Zentraler Vorstand . Central Executive Committee . Bureau Central 07.12.2009 ex09169cp - 0.2.1/0.3.2

Interview with Dr. Rob J. Aerts

International research scientist a.o. molecular biology and biotechnology, European and Dutch patent attorney, currently principal patent attorney with Solvay Pharmaceuticals B.V., Netherlands.

1. The origins of patent law-making in Europe and the U.S.

Dr. Aerts, relating to European patent law and its origins, you talk about a "hybrid structure". What does this mean?

Dr. Rob J. Aerts: Currently, patent law in Europe is governed by two distinct legal systems with very different origins. On the one hand, the principal system within Europe for the examination of European patent applications and the grant of European patents is through the European Patent Convention (EPC), which ultimately was an initiative of the Council of Europe and is purely intergovernmental in nature. On the other hand, the European Union, and more specifically as part of it the European Community, which provides a body of law which is supranational in nature, involves itself more and more with various aspects of European patent law, for instance by promulgating the Biotechnology Directive (Directive 98/44/EC), or more generally through Regulation 44/2001 on jurisdiction and the recognition and enforcement of judgements in civil and commercial matters, through Directive 48/2004 on the enforcement of intellectual property rights, and through the recent initiative for a Unified Patent Litigation System.

Taking the doctrine of division of powers within legal systems into consideration – the division into a legislative, an executive and a judicial power – what are the main differences between European patent law and U.S. patent law and the way in which patent law is made?

Dr. Rob J. Aerts: Under the EPC system, the European Patent Organization, i.e. the European Patent Office (EPO), its President and the Administrative Council together, exercises in fact the combined powers of initiative of lawmaking, law-making itself and execution of the law. The Conference of Contracting States has an important legislative function, whereas the Boards of Appeal and Enlarged Board of Appeal interpret the law. There is no possibility of review of law-making under the EPC. At the other end of the spectrum, under U.S. patent law-making, the power slots are carefully separated over appropriate bodies. Thus, Congress has exclusive legislative power subject to the veto of the President, the President has delegated his or her exclusive power to execute the patent laws to the USPTO, and the U.S. Court system reviews the constitutionality of adopted legislation and interprets the law. Each of the bodies involved has its own specific power slot. Under European Community law there is a comparable functional separation of powers over the institutions. Under the ever more important Article 251 EC Treaty procedure, as used for the adoption of the Biotechnology Directive and the drafting of the software directive, the Commission initiates law-making, whereas the Council of Ministers and European Parliament have combined legislative power. The Commission sees to the execution of the law, and the European Court of Justice (ECJ) interprets the law, and reviews the lawfulness of adopted legislation, like it did in the action for annulment of the Biotechnology Directive². The ECJ has been very much aware of its responsibility to uphold a system of checks and balances between the legislative, executive and judicial functions within the European Community³. Thus, separation of powers seems ensured during patent law-making under the supranational Community system as well as the federal U.S. system. In contrast, under the intergovernmental EPC system it is difficult to speak of a functional separation of powers.

	European Patent Convention	European Community Law	U.S. Patent Law
Initiative of law-making	President EPO & EPO Departments	Commission	Congress (Sponsors)
Legislative power	Administrative Council & Conference of the Contracting States	Council of Ministers & European Parliament	Congress (President has veto)
Executive power	EPO & Administrative Council (Supervisory role)	Commission	USPTO & Department of Commerce (Supervisory role)
Review of law-making	No judicial review of adopted legislation	European Court of Justice	U.S. Court system (Up to Supreme Court)
Interpretation of the law	Boards of Appeal & Enlarged Board of Appeal	European Court of Justice & National Courts	U.S. Court system

From: Aerts, R.J. (2007) The legitimacy of patent law-making in Europe and the US - a tentative comparison. International Review of Intellectual Property and Competition Law (IIC) 38(2), 165-182

2. Democratic control over patent law-making in Europe

Concerning patent law-making under the EPC system you say: "Amendments are designed and adopted within the system: there is no active participation of a democratically elected body". Does this mean there is a difference in democratic legitimacy of patent law-making under the two current European systems?

Dr. Rob J. Aerts: Although during law-making under the EPC system it can be said that the negotiating Contracting States represent the citizens in one way or another, it is clear that democratically elected national parliaments are

not actively involved in the law-making process itself and that parliaments can only ratify submitted legislation, indicating only minimal democratic control over the process. In case the Administrative Council acts alone, national parliaments are not involved at all. In contrast, under the European Community's co-decision procedure of law-making the European Parliament plays a crucial role as is exemplified by the fact that the first draft of the Biotechnology Directive was rejected by Parliament, and that Parliament insisted on addressing ethical issues in the Directive. Crespi noted: "It was important to have this debate for the sake of legal clarity and competence in European intellectual-property law, and also as a contribution to the wider issue of the public perception of biotechnology"⁵. Thus, democratic legitimacy of patent law-making would appear to be ensured under European Community law, but far less so under the EPC.

What does this mean in terms of trust of society at large in European patents?

Dr. Rob J. Aerts: The promotion of technological and scientific progress by means of patent law entails that this body of law has to adjust constantly to newly emerging technologies and scientific developments. But as we know, adaptation of patent law to new technologies often is not without controversy, and initiates societal debates. These are necessarily political issues, and the adaptation of patent law to new technologies ultimately begs the question of the very legitimacy of patent law-making itself. Insufficient democratic control like under the EPC system entails the danger that a publically perceived lack of legitimacy of law-making results in a distrust of the system, and resistance against the patenting of new technologies.

3. Changes to the current system?

Do you think it is necessary to change the current system and to have a more powerful participation of democratically elected bodies in renewing European patent law? Which possibilities exist to realise such a change?

Dr. Rob J. Aerts: There are considerable differences in the way law is made under the EPC system, on the one hand, and under the European Community system, on the other hand. There are also considerable differences in the degree of legitimacy of law-making under the two systems, in terms of a guarantee of separation of powers within the system, democratic control, and appliance to the rule of law in general. However, given the entirely different bases, historical backgrounds and purposes of the two systems, any comparison is inherently difficult. For instance, it should be kept in mind that the EPC was never intended to be a highly legitimate system of law-making. It merely is an intergovernmental treaty, designed to provide for

an overarching system for the examination and grant of European patents, by an efficient, centralized system that covers a multitude of countries. As such the EPC has proven to be a very successful system. Still, as was noted before, it is undesirable that European patent law is subjected to diverging rules in command of different bodies⁶. For instance the implementation of the Biotechnology Directive, a body of supranational law, by the Administrative Council into the Implementing Regulations of the EPC, a body of intergovernmental law, has resulted in legal uncertainty. Whereas the Directive is substantive law within the European Union and pursuant to Article 249 EC Treaty binding upon the Union Member States as to the result to be achieved, the same provisions codified in the Rules of the EPC are merely subordinate to the Articles of the EPC⁷. Given the different wording of the Articles and the Rules, this resulted in legal uncertainty with respect to the requirement of industrial applicability of gene sequences⁸, and the exclusion of patentability of essentially biological processes for the production of plants⁹. Also, the incorporation of the Biotechnology Directive into the Rules of the EPC means that the Enlarged Board of Appeal now has to give an interpretation to Community law, yet the Board is unable to submit questions to the ECJ under Article 234 EC Treaty like courts of European Union Member States can do¹⁰. Such a strict separation of the two legal systems is an unfortunate situation. A possible solution to the outstanding problems, which has been advocated by several authors for more than one decade, is the transfer of the entire EPC system into the European Union's legal order¹¹. Such a transfer would also secure sufficient legitimacy of the European patent law-making process. Also the pressure of aligning the provisions of the EPC with those issued by the Community would be solved. European trademark law is a prime example of the involvement of the Community with a complete discipline of intellectual property law at large. Likewise, the transfer of the entire EPC into the Union's legal order would arguably provide a single patent-law instrument wholly commensurate with the single, common market.

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- 2. Kingdom of the Netherlands v. European Parliament and Council of the European Union, ECJ 9 October 2001, case C-377/98, Official Journal of the EPO, 231 (2002).
- 3. Lenaerts, K. (1991). Some reflections on the separation of powers in the European Community. Common Market Law Review, 28, 11-35.
- 4. Aerts, R.J. (2007) The legitimacy of patent law-making in Europe and the US a tentative comparison. International Review of Intellectual Property and Competition Law (IIC) 38(2), 165-182.
- 5. Crespi, R.S. (1999). The biotechnology patent directive is approved at last! Trends in Biotechnology, 17, 139-142.
- 6. Straus, J. (1997). The present state of the patent system in the European Union as compared with the situation in the United States of America and Japan. Luxembourg: Office for Official Publications of the European Communities.
- 7. Article 164(2) EPC2000.
- 8. Aerts, R.J. (2008) Biotechnological patents in Europe: functions of recombinant DNA and expressed protein and satisfaction of the industrial applicability requirement. International Review of Intellectual Property and Competition Law (IIC) 39(3), 282-306.
- 9. Bostyn, S.J.R. (2009) How biological is essential biological? The referrals to the Enlarged Board of Appeal G-2/07 and G-1/08. European Intellectual Property Review (EIPR) 31(11), 549-558.
- 10. Decision G-2/06 of the Enlarged Board of Appeal of 25 November 2008.
- 11. Nr. 1 above; Nr. 4 above; Nr. 6 above; Bossung, O. (2003). A Union patent instead of the Community patent developing the European patent into an EU patent. International Review of Industrial Property and Copyright Law (IIC) <u>34(1)</u>, 1-30.

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The opinions expressed in this interview reflect the personal view of the interviewee only.