Biomedics and Creative Commons

C Roosendaal, A.P.

Published in:
Business Law and Technology

Publication date:
2006

Biomedics and Creative Commons: a perfect match?

Arnold Roosendaal

Tilburg Institute for Law, Technology and Society (TILT)
E-mail: A.P.C.Roosendaal@uvt.nl

Abstract: Biomedics is one of the most important new research fields. The development of drugs and health care is of major importance for the general public. To create more openness and to promote development, Open Source initiatives from the ICT domain have been applied to biomedics. There are however certain problems arising, especially if commercial companies are invited to join the projects. This paper aims at identifying the problems that occur as a result of the tension between traditional proprietary regimes and new approaches such as Open Source and also tries to give a starting point for solving the issues.

Keywords: biotechnology; open source; creative commons; CC; patents.

Reference to this paper should be made as follows: Roosendaal, A. (2007) 'Biomedics and Creative Commons: a perfect match?', *Int. J. Intellectual Property Management*, Vol. 1, No. 4, pp.316–324.

Biographical notes: Arnold Roosendaal is a research assistant at the Tilburg Institute for Law, Technology, and Society (TILT). He is currently studying Law and Technology (LLM). He has published several papers in different fields of technology in relation to law and the societal implications of technological development.

1 Introduction

New inventions in biotechnology can have an enormous impact on the evolution of medical treatment. The development and creation in laboratories of stem cell lines and even complete human organs are current practices. Numerous research institutes, non-profit as well as commercial, are searching for new possibilities and methods to enlarge their capabilities. The wish to enable proper cure of diseases such as cancer and Parkinson forms a great impetus to biotechnological inventions. With regard to Parkinson, scientists Lozano and Kalia state:

> "Recent genetic and cellular discoveries are among the advances pointing to improved treatments for this increasingly common disorder." (Lozano and Kalia, 2005)

However, research and development need great investments and funding. This implies that researchers need to achieve a return of their investments by selling their products. Besides, they want recognition for their innovations. The challenge for legislators is to find a way of regulation that enables both the interests of the researchers to be fulfilled on the one hand and on the other hand reduces the restriction of medical development

because of patents to a minimum. That patents can have a restrictive effect on innovation has been recognised earlier. Burk and Lemley for example, suggest

> "that courts should strictly interpret the obviousness requirement, so that fewer biotechnology inventions qualify for patent protection, but interpret the disclosure requirement liberally, so that the biotechnology patents that do issue are broad and strong." (Burk and Lemley, 2003)

There have been proposals and initiatives for open source licensing of biotechnological inventions. Open source licences emphasise the source of the inventions, e.g., the stem cell line. In this paper, I will criticise the open source initiatives and also a system comparable to the Creative Commons (CC) licenses. In my opinion, this will not bring a better balance between the different interests of researchers, governments and the general public in the way it is used currently. I will try to propose some solutions for problems that occur in relation to investments and subsidies as a result of the new approach of intellectual property rights.

I will first give an overview of the current situation in the Netherlands, whereby I will discuss relevant European initiatives that provide the regulatory framework for the Dutch position. Then I will describe the Open Source initiatives and its consequences for the intellectual property landscape. In the subsequent chapter I will present the CC licenses and also make a comparison with the open source licenses. Afterwards, I will discuss related shortcomings of this system and try to find solutions for these problems. In the final chapter, I will make a brief summary and draw some conclusions.

2 The current situation

2.1 Biomedics

Biotechnology is an increasing field of research and innovation. This paper focuses on the so-called 'red biotechnology', the part for applications in health care such as production of vaccines, gentherapy, genetics research and DNA-diagnostics (van Opstal, 2005), also called biomedics. The aim of biomedics is to cure and to avoid diseases by manipulating and selecting genes, stem cells and DNA, or by using these materials to 'repair' sick parts of the body. Together with the USA and Japan, Europe is in the leading group of biomedical innovating countries.

The field of biomedics seems to be very promising, although there are uncertainties related to ethical opinions of the public and potential risks of these new technologies. At this moment, the benefits of most applications are deemed to be bigger than the costs and risks. The most obvious exception in this, according to recent discussions in media and magazines, is gentherapy. The uncertainty of proper cure with this new technology leads to speculations and criticism. However, governments and the European Community are positive and generously investing in research projects on biomedics. The European Commission says the following about the Sixth Framework Programme for Research and Technological Development (FP6):

> "FP6 will help to address some of the outstanding problems hampering the development of biotechnology in Europe, such as insufficient mobility, 'brain-drain' of our researchers, fragmentation of research efforts and lagging transformation of research results into products and services. This European public research effort will complement and spur the investments made by entrepreneurial biotechnology companies, totalling €7.5 billion in research in 2001." (EUComm, 2003)

Private companies are also investing in their own research projects. Most projects are focused on very specific problems, such as the cure for cancer and Parkinson's disease. Genetics research tries to compose a map of different types of genes and their characteristics and effects on the development of human beings. Once this map is ready, an analysis can be made of the specific genes that are causing problems. By manipulating these genes or by repairing them with stem cells, diseases can be cured or avoided. It is not difficult to imagine that these research projects are extremely expensive. For that reason, companies encounter a high level of dependence on subsidies from governments. Besides, they try to obtain patents in order to gain a return on their investments.

2.2 Patents

The current legal system of awarding subsidies is strongly connected to the patent system. The innovative level of companies is judged on the basis of the amount of patents the company applied for. The more patents a company has, the more subsidy it can receive. Of course, it is not that transparent. There are more criteria, but at least this one is of great importance in the selection of research projects to be subsidised. For example, point 6 in the guidelines of the STW Technology Foundation requires a report on patent search and an overview of patents and current applicants for patent. The result of granting projects with this system is that companies are trying to patent all new inventions or parts of inventions, almost apart from the relevance of the inventions.

Obtaining patents can be done under different laws. On a national level, the Netherlands has the National Patent Act 1995 (Rijksoctrooiwet, 1995), but more common is filing with the European Patent Office, conferring a patent under the European Patent Convention (Munich, 1973; van Vliet, 2006). More recent development can be found in Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (Biotech Directive). This Directive aims to clarify and harmonise the specific patent requirements for biotechnological inventions in the Member States (Rethmeier, 2002). In November 2004, the Netherlands implemented this Directive with delay by amending, as far as relevant in this context, the National Patent Act.

There are three main conditions for the acceptance of a patent: the innovation has to be new; it has to be ingenious (not obvious for an expert); and it has to be industrially applicable. As stated above, this applicability seems to be judged apart from the purpose or relevance of the innovation.

Because the patent is meant to be a stimulus for innovation, there appears to be some friction to this point. The stimulus is incorporated in the exclusive right to exploit the innovation. Once there is a patent on some invention, others cannot use it freely. If there are patents on small inventions which have no significant value as such but can have an enormous value once they are developed further, this might prevent innovation, or at least make it more difficult. Since biomedics is a relatively new area of research and

the development of medicines and methods of cure depends on innovations, this situation is of great concern. At this point, I am focussing on the development and the values for health. Other issues, for example- ethical discussions on the permissibility of biomedical research and development, are not addressed in this paper.

The problem mentioned above has been recognised before and not without result. Inspired by the computer software industry, initiatives have been expanded for open source patenting. According to Boettiger and Burk

> "open source patenting presents a promising and intriguing approach to resolving the tension between the communality of science and the economic incentive of patent law." (Boettiger and Burk, 2004)

In the next paragraph I will give some background information and examples of open source initiatives.

3 Open source initiatives

The open source model originates from the software industry. In reaction to the monopolist positions of large companies, some producers started to develop software programs and to provide these programs for free. In addition, they also delivered the source code of the programs. This would enable users to make changes in the software and to develop it further. Another consideration to deliver the code was the idea that the software would gain a higher standard. Programmers and hackers were enabled to trace bugs and leaks at a very early stage and to fix them. Optimisation was the keyword.

Obviously, this new model has major consequences for the intellectual property rights system. In fact, by providing software and its source code for free, the author relinquishes his rights. This implies that there remains no possibility to financially exploit the program, unless the program, including the source code, is for sale. However, that would not be in accordance with the general, maybe idealistic, idea of the open source movement. By using the open source model, patent policies are set aside and no longer regulate the innovation market.

The wish to apply the idea to other fields of research and development is the logical result. As the Australian molecular biologist Jefferson says:

> "If multinationals are allowed to hold patents on basic tools and gene sequences that are the very operating systems of life, promising new sectors will be left undeveloped and society will lose out." (cited in Herring, 2006)

And "freeing the basic tools of biotech – the keys to inventions affecting human and plant- is crucial to spurring innovation". Jefferson is one of the key figures in the open source biotech initiatives. He started in 1987 to share his scientific discoveries for free. Biotechnological development and innovation being the motive, financial reimbursement for his scientific work became of minor importance.

International organisations also recognised the possible problems of the current patent system, resulting for example in 2001, in the Ministerial Doha declaration, which calls on TRIPs Member States to use the flexibilities in intellectual property law to the fullest to protect public health (Schellekens, 2006). Intellectual property rights should not hinder human health care, implying that there can be restrictions to the absolute rights in order to ensure proper cure of diseases and the quick solution of health crises in circumstances of extreme emergency.

Further open source initiatives have followed, for biotechnology mainly in the area of genomics, like, for example, the Hapmap Project and the CAMBIA BIOS Initiative. Unfortunately, these initiatives are only taken by non-profit institutes and organisations because of the fact that commercial exploitation is difficult. In contrast with the software industry, there are rarely options for related activities, such as helpdesks and personal adaptation services, to gain money in biotech.

Just like the developments in software, the open source biotech initiative is followed by the CC principle. In the next paragraph this principle will be presented and some advantages and problems will be addressed.

4 Creative Commons (CC) and science commons

As a follow up on the open source movement, the CC saw the light. The basic idea of CC is that audio, video, images and texts are publicly available and can be used, but there can be restrictions on the use of the work. There are core licenses like attribution, non-commercial, no derivative works and share alike or combinations. Each of the licenses has its own specifications on how the work can be used. Offering work under a CC license does not mean giving up copyright, but giving some parts of your right to others on certain conditions.

Sharing the copyrights also has implications for the reimbursement facilities based on copyright. The original right stays with the author, but to no effect. However, the license is binding on the basis of the licensing contract and the author will expect compliance. Commercial benefits for others than the original author will not be tolerated, because the author himself is not making a profit either.

The idealistic starting point of sharing artistic or innovative insights and knowledge and to develop works together with others is favourable in essence. The application of the ideas on different areas is not astonishing. In 2005 the Science Commons were founded. On the project of biotechnology their website says:

> "Research materials are essential to the practice of modern life sciences experimentation. Cell lines, model animals, DNA constructs and screening assays each represent a tool for testing and validating hypotheses of biological function and human health. Each offers a perspective into biology that cannot be replicated without access to the material."

Access is the keyword in this field of research. To enable access, scientists use the so-called Material Transfer Agreements (MTAs). The tools that are needed for research are transferred to others on a contractual basis. Unfortunately, even though the transfer of materials is possible, there remain problems with the licensing. In general, it is not clear which ways of using the materials are allowed. By implementing the CC system, this problem can be solved. The broader Science Commons initiative and its biotechnology programme is a welcome starting point towards knowledge and materials sharing in order to promote innovation. However, two challenging questions remain unsolved.

5 Problem definition

When applying Science Commons to biomedics, two main problems that need to be solved in order to promote development in the commercial sector can be addressed. Both of them are strongly interwoven with money aspects, the main issue for commercial innovations. The first problem arises in the field of gaining a return on investments for innovation projects. The other one is related to the system of how subsidies are being awarded to research projects beforehand.

5.1 Gaining a return on investments

In the traditional system, investments in research and development from commercial companies are returned by patenting inventions. Patents are the safeguard for companies to exploit their products. A patent, as an intellectual property right, gives the inventor the exclusive right to exploit the product or invention. This is intended to be a reward for the inventor's efforts and investments. For (commercial) companies this offers the opportunity to gain a return on the investments and to make a profit from the new product.

In the Science Commons system, this is more difficult. The exclusive right is restricted because the invention has to be available for other scientists and inventors. It is true that the inventor can choose which type of license he connects to each particular invention, thereby defining the competences of others with regard to the use of the invention. However, if the license allows use after having paid a certain amount of money, the result is the same as with traditional patents. The aim of the Science Commons will not be realised.

Another possibility is offering a license free of charge, but then the company will lose its commercial benefit and thus will not extend any license. Perhaps, licensing others to use an invention for further research and development with a prohibition on commercial use might be an option. However, in that case there would still be the need for a patent to safeguard the intellectual property rights in relation to other companies.

A counter argument might be that the participation in an open source initiative gives access to innovations of others as well. However, gaining a return on investments on the basis of intellectual property rights for innovative work remains a problem.

5.2 Subsidies

Another problem arises in relation to the system of awarding subsidies for research and development as it is used in several countries. If a company or institute wants to start up a research project, they can apply for a subsidy from the government. A request should include information on the research topic, method and approach, the innovative value and a motivation of the importance of the research project. Another part of the request needs to give information about the institute or company itself, so it can be estimated. The estimation needs to provide an insight into the scientific value, earlier innovative successes (past performance) and the appropriateness of the company due to, for example, specialisations in research areas.

This is the point where the problem arises. The insight into the appropriateness of the company depends largely on patents. Subsidy request forms, such as the STW guidelines (2006), include a section for patents, results of a patent search and an overview of patents and current applications for patent in the respective research area. This means that patents are very important in the considerations of the award of subsidies to specific companies or institutes.

If the Science Commons system is applied by commercial companies, they will not have patents anymore, implying that the appropriateness of companies can be misunderstood. In that case, the subsidies will not be awarded to these companies. The innovative process then has to rely completely on the account of the company itself. This might hamper development, because companies will make a consideration based on a cost-benefit analysis, where the costs might be so high that the innovation project will not be started. The benefits are in most cases uncertain.

It needs to be said that open source does not always imply a prohibition to patent an innovation. However, companies apply for patents to safeguard their intellectual property rights in the first instance. If they participate in an open source programme and also have to apply for a patent, this would only be extra work.

The problems addressed above seem to show a kind of vicious circle. If one problem is solved, the other one shows up. In the next paragraph, I will try to propose a solution.

6 Proposal

The development of biomedical inventions is most important for the general public. Health care is a major issue in today's politics, not only in Europe, but, maybe even more so, in developing countries. A system of patents that restricts, or at least slows down, this development is not favourable. However, a Science Commons system, as described above, also has its disadvantages. It is clear that the system is appropriate as long as there are no commercial companies involved. But a quick development and innovation requires the participation of commercial companies. The main question is, therefore, how to make participation in Science Commons attractive for commercial companies as well. There is a need to break through the vicious circle. On the one hand, there needs to be a possibility to gain a return on investments like there is under the traditional patent system. On the other hand, innovations need to be recognised for the awarding of subsidies, even if there are no patents to measure this.

Because the point of focus is related to biomedical development in order to facilitate better health care, the restrictions on the availability of inventions should be reduced to a minimum. An option to start with is to make public availability of certain inventions obligatory by law in the public interest. This might solve the availability issue, but in addition the other problems mentioned need to be solved.

The Science Commons system can serve as a guide because of the option for different types of licensing. In essence, the license is a contract and, except for some restrictions on morality, there is a freedom of contract. One can agree about whatever he or she wants in a contract. In paragraph 4, some examples of agreements were given. A quite common provision in licenses is the obligation to mention the name of the first author or inventor. This obligation can help to recognise the company who has invested in the first instance in a project or invention. On the basis of this recognition, the appropriateness of a

company can be judged if the licenses can count in a similar way as the patents. Solving this problem, therefore, requires a change of the guidelines used by organisations which award the subsidies from the government.

In this case, mentioning the inventors name as an obligatory provision in license agreements can solve the issue of the subsidies. But it might also help to solve the problem of gaining a return on investments. The traditional patent system provided the possibility to regain investments by selling licenses to use the patented invention. By mentioning the name of the original inventor and selling or giving individual licenses, it may be possible to set up a distribution code for profits made with derivative products. One very important condition then, is that licensees have to consult the original inventor if they want to sell or license their product to others.

The main advantage of this system is that inventions will be publicly available immediately, but there is no need for big investments in buying licenses in advance. If commercial profit can be made from a derivative product, then the licensee has to pay a certain amount to the original inventor.

The exact way of setting up the model and the system of distribution is a specific issue that might be an interesting task for economists. Economic considerations related to investments and cost-benefit analyses have to be taken into account. This proposal is only an indication of a possible solution.

7 Conclusion

This paper paid attention to problems related to the new approaches on intellectual property rights and its application to the domain of biomedics. I first gave a description of the current situation in the Netherlands and its relation to European initiatives. The traditional patent system has its disadvantages for development because of restrictions on the use of patented innovation, mainly from a commercial perspective. This is the reason why open source, CC and Science Commons initiatives were introduced. The aim of these projects was to gain an openness of innovations and to make information and materials publicly available. The founders of these initiatives, on the one hand, wanted to enable innovation on a higher quality level and, on the other hand, to reduce costs related to intellectual property rights as much as possible. This would be in the interest of the general public. The development of drugs and health care with biomedics is of importance for all people.

However, two main problems occurred. The first problem was that gaining a return on investments without patents becomes more difficult. This might be a reason for commercial companies not to contribute to an open source movement. The participation of commercial companies is needed to promote development as much as possible.

The second problem was related to subsidies. If governments or organisations award subsidies they analyse the appropriateness of the companies that require support. The amount of patents and patent searches are of great importance to gain insight into companies. The two problems are in some kind of a vicious circle which needs to be broken through.

In the previous chapter, I proposed a specific license with some obligatory conditions. The name of the original inventor needs to be mentioned and the licenses for open source or Science Commons need to be recognised in a similar way as patents in order to enable proper insight in appropriateness of companies as well.

The proposed model needs some further research and should perhaps also be checked by economists to investigate the feasibility in practice. However, raising the matters that occur in practice by using open source licensing for biomedical inventions should be a starting point for discussion and working towards solutions. The interest of the general public needs to be fulfilled as much as possible, and proper cure and health care certainly belongs to that interest.

Acknowledgement

A version of this paper was published in Kierkegaard (2006).

References

Boettiger, S. and Burk, D. (2004) 'Open source patenting', *JIBL*, Vol. 1, pp.221–231.

Burk, D. and Lemley, M. (2003) *Policy Levers in Patent Law*, 89 Va.L.Rev.1681–1682; cited in Opderbeck (2004).

EUComm (2003) *Life Sciences and Biotechnology: A Strategy for Europe Progress Report and Future Orientations*, Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee, Brussels, (COM(2003) 96 final), p.9.

Herring, R. (2006) 'Open-source biotech, borrowing the software model to spur innovation in life sciences finds common ground with IT', in Herring, R. (Ed.): *The Business of Technology*, April 17, available at: http://www.redherring.com/Article.aspx?a=16473, Visited September 26th 2006.

Kierkegaard, S. (2006) 'Business law and technology', *IBLT Conference Proceedings*, Vol. 1, pp.63–71.

Lozano, A.M. and Kalia, S.K. (2005) *New Movement in Parkinson's, Scientific American.com*, July, Available at: http://www.sciam.com/article.cfm?chanID=sa006&colID=1&articleID=00078984-3758-12B3-A92783414B7F0000.

Opderbeck, D. (2004) 'The penguin's genome, or Coase and open source biotechnology', *Harvard Journal of Law and Technology*, Vol. 18, No. 1, Fall, pp.167–227.

Rethmeier, N. (2002) 'Octrooieerbaarheid van biotechnologische uitvindingen', *Conceptuur*, No. 33, December, pp.12, 13.

Rijksoctrooiwet (1995) *Rijkswet van 15 December 1994, Houdende Regels Met Betrekking Tot Octrooien*, Available at: http://wetten.overheid.nl/cgi-bin/sessioned/browsercheck/continuation=21052-002/session=062343105681473/action=javascript-result/javascript=yes.

Schellekens, M.H.M. (2006) 'Open source biotechnology: a drug for developing countries' health problems?', Unpublished.

STW Guidelines (2006) *Guidelines for the STW Technology Foundation Utilisation Plan*.

van Opstal, M. (2005) 'Moderne biotechnologie belooft effectievere gezondheidszorg', *Diagmed*, Mei, pp.16, 17.

van Vliet, L.P.W. (2006) *The Boundaries of Property Rights*, Netherlands National Report, p.8.

Websites

http://www.creativecommons.org, last visited October 13th 2006.

http://www.hapmap.org/index.html.en, last visited October 14th 2006.

http://www.sciencecommons.org, last visited October 13th 2006.