economic and Social Committee by the Lisbon Treaty, and the launch of the EU 2020 Strategy (however perfectible it may be) all form a perfect constellation of factors that should not be missed.

All stakeholders are not merely observers and addressees of this agenda. Their responsibility is to provide data that is reliable and well-timed. They must promote a constructive debate on IA, risk, and regulatory reform with the institutions. This necessarily implies also maintaining an effective dialogue among other constituencies. At the same time, stakeholders should not abandon their role as partners to the public administrations, not afraid to challenge them if necessary, but always ready to help by monitoring and steadily promoting their advances.

V. Instead of a conclusion: the new EJRR Impact Assessment section

The above observations have set the background of the launch of the EJRR Impact Assessment section. The section will regularly address IA at EU level and in Europe. Academics, practitioners and experts from various backgrounds and affiliations will be invited to contribute to the debate by reporting on and critically assessing recent developments, developing strategic thinking, and making constructive recommendations for ever improving IA processes. Clearly, there is no simple answer. No "plug-and-play model" will ever work. The multidisciplinary nature of the journal will help address the heterogeneity of the challenges and the contexts to be tackled. This will be reflected in the various approaches to IA, from its interface with risk analysis and studies on methodological aspects to some aspects belonging more to the legal domain and political science.[24]

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24 Ideas and proposals for contributions may be forwarded to Alberto Alemanno (alemanno@hec.fr) and Lorenzo Allio (lorenzo.allio@gmail.com).

Pharmaceuticals

This section updates readers on the latest developments in pharmaceutical law, giving information on legislation and case law on various matters (such as clinical and pre-clinical trials, drug approval and marketing authorisation, the role of regulatory agencies) and providing analysis on how and to what extent they might affect health and security of the individual as well as in industry.

The Institutional Growth of the European Medicines Agency*

On 26 January 2010 the European Medicines Agency celebrated its 15th anniversary. The inspiring "life cycle" theory of Bernstein[1] suggests that we should regard the growth of a regulatory body as somewhat similar to the development of a human being. This anniversary marks the Agency's well-deserved entry into maturity now that it has grown to have six scientific committees and numerous other working parties. The Secretariat of the Agency has been recently restructured, and the old EMEA acronym has been dropped. In recent years, the Agency's sphere of responsibilities has been gradually expanding in line with new European legislation, most recently in the field of medicinal products for paediatrics and advanced therapies. The Agency has become established as the competent body to provide EU institutions and Member States with scientific advice on the evaluation and supervision of medicinal products – with claims that it enjoys a *de facto* or *semi*-regulatory power. After the entry into force of Regulation 1901/2006, the Agency may now also take decisions with legally binding effect *vis-à-vis* third parties on medicinal products for paediatric use[2]. New legislation in the pipeline, part of the "pharmaceutical package" (in the fields of counterfeiting and pharmacovigilance) will further increase the coordinating role of the Agency. Moreover, the Agency's unique institutional architecture, together

* All views expressed in this paper are strictly personal and should not be understood or quoted as being made on behalf of the European Medicines Agency.

1 Bernstein, M., *Regulating Business by Independent Commissions* (Westport Conn.: Greenwood Press 1977).

2 This has resulted also in the first dispute, still pending before the General Court, directed only against an administrative act of the Agency, *Nycomed Danmark v. European Medicines Agency*, T-52/09.

https://doi.org/10.1017/S1867299X00009X Published online by Cambridge University Press