CONSTRUCTING ACCESS THROUGH EXCLUSION. THE EFFECT OF INDIVIDUAL AND COLLECTIVE PATENT OWNERSHIP AND LICENSING ON OPENNESS IN HUMAN GENOMIC SCIENCE

Geertrui R.L. Van Overwalle
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Geertrui Van Overwalle

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Abstract
Human genomic science and intellectual property are often considered to be at odds. The present paper is an attempt to analyse the current problems in gene patenting through the lens of individual, multiple and collaborative ownership. The objective of the present chapter is to systematize the relation between modes of ownership, modes of licensing and their effect on access.

Individual and multiple ownership have different effects. Individual ownership may result in blocking patent positions and multiple ownership may lead to hindering patent thickets. Both phenomena frustrate follow-on innovation. The effect of individual and multiple ownership, blocking patents and patent thickets may be attenuated by the creative design of (new) individual,
collaborative and collective (voluntary and compulsory) licensing models, leading to semi-open or totally open biotechnology infrastructures.

1. Introduction

A shock wave swept through the biotechnology community when Judge Robert W. Sweet of the District Court for the Southern District of New York decided to deny patent protection for isolated human genes and associated diagnostic methods. The case related to genetic tests for familial breast and ovarian cancer developed by Myriad Genetics. Although the decision was partly reversed in appeal and may well be debated again before the Supreme Court, many of the concerns relating to the impact of gene patenting which are extensively discussed in this case, will continue to exist. The Myriad case is an exponent of a systemic problem. The disputed issues in the Myriad case point to the uneasy relationship between human genomic science and intellectual property (IP). The debate particularly revolves around the alleged hindering effect of single, blocking patents, on the one hand, and patent thickets, on the other hand, in the area of genetics.

Inspired by the ongoing exchange of ideas on distinct modes of ownership and their respective impact on exclusivity and competition, the present paper is an attempt to analyse the current problems in gene patenting through the lens of individual, multiple and collaborative ownership. The objective of the present chapter is to systematize the relation between modes of ownership, modes of licensing and their effect on access. The underlying (normative) starting point of the present study is the legitimacy of IP ownership over human genes. Another assumption is the merit of openness for fostering research and

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2 United States Court of Appeals for the Federal Circuit, Association for Molecular Pathology v. USPTO and Myriad Genetics, July 29, 2011 (Appeal from the United States District Court for the Southern District of New York in Case No. 09-CV-4515, Senior Judge Robert W. Sweet). Association for Molecular Pathology filed a petition seeking a rehearing of the federal Circuit decision, which petition was denied.
3 Association for Molecular Pathology has petitioned the Supreme Court to overturn the CAFC decision.
4 The current essay does not seek to look into issues relating to ownership and access (to knowledge) in patent law, but is interested to learn about the effect of ownership on access and (legitimate) use of patented knowledge. Hence, the issue of (enabling) disclosure, and its contribution to access to knowledge, will not be dealt with here. Also see infra, section 4.1.
5 This starting point is substantiated infra (see section 3.3.), where we explain why we will not enter into the debate on the patentability of human genes.
development in genetics. The central question of the present essay is which measures can be taken to assist patent law in responding to the alleged hindering effect of various forms of ownership and the intensified appeal for access in genetics. The core question is not what will change if the rules or forms of IP ownership are modified in genetics, but what might change if the conventional modes of licensing are altered. In other words, the key question does not revolve around proprietary or non-proprietary approaches in genetics, but around access improving license management structures.

The central question will be dealt with in two steps. First, we will examine different forms of ownership and their effect on access: do different forms of ownership have a different effect on access in genetics? Then, we will explore different forms of licensing and their effect on openness: do different forms of licensing result in different degrees of access?

Section 2 defines the contours of individual ownership, discusses its potential hindering effect on access and use in genetics, and suggests possible individual license policies and their effect on (re)establishing openness. Section 3 analyses the various forms of multiple ownership, looks into their effect on access and use in biotechnology, and investigates various collaborative licensing models and their effect on openness. Section 4 explores how these individual and collaborative license policies may assist in achieving “open biotechnology”. Section 5 sets forth the most striking conclusions and suggests some avenues for further research.

The present study will conclude that in genetics, individual and multiple ownership have different effects. Individual ownership may result in blocking patent positions and multiple ownership may lead to hindering patent thickets. Both phenomena frustrate follow-on innovation. The effect of individual and multiple ownership, blocking patents and patent thickets may be attenuated by the creative design of (new) individual, collaborative and collective (voluntary and compulsory) licensing models, leading to semi-open or totally open biotechnology infrastructures.

2. Individual ownership

2.1. Concept

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6 Empirical evidence and economic analysis would be helpful in providing a wider scientific basis for this assumption.
Ownership refers to the legal right a legal system grants to a person or a group of persons allowing him/her/them to exercise the maximum degree of control over a scarce resource. In other words, ownership refers to any kind of attribution of legal protection of (intangible) subject matter to a person or group of persons by way of specific regulation. Individual ownership refers to a single person acquiring a single protection right. Translated into the patent context individual ownership refers to one inventor holding one patent right (also see Table 1).

2.2. Individual ownership and “blocking patents”

At first sight, the exclusivity provided for by individual ownership seems predestined to have a problematic impact on access and use in genetics. This derives from the very nature of human genes and the character of patent claims on genes. Patent claims on genes are generally difficult, if not impossible, to invent around. Consequently, gene patents emerge as blocking IP entitlements. We define a blocking patent as a patent covering essential features of an invention which cannot be invented around, bearing in mind that a blocking patent is a relative concept.

It is a relative concept as it relates to the presence of two distinct components or layers: an essentiality component and an instrumentality component. Given that a certain activity or function is envisaged (instrumentality component), an assessment is required as to which elements are essential to perform that activity or function and whether these essential elements are claimed by the patent at stake (essentiality component). Only when the elements are indispensable or essential to achieve a specific result – in other words, when the essential elements are a necessary means to an end – and only when they are claimed in the patent, the patent concerned is a blocking patent.

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9 The patent applicant or patent holder may be different from the inventor. The patent applicant-holder may well be an employer (of the inventor) to whom the right to (apply for) protection has been transferred or to whom the granted patent right (or patent application) has been sold.
11 In a wider sense, any patent is by definition a blocking patent, as a patent confers upon its proprietor the right to stop others from making, using, offering for sale, selling, or importing the patented invention (See art. 28 I TRIPs Agreement). Used in this sense, the notion blocking patent is a tautology.
12 Van Overwalle, supra note 9.
blocking patent. In other words, a blocking patent appears when the patent covers essential features of an invention relevant for achieving a specific result. In the area of genetic diagnostics, a patent encompassing claims on the entire (or relevant part of the) gene sequence, on a common pathogenic mutation or on the fundamental method to determine the association between a mutated gene and an inherited disease, is blocking for carrying out the genetic test based on nucleotide analysis for that disease. A patent including the same claims is most likely not blocking when it comes to carrying out the test based on an analysis at the protein level (a so-called protein determination assay).

Some recent data suggest that a substantial number of gene patent claims are indeed hard or impossible to circumvent and therefore qualify as blocking patents. Blocking patents do not per se have a negative impact on openness. Whether blocking patents have an unfavourable impact on access and form a threat to openness, largely/totally depends on the licensing policy applied by the individual right holder.

2.3. Licensing and openness

2.3.1. Bilateral or cross licences

A single right holder may be willing to share the benefit of his (blocking) gene patent with others in an attempt to improve his market position. Sharing with one person usually takes place under the form of a one-to-one bilateral license in return for a fee or for a license, resulting in restricted access (see Table 1). Sharing with multiple (though limited in number) persons may take place by granting a bilateral license to each of them, resulting in a series of bilateral licenses and royalty fees, but still resulting in restricted access (see Table 1). In both cases, only restricted

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13 Van Overwalle, supra note 9.
14 Van Overwalle, supra note 9.
16 The terms "access" and "openness" are used alternately. Access and openness refer to access to and use of patented technology, see infra section 4.1.
17 The term license refers to licence in the pure commercial sense, excluding Material Transfer Agreements (MTAs), cf. Esther van Zimmeren, Sven Vanneste & Geertrui Van Overwalle, Patent Licensing in Medical Biotechnology, Leuven, Acco, 2011, at 41.
18 Hence the term cross license. The term cross-licence refers to a special variant of a bilateral licence: it is generally an agreement between two patent owners, where the patent owners grant each other a licence for the exploitation of the subject-matter claimed in the relevant patents. Both patent owners act as licensor and licensee, see van Zimmeren et al., supra note 16, at 59.
access is created, as access and use is limited to a number of well identified licensees (see Table 1). Both access regimes confer access upon payment of a fee, resulting in conditional, restricted access.

2.3.2. License of right

The right holder who wants to share the use of his patented invention with an even wider circle of persons, or, in other words, who is willing to provide access and use to an unlimited number of users, may do so by opting for a “license of right” (see Table 1). The “license of right” is a legal mechanism by which a patent holder voluntarily chooses to give access to the patented invention to anyone else.

Licenses of right are not new. They already appear in the national patent legislation of various EU member states and were envisaged in the framework of the Community Patent Convention of 1975 and the Community Patent Agreement of 1989. Nowadays, they figure in the proposed Community Patent Regulation which provides that “[t]he proprietor of a Community patent may file a written statement with the Office that he is prepared to allow any person to use the invention as a licensee in return for appropriate compensation. In that case, the renewal fees for the Community patent which fall due after receipt of the statement shall be reduced”.

The license of right option also captured some attention in patent practice. IBM launched a proposal for a “soft” Community patent endorsing a license of right. Furthermore, a recent study by legal and economic scholars suggests that a remuneration-based license of right would be attractive for various kinds of patent owners and might encourage a more efficient exploitation of

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19 On “restricted access”, also see infra, section 4.1.
20 On “conditional” versus “unconditional”, also see infra, section 4.1.
21 They exist in several countries, like for instance the United Kingdom, Germany, France and Switzerland. For more details, see Esther van Zimmeren & Geertrui Van Overwalle, ‘Compulsory License Regimes for Public Health in Europe’, International Review of Intellectual Property and Competition Law (IIC), 2011, 4-40.
25 IBM, The European Community Patent - A Realisable Dream, IBM Discussion Paper, available at http://www.epip.eu/conferences/epip02/lectures/European%20Interoperabilty%20Patent%201.1.pdf. The authors of the discussion paper promote “soft IP”, which would serve both open and proprietary innovation, and argue in favor of an EU patent which endorses a license of right in line with the idea of “soft IP”.
patented knowledge.\textsuperscript{26} The study recommends further empirical research on the use and impact of licenses of right in the various EU member states and on the overall effectiveness of a remuneration system.

Licenses of right grant access to the patented invention to anyone else, thus creating \textit{general access}.\textsuperscript{27} The patent owner agrees to receive a pre-determined remuneration for the use of his invention and if the user pays the required amount, the patent owner has no right to prevent the grantee from using the invention anymore.\textsuperscript{28} Hence, the terms “remuneration right” and \textit{conditional access} (see \textit{Figure 1}).

\textbf{2.3.3. Open source license} \textsuperscript{29}

The term ‘open source’ originally came up in the context of copyrighted software. Over time, the term acquired several layers of meaning. Some scholars refer to a set of licensing criteria to define open source. A license is \textit{open source} if “it allows anyone, anywhere, for any purpose, to copy, modify and distribute the software (where distribution takes place either for free or for a fee) without having to pay royalties to the (copyright) owner”\textsuperscript{30}, it being understood that the software program includes source code.\textsuperscript{31} According to other scholars, emphasizing the licensing


\textsuperscript{27} "General access", "total access" or "global access" are used as synonyms here. On "general access", also see infra, section 4.1.


\textsuperscript{29} This section is largely based on Van Overwalle, supra note 9.


\textsuperscript{31} As to source code, the Open Source Definition provides the following: “2. Source Code. The program must include source code, and must allow distribution in source code as well as compiled form. Where some form of a product is not distributed with source code, there must be a well-publicized means of obtaining the source code for no more than a reasonable reproduction cost preferably, downloading via the Internet without charge. The source code must be the preferred form in which a programmer would modify the program. Deliberately obfuscated source code is not
component is “excessively formalistic”. Rather than referring to the legal architecture and the details of licenses to characterize open source, open source refers to a mode of production, centering around “open and collaborative research”. Yet other observers, recognize that the call for open source can refer to both approaches: “a licensing structure […] granting access on the condition of reciprocal access” (= open source as a model or template), as well as “a general pattern for structuring networks of […] researchers” (= open source as a metaphor). In the framework of the present paper, we opt for the rather narrow legalistic definition.

Open source is characterized by three essential elements, namely credible commitment, competition and, optionally, copyleft. Credible commitment means that to be open source, a technology must be protected by IP or other proprietary rights and distributed on terms that are perceived to be legally enforceable. A technology that is made available under the open source model is indeed not in the public domain, but is owned by the licensor, who makes a legally enforceable promise via the licence agreement not to interfere with others’ freedom to use, improve or circulate the technology and thus not to lock them in a web of IP. Competition refers to a level playing field between the licensor and the licensees of open source technologies with respect to the legal freedom to use and commercialise both the technology itself and any downstream innovations. In that regard, an open source licence may not impose field-of-use or

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33 Arti Rai, ‘Open and Collaborative Research: A New Model for Biomedicine’, in Intellectual Property Rights in Frontier Industries: Software and Biotechnology, (Robert W. Hahn ed.), 2005, (131), 137: a model is open – and Mertonian - in the sense that “scientists work openly without secrecy and the usual sorts of exclusionary proprietary rights”; a model is collaborative – and goes beyond Merton – if it requires that “scientists [to] work closely with others outside their own lab or small firm”. As Rai points out, the term ‘open and collaborative’ was invoked in a letter to the WIPO (available at http://www.cptech.org/ip/wipo/kamil-idris-7july2003.pdf), but does not specify the terms.
35 Hope, supra note 29.
36 Hope, supra note 29.
37 Similarly, Richard Jefferson, ‘Science as a Social Enterprise. The CAMBIA, BiOS Initiative’, 1 EconPapers, issue 4, 2006, 13-17. Contra, Rai, supra note 31, 213-218: “… various other flavors of open source essentially amount to a dedication of source code to the public domain. Those who improve upon source code distributed under BSD licenses may feel a [social] norm-based obligation to contribute their improvements back, but they are under no legal obligation to do so”.
38 Hope, supra note 29.
39 Hope, supra note 29.
territorial restrictions, nor may it prevent a licensee to start a new branch of collaborative development (‘code the fork’). Copyleft imposes an obligation on the licensee to make any downstream innovations that it chooses to distribute beyond the boundaries of its own organisation available under the same terms as the original technology.\textsuperscript{40}

Open source models may have various advantages for both the owner-user and the follow-up users.\textsuperscript{41} Addressing the issue of uncertainty of innovation is one of them. Open source functions as a form of incomplete contract when there is uncertainty and informational problems, because knowledge is part of ongoing cumulative innovation.\textsuperscript{42}

But open source models may also entail some risks. Open source models may lead to antitrust concerns.\textsuperscript{43} Whether open source models always follow a free access rationale rather than a business strategy, needs to be examined more closely.

The archetypal open source copyleft license is the General Public License (GPL).\textsuperscript{44, 45} The GPL allows anyone to use the licensed program, to study its source code, to modify it, and to distribute (un)modified versions to others, under the same terms as the initial license.\textsuperscript{46} It is this final proviso that makes the GPL a copyleft licence, giving it its ‘viral’ character.\textsuperscript{47}

Open source principles are currently being tested in other technical areas than software, such as genetics. Some working examples of open source have emerged in the life sciences, mainly in the field of agricultural biotechnology. A prominent example is the Biological Open Source (BiOS) License from the Centre for Applications of Molecular Biology in International Agriculture (CAMBIA), a private non-profit research institute located in Canberra.\textsuperscript{48} Founded by molecular

\begin{itemize}
  \item \textsuperscript{40} Hope, supra note 29.
  \item \textsuperscript{41} Hope, supra note 29.
  \item \textsuperscript{44} See \url{http://www.gnu.org/}.
  \item \textsuperscript{45} Linux is the contraction of Linus' Minix (Minix was version UNIX which Linus Torvalds enhanced). The name Linux was chosen by the developer (Linus Torvald) to refer to the kernel of the “GNU/Linux” operating system (see
  \item \textsuperscript{46} See \url{http://www.gnu.org/licenses/gpl.html}.
  \item \textsuperscript{47} Hope, supra note 29. Similarly, Sara Boettiger & Dan Burk, ‘Open Source Patenting’, 1 JIBL, 2004.
  \item \textsuperscript{48} See \url{http://www.bios.net/daisy/bios/home.html}. Also see Nele Berthels, ‘CAMBIA’s Biological Open Source Initiative (BiOS)’, in Gene Patents and Collaborative Licensing Models. About Patent Pools, Clearing Houses, Open
\end{itemize}
biologist Richard Jefferson about fifteen years ago, CAMBIA pioneered, and subsequently patented the GUS49 and TransBacter50 technology serving as a prominent research tool in agricultural biotechnology. The BiOS initiative was launched in 200451 and is intended to make these biological research tools widely available on open source conditions.52 Another example is the open source style license policy promoted by Diversity Arrays Technology (DArT) Proprietary Limited.53

The translation of open source software principles does not seem to constitute insurmountable obstacles as to the very first key requirement, namely, credible commitment. Although the term ‘credible commitment’ might not always be employed, this feature seems to be well understood by entrepreneurs active in the realm of biotech: “The idea of using patent licenses not to extract a financial return from a user of a technology, but rather to impose a covenant of behaviour, is the single feature of BiOS that is most resonant with Free and Open Source Software”.54 The implementation of the second requirement, competition, in the genetic field may prove to be rather problematic from a principle point of view,55 but may hardly pose a problem as a practical matter.56 The final key element, copyleft, has equally raised concern in a life sciences context. Some critical observers fear that the BiOS License bears resemblance to grant back provisions.


49 The GUS technology relates to the β-glucuronidase (GUS) gene fusion system, and to the cloning and characterisation of the β-glucuronidase and glucuronide permease genes of Escherichia coli. Because of the abundance and availability of useful substrates for β-glucuronidase enzyme, GUS gene fusions may serve as a superior reporter gene system as well as an effective means of altering cellular phenotype. There are also implementations in conjunction with recombinant glucuronide permease, which may be used to render host cells permeable to β-glucuronidase substrates (see http://www.cambia.org/daisy/cambia/2539.html). Also see R.A. Jefferson, R.A., Kavanagh, T.A. and Bevan, M.W., ‘GUS Fusions: Beta-Glucuronidase as a Sensitive and Versatile Gene Fusion Marker in Higher Plants’, 6(13) European Molecular Biology Organization Journal, 1987, 3901–3907. For information on the GUS patents, see Van Overwalle, supra note 9.

50 The Transbacter technology relates generally to technologies for the transfer of nucleic acids molecules to eukaryotic cells. In particular non-pathogenic species of bacteria that interact with plant cells are used to transfer nucleic acid sequences. The bacteria for transforming plants usually contain binary vectors, such as a plasmid with a vir region of a Ti plasmid and a plasmid with a T region containing a DNA sequence of interest (see http://www.cambia.org/daisy/cambia/2538.html). For information on the TransBacter patents, see Van Overwalle, supra note 9.


52 See Berthels, supra note 47.


54 Jefferson, supra note 36.

55 See Hope, supra note 29.

thus establishing a ‘club atmosphere’, a ‘tit for tat’ approach, rather than true openness. Rather than strictly corresponding to open source features in every detail, open source efforts in the biotech area deliver “open source-style” licenses which are “loosely” based on open source principles.

Open source licenses, encompassing as a matter of principle a promise not to interfere with others’ freedom to use, improve or circulate the patented technology, dismantle the exclusivity principle of patent law. They transform the right to exclude others into a duty to include others, on the condition that these others behave in the same sharing way, in exchange for unhampered access to improvement innovations. Open source thus creates total conditional openness, the condition not being monetary remuneration, but covenanted sharing behaviour (see Table 1). The subsequent user can realize his commitment to sustain openness in various ways: he can disclose the knowledge relating to his improvement without applying for a legal entitlement (patent), or he can apply for a patent and then establish a special license regime.

2.3.4. Compulsory license

Real problems arise when blocking gene patents are not licensed or licensed very restrictively. Imagine a patent with claims covering (some or more) DNA sequences that are essential for the diagnosis of a genetic disease, the production of a test kit or the development of a therapy, and which patent is licensed exclusively to one or two laboratories around the world or not licensed at all. Third parties would be refrained from using (part of) the technology deemed necessary to carry out a diagnosis or manufacture a test or develop a therapy. Such restrictive licensing behaviour may result in barriers to research, hinder development that is instrumental to public health, restrict clinical access and decrease the availability of high quality tests and therapies for patients. The Myriad case represents a key example of such a restrictive license policy, resulting

57 Hope, supra note 29. Also see Hope’s detailed critique on the BiOS License posted on the Bioforge website on 16 November 2006 (does not seem to be available any longer).
58 Kilian, supra note 52.
59 Kilian, supra note 52.
60 “General access”, "total access" or "open access" are used as synonyms here. On "total access", also see infra, section 4.1.
61 In some empirical studies a negative impact of ‘blocking’ gene patents could not be found (e.g. John P. Walsh, Wesley M. Cohen, & Charlene Cho, ‘Where excludability matters: Material versus intellectual property in academic biomedical research’, 36 Research Policy, 2007, 1184–1203. That can be explained by the fact that these studies focused on biomedical research rather than downstream product development.
in restrained openness and public disapproval. Several studies have documented other restrictive licensing practices in the area of gene based diagnostic genetic services as well. In the case of blocking gene patents and restrictive license behaviour, openness can be achieved by way of compulsory licenses. In response to the Myriad case, various European legislatures have introduced a compulsory license for public health. Depending on the specific national regime, these compulsory licenses create semi-open or general access (see Table 1).

2.4. Conclusion

Gene patents are prone to be blocking. However, individual ownership of (blocking) gene patents does not per se hamper access and use. Rather than the individual ownership of gene patents as such, it is the subsequent licensing behaviour which leads to potential access problems. If the individual patent owner non-exclusively licenses such patent to multiple interested users, the impact of the blocking patent may be reduced substantially. If the individual patent owner decides to license his patent by way of a license of right to any user, a blocking patent no longer forms an obstacle at all. Especially in the case where the patent owner only grants exclusive licenses or no licenses at all, real problems of access may emerge, which, however, might be attenuated by taking recourse to a compulsory license (when available).

Licenses to multiple users, beneficial as they may be, only create restricted, conditional access. In contrast, the license of right, the open source license and the compulsory license, transform the exclusive right of the individual patent owner, into a right to use, thereby creating semi-open or general access. In the case of the license of right and the compulsory license, access is conditioned

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64 For a detailed discussion, see van Zimmeren & Van Overwalle, supra note 20.
65 Semi-open access refers to access for a certain category of users (see infra, section 4.1.). Under Belgian law, for example, the applicant for a compulsory license must demonstrate that he has, should the compulsory license be granted to him, the resources or the bona fide intention to obtain resources that are necessary for actual and continual manufacture and/or application in Belgium of the patented invention (article 31bis § 2 of the Belgian Patent Act of 1984, inserted April 28th 2005). See Van Overwalle, supra note 27. Also see van Zimmeren & Van Overwalle, supra note 20.
66 General access", "total access" or "open access" are used as synonyms here. On "general access", also see infra, section 4.1.
upon the payment of a fee, thus turning the exclusive right into a right of remuneration or take-now-pay-later rule. In the case of open source, access is awarded in exchange for a sharing behaviour (see Figure 1).

**Figure 1.** Illustration of the various strategies of a knowledge holder [RIGHT OWNER] to establish openness. One way is to waive his (potential) entitlement, resulting in his creation falling into the public domain (unconditional openness). Another way is to license his entitlement to all others, individually through a ‘license of right’ or an open source license, or collaboratively/collaboratively through a pool or a clearinghouse, resulting in general, conditional openness. In some cases, the legislature [STATE] enforces semi-open or total, conditional openness, by way of compulsory licenses.

3. Multiple and collective ownership

3.1. Concept

Different criteria can be employed to spell out multiplicity. Multiplicity can be defined by looking at the way an IP right comes into being, on the one hand, and, by looking at the way in which the IP right is exercised and the effect of licensing on accessibility for third parties, on the other hand.
In other words, multiplicity can be described by pointing to legal ownership or by referring to factual ownership.

The present paper defines the various modes of multiple ownership on the basis of legal ownership. The main reason is that in patent law, legal ownership comes into being by the attribution of a protection right to the inventor by an authorized body (patent office), or by the formal transfer of that right by way of contract by the patent owner to another party. Legal ownership does not come into being through licensing of the right by the patent owner to another party. A license involves the attribution of a right to use to the other party, no the adjudication a right of ownership.

All this brings us to the following definition of multiple ownership. **Multiple ownership** refers to multiple persons each acquiring a single protection right, resulting in a series of independent rights, or in other words, multiple protection rights. Translated into patent parlance, multiple ownership refers to multiple, independent inventors each holding one, single patent right, resulting in many different patent rights. (see Table 1). Multiple ownership needs to be distinguished from collaborative or joint ownership which refers to multiple persons acquiring one single right, in other words, various inventors collaborating together, developing one invention and acquiring one patent right (see Table 1). **Collective ownership** also involves ownership of multiple persons holding one single right, but does not result from prior collaboration between the right holders.

Individual, multiple, collaborative and collective ownership (which are based on the form of legal ownership) is further distinguished from bilateral, collaborative and collective licensing (which is based on the various forms of licensing), and from individual and shared use (which is based on the scope of actual use).68 (see Table 1).

The categorisations and qualifications suggested here are meant to be helpful intellectual tools to analyse complex legal architectures. Only a correct understanding of essential features can lead to correct starting assumptions, and can result in opening certain perspectives and crafting adequate responses. It goes without saying, however, that definitions and typologies are not an end in themselves. The debate on ownership and licensing should not be led astray by semantic subtleties.

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67 On the distinction between collaborative and collective, see infra, section 3.3. Joint ownership in patent law can be characterized as collaborative ownership, but not as collective ownership.

68 Confusingly termed “factual ownership” by some authors.
and incongruities. What counts is the effect licensing measures achieve in fulfilling the objective of accessibility and sharing in practice, disregarding the way in which ownership and licensing arrangement can be qualified.

### 3.2. Multiple ownership and “patent thickets”

Multiple ownership may have a negative impact on access when it accumulates into a patent thicket. Although the term ‘patent thicket’ has been widely used over the past years, its exact meaning and scope is still not clear. Merges defines an intellectual property thicket as “a tangled, twisted mass of intellectual property rights, which criss-cross the established walkways of commerce” and where progress requires “numerous contracts with multiple, independent right holders”. Shapiro speaks of “a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology”.

Careful reading of these definitions suggests that a patent thicket is likely to emerge when multiple patents are held by multiple patent owners. However, various questions are left unanswered. Merges and Shapiro do not clarify whether a patent thicket is only present when the patents are numerous, or also when the patents are confined. Although their wording suggests the presence of a large number of patents, it may very well be that in a certain field of technology a relatively small number of scattered patents leads second comers to decide not to engage in related research. Neither do Merges and Shapiro articulate whether a thicket only appears when the many patents at stake are essential, or also when they are independent of one another. Shapiro says that “overlapping” patent rights create a patent thicket, suggesting that a patent thicket is present when a set of somehow “related” patents needs to be aggregated to develop a certain technology. Based on these insights and experiences from experts in genetics, we define a

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69 Robert P. Merges, ‘Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organizations’, 84 Calif. Law Rev., 1996, 1293-1393. Merges already introduced the “thickets” metaphor in this article: “Intellectual property experts, especially scholars, have responded to this burgeoning thicket of rights…” (p. 1386) and “This Article is aimed at providing conceptual guidance for those who need to traverse the new thicket of intellectual property rights. Each vine, each plant, standing in one’s path represents a distinct IPR owned by an individual. To pass through, one needs a license from each owner. Where a single right blocks the path, this is easy: a single licensing contract does the trick. Today, however, business people more often than not encounter a tangled, twisted mass of IPRs, which criss-cross the established walkways of commerce. Progress along this path does not come cheaply: rather, it requires numerous contracts with multiple, independent right holders.” (p. 1295)


71 Larry Horn suggests that a patent thicket is really present if there is a “critical mass of essential patent holders with a critical mass of essential patents” (see Larry Horn, ‘Case 1. The MPEG LA Licensing Model. What Problem Does It Solve in Biopharma and Genetics Ethics and Patents for Genetic Diagnostic Tests’, in Gene Patents and
**patent thicket** as the existence of *multiple, essential* (blocking) patents necessary to develop *one* product or process, which are held by *multiple, independent* patent owners.\(^72\)

A patent thicket raises concern because the negotiation of a number of licences can be so difficult and costly, that it can become impossible “to work naturally coherent pieces of technology”.\(^73\) The transaction costs related to patent thickets may lead to royalty stacking and ultimately result in a “tragedy of the anti-commons”.\(^74\) Patent thickets, per definition, have a higher negative impact on access than blocking patents: even if all patent holders involved display a favourable licensing policy, aggregation problems remain, and the cost of trading patent rights (searching and bargaining costs, cost of multiple license fees, etc.)\(^75\) can still be prohibitive.

As of now, empirical data have not yet confirmed the existence of a wide patent thicket in genetics at large.\(^76\) However, several surveys clearly point to potential problems in the field of diagnostic...
Moreover, it is quite possible that thicket problems in genetic diagnostics grow with the switch from monogenetic testing to multifactorial testing (multiplex diagnostics) and the shift towards diagnostics based on genome-wide association studies driven by the high-throughput of SNP platforms and the next-generation sequencing possibilities. Although the Myriad case is not an illustrative example of this phenomenon, the Myriad decision has invigorated concerns about the potential negative effects of a dispersed patent landscape affecting further research and development, and harming clinical and patient access in the long run.

3.3. Licensing and openness

Various strategies have been suggested to mitigate the alleged hindering effect of patent thickets and to facilitate access to genome related inventions. One way to achieve this goal is to narrow down patentable subject matter. As valuable as such an approach may be, it is more easily said than done, given the (global) change in legislation it would require. Another approach, oriented to cut down on the mass of ‘trivial patents’ of dubious merit, is to strengthen patentability requirements and ‘raise the bar’, or to apply existing standards more stringently and reserve patent protection for ‘high quality patents’. Reserving the patent premium for high quality inventions is a must, and various initiatives seem to be under way to implement this idea. But even if only

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79 See e.g., the Genomic Research and Accessibility Act, introduced in 2007 by US Congressmen Xavier Becerra and Dave Weldon, to amend § 106 of the Patent Act, as follows: ‘Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.’ H.R. 977, 110th Cong. (2007), at http://thomas.loc.gov/cgi-bin/query/z?c110:H.R.977. See also ‘Rights to Human Genes. Time has Come to Reassess the Benefits of the Present Practice of Patenting Human Genetic Material’, Editorial, 127 Nature Immunology 2009.

80 Dietmar Harhoff offers a useful and rather comprehensive definition of ‘high quality patent’, see his paper presented at the European Patent Conference (EUPACO), Brussels, May 15, 2007 at http://www.eupaco.org/eupaco2. For Europe, see Cowan et al., supra note 25; European Patent Office (EPO), Scenarios for the Future 105 (2007) at http://www.epo.org/topics/patent-system/scenarios-for-the-future.html; EUROPEAN PATENT OFFICE (EPO), Annual Report 2008, Munchen, Gerber, 2009, more in particular the section Quality Over Quantity: On Course to Raise the Bar 8–11. Quite significant in this section is the admission that ‘[w]hile the volume of applications the EPO has to examine has been on an upward trend, the same cannot be said of their quality. Applications that are
high quality inventions are awarded patent protection, patent thickets may emerge. Yet another – complementary – option is to explore solutions which focus on the exercise of high quality patent rights. Swift and plastic responses to the current proliferation problem in patent law might be helped by contractual tools resulting from party autonomy, rather than from legal reform measures resulting from an initiative of the legislator. A first approach in this regard may be the large scale use of individual measures such as licenses of right or open source licences. In a world of technology covered increasingly with IP rights, and in which companies are spending large amounts of time and resources in order to obtain licenses to prevent hold-ups from right-owners, large scale use of specially crafted individual measures can already significantly reduce these problems.82 An alternative strategy may be the design of tools organizing the transaction of IP rights more effectively, such as patent pools or clearinghouses. A distinction can be made between collaborative and collective tools. To collaborate means “working jointly with others or together especially in an intellectual endeavour”.83 **Collaborative licensing measures** thus refer to measures where people *work together*. Hence, some efforts, such as patent pools, are collaborative in nature, as they presuppose active cooperation between the various rights owners.84 Collective means “involving all members of a group as distinct from its individuals”.85 **Collective licensing measures** thus refer to measures which *involve* all members. Hence some other initiatives, such as clearinghouses, are collective as they affect all rights holders, without presupposing prior collaboration between them (see *Table 1*).86

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82 Cowan et al., *supra* note 25.

83 The term ‘open and collaborative’ was invoked in a letter to the WIPO, but does not specify the terms (see [http://www.cptech.org/ip/wipo/kamil-idris-7july2003.pdf](http://www.cptech.org/ip/wipo/kamil-idris-7july2003.pdf)). The present explanation is taken See *Merriam-Webster’s Online Dictionary* - also for further etymological background - available at [http://www.merriam-webster.com](http://www.merriam-webster.com).

84 In our previous research we catalogued open source as a collaborative licensing mechanism (see Van Overwalle, *supra* note 9). But, open source can be introduced starting from the willingness of *one* legally entitled patent owner, hence we classify it here under individual license mechanisms. As the success of open source will depend on the attitude of subsequent knowledge holders to share under the same open source conditions, it might still be qualified as a collaborative licensing measure as well.

85 See *Merriam-Webster’s Online Dictionary* - also for further etymological background - available at [http://www.merriam-webster.com](http://www.merriam-webster.com).

86 Although we previously made a distinction between collaborative and collective measures as a matter of principle, we classified pools and clearinghouses both as collaborative licensing models (see Van Overwalle, *supra* note 9). However, rethinking these definitions, it seems more adequate to qualify pools as *collaborative efforts* (as they presuppose active, mutual collaboration between patent holders to conclude a set up agreement) and clearinghouses as *collective measures* (as they involve various patent holders, but do not require their mutual collaboration). See below. Also see Geertrui Van Overwalle, ‘Designing Models to Clear Patent Thickets in Genetics’, in *Working within*
Both the impact of joint ownership on access and the effect of licensing on openness largely follow the lines of individual ownership, and will therefore not be further discussed here.

### 3.3.1. Patent pools

#### a. Concept

The term ‘patent pool’ has acquired different meanings. In its widest sense a patent pool refers to a loose collection of patents held by different patent owners. In a more narrow sense, and as employed here, a **patent pool** points to an agreement between two or more patent owners to license one or more of their patents to one another, and to license them as a package to third parties who are willing to pay the royalties that are associated with the license. Licenses are provided to the licensee, either directly by the patentee, or indirectly through a new entity that is specifically set up for the administration of the pool (see Figure 2).

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**Figure 2.** Comparative illustration of the different licenses needed in the absence or presence of a patent pool. P1–P4 represents the patent holders. L1–L4 represents the licensees. In the absence of a patent pool, licensees have to enter into negotiations with all the patent holders, which is a time consuming and expensive process. By contrast, in the presence of a patent pool licensees turn to the patent pool for acquiring the rights as one package, which results in simplification and a significant reduction of transaction costs.\(^{89}\)

Patent pools may have significant benefits. In a nutshell, pools may eliminate stacking licenses\(^{90}\), reduce licensing transaction costs through the introduction of a system of ‘one stop licensing’ for non-member licensees\(^{91}\), decrease patent litigation and contribute to the institutionalized exchange of technical information that is not covered by patents, through a mechanism for sharing technical information relating to the patented technology, which would otherwise be kept as a trade secret.\(^{92}\)

As well as providing a possible solution to the problem of patent thickets, the creation of a patent pool might also stimulate funding for research and development, benefiting all partners in the pool.

Patent pools might also carry some risks. In brief, pools might shield invalid patents\(^{93}\) and entail inequitable remunerations.\(^{94}\) Additionally, patent pools might cover for a cartel and, subsequently, have anti-competitive effects.\(^{95}\)

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\(^{89}\) Reprinted from Verbeure (2006), *supra* note 86, at 116, with permission from Elsevier.

\(^{90}\) Clark, *supra* note 87.

\(^{91}\) Merges, *supra* note 87, at 144.

\(^{92}\) Clark, *supra* note 87; Merges, *supra* note 87, at 139; Shapiro, *supra* note 69.

\(^{93}\) Shapiro, *supra* note 69.

\(^{94}\) *Business Review Letter from Joel I. Klein to Gerrard R. Beeney, supra* note 87.

Patent pools are not new, having been used occasionally but regularly since the nineteenth century. The first licensing pool was established in 1856 among members of the sewing machine industry. A further prominent example of an early patent pool is the 1917 aircraft pool that was formed between almost all US aircraft manufacturers. This patent pool was crucial to the US government entering World War I.

Information, communication and entertainment (ICE) technology

In the 1990s the patent pool model gained wide interest in the ICE-sector and several pools with worldwide coverage were formed. In contrast to the early patent pools, those modern pools usually cover relevant patents for one particular standard, rather than covering all patents of an industry. Further, their licensing rules are more complex than those of the early licensing pools.

A key example of a modern patent pool in the ICE area is the pool related to the digital video compression standard known as MPEG-2. The MPEG-2 pool emerged as a consequence of MPEG-2 having been established as international standard by the International Standards Organization (ISO) in 1995. The MPEG-2 technology is covered by more than 425 essential patents owned by some 21 patent holders. In the presence of the pool, users of the technology can acquire access to the bulk of patents with one, single license. The MPEG-2 pool has a central entity, MPEG LA, which administers the patent pool on behalf of its members based on a set of formal codified internal rules. These rules also organize the admission of new members to the pool, after having been evaluated in detail by experts, and the resulting changes in the licensing profits among the members.

A second trendsetting patent pool of the 1990s is the DVD pool. Similar to the MPEG-2 pool, this pool emerged within a consortium setting a standard for the DVD technology. However, the consortium did not lead to one single pool, but to two distinct pools. A first pool, the so-called

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98 Merges, supra note 95.
99 For more details, see Horn, supra note 70. Also see Merges, supra note 87 at 147-150 and 161-162.
103 Merges, supra note 95.
DVD4C patent pool, united four of the ten core DVD developers and was cleared by the Department of Justice (DoJ) in 1998. A second pool, the DVD6C patent pool, assembled six other core members and covered more than 840 patents. The pool was cleared by the DoJ in 1999.

**Biotechnology**

Transplanting the patent pool concept from ICE to genetics was suggested by the Organization for Economic Co-operation and Development (OECD). The OECD considered the patent pool concept to be interesting for biotechnology, but called for further study. The OECD feared that the fact that biotechnological companies rely heavily on their IP and foster what has been called a “bunker mentality” might cause difficulties in the process of creating a pool.

Notwithstanding the scepticism of the OECD, some patent pools have already been set up in genetics. A first, instructive genetic patent pool which gained wide attention, is the Golden Rice pool. Potrykus succeeded in genetically enriching rice grains with β-carotene and wanted to transfer the Golden Rice materials to developing countries for further breeding in order to introduce the trait into local varieties that are consumed in these countries. Six key patent holders were approached and an agreement was reached that allowed Potrykus to grant licenses, free of charge, to developing countries, with the right to sub-license. This agreement is an example of how private and public organizations, in a combined effort, dealt with the surrounding patents to create a non-profit humanitarian (and therefore probably a-typical) patent pool in the form of a single licensing authority.

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Another genetic pool, supported by the World Health Organization (WHO), is the Severe Acute Respiratory Syndrome (SARS) corona virus pool. The relevant patent holders have been identified and agreement has officially been gained by the signing of a letter of intent. The SARS pool highlights the opportunities that are offered by the patent-pool concept for biomedical genetic inventions. However, the pool is no longer actively being pursued, because with no further outbreaks of SARS, the economic driver for the formation of such a pool has been removed.

c. Effect on openness

Patent pools, requiring as a matter of competition law open and non-discriminatory licensing policies vis à vis everyone, convert the exclusivity principle of patent protection into a liability regime – a "take now, pay later" regime introducing a rule that takes the form of "an automatic license without the power to exclude". The major difference between an IP right and a liability rule is that a liability rule, in contrast to an IP right, does not allow to control follow-on applications: a liability rule allows companies within a defined period of time, to borrow one another’s innovation, on the condition that they contribute to the costs of development (see Figure 1). A patent pool is an example of a contractually-constructed liability regime, created when “contracting parties start with property rule entitlements, and wind up subject to a collectively-determined liability rule”, which takes place when stakeholders voluntarily seek to

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Merges, supra note 68, at 1302.


See Reichman, supra note 113. Also see Reichman & Lewis, supra note 113.

See Merges, supra note 68, at 1303, who called the process of creating “contracting into liability rules”, and the resulting organizations “private liability rule organizations”. Also see Merges, supra note 87, at 132.
obtain private ordering with outcomes that differ from what the default rules of IP law might otherwise provide.\(^{117}\)

Patent pools create **general**, but **conditional openness**, the condition being payment of a fee. In exchange for a fee, they turn exclusive patent rights into commonly shared assets (see *Table 1*).\(^{118}\)

### 3.3.2. Clearinghouses \(^{119}\)

#### a. Concept

Clearinghouse models might be another approach to facilitate access when many patents are present. The term ‘clearinghouse’ is derived from banking institutions and refers to the mechanism by which cheques and bills are exchanged among member banks to transfer only the net balances in cash. Nowadays the concept has acquired a broader meaning and the term **clearinghouse** refers to any mechanism by which providers and users of goods, services and/or information are matched.\(^{120}\) (See *Figure 3*).

![Figure 3](image-url)

*Figure 3*. Comparative illustration of the different licenses needed in the absence or presence of a clearinghouse. P1–P4 represents the patent holders. L1–L4 represents the licensees. In the absence of a clearinghouse, licensees have to

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\(^{118}\) Van Overwalle, *supra* note 9, at 381.

\(^{119}\) This section is largely based on previous work, see references *supra* note 86 and Esther van Zimmeren, Birgit Verbeure, Gert Matthijs & Geertrui Van Overwalle, ‘A Clearinghouse for Diagnostic Testing: the Solution to Ensure Access to and Use of Patented Genetic Inventions?’, *Bulletin of the World Health Organization*, 2006, 352-359.

\(^{120}\) Anatole F. Krattiger, ‘Financing the Bioindustry and Facilitating Biotechnology Transfer’, *8 IP Strategy Today*, 2004; van Zimmeren et al., *supra* note 118.
enter into negotiations with all the patent holders. In the presence of a clearinghouse, licensees turn to the clearinghouse entity for acquiring the rights.

Based on the various functions a clearinghouse may fulfil, five types can be distinguished.\(^\text{121}\) Two models merely provide access to (protected) information: the information clearinghouse and the technology exchange clearinghouse. The information clearinghouse provides a mechanism for exchanging technical information and/or information that is related to the IP status of that information.\(^\text{122}\) The technology exchange clearinghouse is inspired by the internet-based business-to-business (B2B) model and provides an information service that lists the available technologies to allow technology owners and/or buyers to initiate negotiations for a license. Additionally, it may provide more comprehensive mediating and managing facilities.\(^\text{123}\) It is important to underline that actual access to the patented inventions is not usually granted by the technology exchange clearinghouse but by the individual patent holder after one-to-one licensing negotiations have taken place with the licensee. These negotiations are, however, based on the information on the inventions which was provided by the clearinghouse.\(^\text{124}\) Although the technology-exchange clearinghouse model is generally cheap to maintain and generates only low operating costs, it might be difficult to bring together the critical mass of genetic patents that would be needed to turn platforms of this type into useful tools. At present, most of the platforms offer only a small proportion of the market and a low density of patents, and one has to search various web sites (sometimes paying considerable registration fees). Moreover, this model might only be suitable for technologies that can be easily defined and valued. Therefore, it might be limited as a model for general-purpose research methods, such as Polymerase Chain Reaction (PCR), and for patents that protect specific and well-defined improvements to familiar downstream products or processes.\(^\text{125}\)

Three more elaborate models provide access and also standardize the use of the (patented) inventions: the open access clearinghouse, the standardized licenses clearinghouse and the royalty collection clearinghouse. The open access clearinghouse not only fosters open access to


\(^{122}\) Krattiger, *supra* note 119 at 1-45; Graff & Zilberman, *supra* note 109; Graff et al., *supra* note 109 at 989-95; van Zimmeren et al., *supra* note 118.

\(^{123}\) Krattiger, *supra* note 119; Graff & Zilberman, *supra* note 109; van Zimmeren et al., *supra* note 118.

\(^{124}\) van Zimmeren et al., *supra* note 134.

information about inventions to everyone, as its name may suggest, but also offers exchange and use of inventions at no charge. Open access clearinghouses might be a readily available model for sharing and exchanging unpatented technology. However, most genetic inventions are the outcome of long-lasting research that requires high levels of investment. Both private enterprises and universities wish to recover those investments and so do apply for patent protection. Therefore, the scope of application for this model might be limited in the area of genetic inventions, at least in the near future.

The standardized licenses clearinghouse provides access to and standardizes licenses for the use of protected inventions.

The royalty collection clearinghouse comprises all the functions of the information clearinghouse, the technology exchange clearinghouse and the standardized licenses scheme. In addition to these functions, the royalty collection clearinghouse sets up a mechanism to collect license fees from users on behalf of the patent holders in return for the access to and use of the inventions. The patent holder is reimbursed by the clearinghouse pursuant to a set allocation formula, which has been negotiated beforehand.

b. Examples

**General examples**

Examples of information clearinghouses include general patent search sites, either freely accessible, such as Espacenet from the European Patent Office (EPO), or fee-based, like Delphion or Micropatent.

An interesting example of a global technology exchange model is TechTransferOnline. It is an internet-based platform that brings together offers and demands for innovations, and provides

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126 van Zimmeren et al., *supra* note 118; van Zimmeren, *supra* note 120.
127 van Zimmeren et al., *supra* note 118; van Zimmeren, *supra* note 120.
128 van Zimmeren et al., *supra* note 118; van Zimmeren, *supra* note 120.
129 Merges, *supra* note 68.
130 van Zimmeren et al., *supra* note 118.
services dedicated to finding and facilitating contacts between technology holders and technology seekers. More than 102,000 technologies are currently searchable by investors, entrepreneurs and scientists who are looking for new business or scientific opportunities.

An example of the *standardized* license clearinghouse is Creative Commons (CC).\(^{135}\) CC has already been in operation for a couple of years facilitating the use of copyrighted material, such as music, movies, photos, books, course materials, scientific and medical literature (e.g. PLoS Biology) by way of standardized, simplified licenses and has been very successful.

Classical examples of *royalty* collection clearinghouses include copyright societies such as ASCAP (the American Society of Composers, Authors and Publishers\(^ {136}\)) or other national agencies.\(^ {137}\)

### Biotechnology

Since quite some time, the Human Genome Organization (HUGO), the OECD and various other international and national bodies have suggested that clearinghouses should be set up in the field of patents and genetic inventions as well.\(^ {138}\) And, indeed, the clearinghouse model found some reception in the biotech area. A well known example of a biotech *information* clearinghouse is Patent Lens.\(^ {139}\) Patent Lens is established in the framework of the Biological Open Source (BiOS) initiative and offers a free, fully text-searchable database of US, European and Australian agricultural and life science patents, as well as complementary advisory and educational services.\(^ {140}\)

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\(^{135}\) See [http://creativecommons.org](http://creativecommons.org).

\(^{136}\) See [http://www.ascap.com](http://www.ascap.com).


\(^{140}\) See [http://www.bios.net/daisy/bios/home.html](http://www.bios.net/daisy/bios/home.html).
Specific healthcare technology exchange platforms include Innovare Pharmalicensing\textsuperscript{141} or TechEx.\textsuperscript{142} They provide online partnering support that enables companies in the biopharmaceutical and biomedical industry to find licensing partners and conclude licensing contracts. Specific biotechnology clearinghouses include PIPRA (Public Intellectual Property Resource)\textsuperscript{143}, a collaboration between universities, foundations and non-profit research institutions to make agricultural technologies more easily available for humanitarian use.

A well-known example of an open access clearinghouse in the life sciences is the SNP Consortium.\textsuperscript{144} The goal of the non-profit SNP Consortium is to identify and collect single nucleotide polymorphisms (SNPs) and create and make the SNP map of the human genome publicly available, without any proprietary rights retained by the members of the clearinghouse, in order to enable further drug discovery.

An example of a standardized biotech license clearinghouse is Science Commons.\textsuperscript{145} This constellation aims to encourage data sharing, technology transfer and IP licensing, by stimulating stakeholders to adopt standardized licenses in order to create greater transparency.

At present, an example of a royalty collection clearinghouse is on its way in the field of patents and genetics. The Unitaid-Medicines Patent Pool aims at establishing a voluntary licensing mechanism to enhance the availability of improved, affordable and high quality medicines for the treatment of HIV/AIDS in developing countries. The pool will work towards obtaining voluntary licenses for HIV/AIDS medicine(s) patents from patent holders and then make such licenses available to qualified third parties (such as generic manufacturers). The Medicines Patent Pool is an independent legal entity based in Geneva, Switzerland, established with the support of Unitaid.

Unitaid is an innovative Global Health financing mechanism, whose mission is to contribute to scaling up access to treatment for HIV/AIDS, malaria and tuberculosis in low and middle income countries.\textsuperscript{146} Although the Unitaid HIV/AIDS patent initiative is termed a pool, close examination

\textsuperscript{141} See http://www.pharmalicensing.com.
\textsuperscript{142} See http://www.techex.com.
\textsuperscript{144} See http://snp.cshl.org.
of its structure and tasks,\textsuperscript{147} leads us to conclude that it is not a pool proper, but a clearinghouse. It is a one-stop-shop or “hub” that facilitates in- and out-licensing of HIV/AIDS related patents: patent holders unilaterally out-license their patents to the “hub”, qualified users in-license patents of their choice from the hub in exchange for a fee, after which the hub distributes the collected royalties among the patent holders.

c. Effect on openness

*Standardized* and *royalty* collecting clearinghouses, if characterized by *ex ante* disclosure of standardized licensing and royalty conditions, also convert the exclusivity principle of patent protection into a liability regime (see *Figure 1*), thereby creating *general, conditional access*, the condition being payment of a fee. This type of clearinghouse also turns the exclusive patent right into shared use (see *Table 1*).\textsuperscript{148} However, if the licenses offered by the clearinghouse are only available for qualified users (e.g. generic manufacturers, as in the Unitaid pool case), the effect, strictly speaking, would be restricted access, even though such an effect might be negligible in practice, as – apart from the qualified users – no one would probably apply.

*Technology exchange* clearinghouses do not trigger this transformation from a right to exclude to a right to remuneration, as they mainly serve as a marketplace to find licensing partners, where the patent holder keeps the authority to exclude certain licensees, and where – in the event the licensee is accepted – licenses are individually crafted.

3.3.3. Open source licenses

A license is *open source* if “it allows anyone, anywhere, for any purpose, to copy, modify and distribute the software (where distribution takes place either for free or for a fee) without having to pay royalties to the (copyright) owner”.\textsuperscript{149} An open source license regime can get started from individual ownership, in particular with the willingness of one legally entitled patent owner. Hence, we have classified open source under the range of individual license mechanisms. As the success of open source will largely depend on the attitude of subsequent knowledge holders to


\textsuperscript{148} Geertrui Van Overwalle, supra note 9, at 381.

\textsuperscript{149} See section.
share under the same open source conditions, open source may also be qualified as a collaborative licensing measure as well.\textsuperscript{150}

Effective as it may be from a blocking perspective, it remains to be seen to what extent open source licensing can deal with cumulative technology and subsequent patent fragmentation.\textsuperscript{151} Some cases clearly demonstrate that the open source license model is a viable commercial strategy through the provision of accessory genotyping services in the context of the licensed core technology package, but it is unclear to what extent the open source-style license offering access to the core technology, has facilitated and simplified uptake of this technology.\textsuperscript{152} Furthermore, the DArT experience seems to suggest that the open source philosophy will be difficult to be put to practice in market segments aiming at the largest potential profit margins, such as the biomedicine sector, unless a specific niche can be identified, likely in an area of limited financial opportunity, where competition with “mainstream” companies would be less intense.\textsuperscript{153}

3.4. Conclusion

Multiple ownership (the occurrence of multiple, independent inventors each holding one – or more – single patent) is likely to create problems of access in the area of genetic diagnostics, because multiple ownership may give rise to patent thickets (the existence of multiple, independent inventors in all holding multiple, essential (blocking) patents necessary to develop one product or process).

Individual licensing, taking the form of licenses of right or open source licences, may help to mitigate patent thickets. However, collaborative and collective licensing may attenuate the effect of multiple ownership more adequately and facilitate access to a web of gene patents even more effectively. Collaborative licensing models, presupposing mutual collaboration between the

\textsuperscript{150} As we did in our previous work, See Van Overwalle, supra note 9.
\textsuperscript{151} Sara Boettiger and Brian D. Wright, ‘Open Source in Biotechnology: Open Questions’, Innovations, 2006, 45-63. On patent fragmentation and patent thickets, see supra.
\textsuperscript{152} This conclusion is based on Kilian, supra note 52: “Under this [the present] arrangement, CAMBIA offers DArT through its BiOS initiative while we at DArT PL are offering a licence to practices the technology in the context of a complete technology package”. “…as the list of BiOS licensees is not publicly available it is impossible to judge the extent of DArT’s uptake or development through this channel.” And also on Kilian: “Interestingly, a few years after the separation of DArT PL from CAMBIA the level of interest in licensing just the right to practice the technology in general is very low (practically non-existent), while at the same time the level of interest in our genotyping services and technology provision in general is rapidly increasing.” [Our italics]
\textsuperscript{153} Cf. Kilian, supra note 52.
various patent holders, include patent pools. Patent pools create general, conditional openness, the condition being payment of a fee (see Table 1). **Collective licensing models**, involving all patent holders without requiring prior collaboration, include clearinghouses. Standardized and royalty collecting clearinghouses create global, conditional access, the condition being payment of a fee (see Table 1). Open source licenses, encompassing as a matter of principle a promise not to interfere with others’ freedom to use, also create global, conditional openness, the condition being covenanted sharing behaviour (see Table 1).

4. Open biotechnology

4.1. Concept and typology of access

So far, we have discussed the impact of (individual and multiple) ownership on access and use in biotechnology. In doing so, we have used the terms access and openness alternately. **Access** and **openness** refer to access and use of patented technology, establishing freedom to operate. Access encompasses both access for end-users (e.g. geneticists using as a matter of routine in their daily work the recombinant DNA technology patented by Cohen and Boyer) and for follow-on innovators (e.g. molecular scientists aiming to improve the recombinant DNA technology).

**Restricted access** refers to access which is restricted to a limited, well defined number of users (e.g. a series of clearly identified companies). **Semi-open access** refers to access for a certain category of users (e.g. generic manufacturers). **General, total or global access** refers to access which is awarded to an indefinite number of users and where nobody can be excluded.

**Conditional access** refers to access which is possible in exchange for a certain (monetary or non-monetary) compensation (*quid pro quo*). Bilateral licenses create restricted, conditional access, where a fee has to be paid. Cross licenses also create restricted, conditional access, but differ in the condition which has to be met: access to one's own technology, rather than a fee has to be given in return for access. Compulsory licenses induce semi-open or totally open, conditional access. Licenses of right, patent pools, standard clearinghouses and royalty collecting clearinghouses are examples of general, conditional access, where a royalty fee has to be paid to

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154 Cf. van Zimmeren et al., *supra* note 118: “A clearing house for diagnostic testing: the solution to ensure access to and use of patented genetic inventions?” (My Italics).

155 “Freedom to operate” is generally defined as a situation where “the commercial production, marketing and use of a product, process or service does not infringe the patent rights of others (‘third party patent rights’),” see van Zimmeren, *supra* note 16.
obtain access. Open source creates general, conditional access where a certain behaviour has to be displayed in return for access. **Unconditional access** refers to access which is possible without compensation (free access). Access can be achieved by knowledge holders themselves through formal rules of contract \(^{156}\) (individual or collaborative/collective license agreements) or by the legislator through formal legal rules (e.g. compulsory license regimes).

Licenses result in **shared use**, as the legally entitled (individual, multiple or joint) grantees all share the benefit of exclusive right of the IP owner, be it on certain conditions. Licenses usually do not seem to establish a form of **collective use**, where the legitimate other users exert their right of use in dialogue with one another.

**4.2. Concept and typology of open biotechnology**

Recently, scholars have introduced the term ‘open biotechnology’, \(^{157}\) a term that calls for some explanation. At first sight, the term encompasses a variety of projects, ranging from open journals such as PLoS, \(^{158}\) new bioinformatic tools, \(^{159}\) databases, \(^{160}\) big science projects such as HapMap or the Human Genome Project, \(^{161}\) projects to facilitate access to biotech research tools, such as BiOS, \(^{162}\) or a combination of these. **Open biotechnology** seems to be used as a container term for all kinds of projects and approaches fostering open research in the biotechnology sector.

At closer sight, these projects differ greatly in terms of ownership, however. A first type of open biotechnology projects can be catalogued as **public domain** initiatives. Public domain status is achieved by **renouncing** any form of (potential and available) IP entitlements (see **Figure 1**), thus

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\(^{158}\) E.g. Public Library of Science, see [http://www.plos.org/](http://www.plos.org/).

\(^{159}\) E.g. the BioMoby messaging standard, for interoperability between biological data hosts and analytical services. The Moby-S system defines an ontology-based messaging standard through which a client will be able to automatically discover and interact with task-appropriate biological data and analytical service providers, without requiring manual manipulation of data formats as data flows from one provider to the next, see [http://biomoby.open-bio.org/](http://biomoby.open-bio.org/).


\(^{162}\) [http://www.cambia.org/daisy/cambia/home.html](http://www.cambia.org/daisy/cambia/home.html).
creating total openness (see Table 1). Examples here include big science projects, such as HapMap and the Human Genome Project.

A second type of projects relates to open access endeavours. The term "open access" was originally used in a copyright context. Open access refers to the free and unrestricted online availability of peer reviewed literature, to all scientists, scholars, teachers, students, and other curious minds, permitting them to read, download, copy, distribute, print, search, or link to the full texts of these articles, crawl them for indexing, pass them as data to software, or use them for any other lawful purpose, without financial, legal, or technical barriers other than those inseparable from gaining access to the internet itself. The basis of open access is the willingness of the (individual or multiple) copyright holder(s) to allow access. Open access in this context creates total and unconditional (?) access. Examples here include open journals, such as PLoS. The term "open access" could also be used in a patent context, referring to access and use of patented technology.

A third type of projects embraces open source or open patent. “Open patent” is a translation of the open source principles into patented software technology. The basic idea is to change the rules in such a way that they are beneficial to participants in solving the problems of software patents. Stated differently, the open patent movement seeks to build a portfolio of patented inventions that can freely be distributed under a copyleft-like license. Open source creates general, conditional access. Examples here include projects such as Cambia Bios.

All these initiatives are genuine attempts to (re)establish open science. Open science refers to a research climate where openness of knowledge and the ethos of sharing prevail. Traditionally, the concept of scientific progress, dating from the 16th-17th century, has been linked with an ideal of free and open dissemination of scientific information. Scientific knowledge was wholeheartedly

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164 Supra, section 4.1.
167 The open patent movement should not be confused with the open patents initiative, an interface for those looking for new free ideas to patent, or to deposit ideas which are never going to be patented. Open Patents is a platform where “bright and good people from around the world donated their free ideas for you to patent, and many entrepreneurs are waiting for your ideas, right now!”, see http://www.openpatents.net/.
168 On CAMBIA BIOS, also see supra.
qualified and supported as a true public good, characterized by non-excludability and non-rivalry. Open availability of scientific data, full disclosure of results, freedom to read and freedom to use were regarded as cornerstones of academic research, long upheld by the scientific community. Universities were depicted as “the realm of truth” and as “the gift of nonproperty” where independent scientists, driven by curiosity, aspire knowledge and share insights with one another. Scientific norms of openness were not codified or necessarily explicit. Rather, they operated as “prescriptions, proscriptions, preferences and permissions [...] legitimated in terms of institutional values [...] transmitted by precept and example and reinforced by sanctions”. Over time, a growing strain emerged on universities and scientific institutes to appropriate knowledge and to cash in the commercial potential created by their research. Both universities and individual academics are increasingly prone to regard their knowledge as targets for opportunities for creating income through patents and secrecy. At present various initiatives emerge aiming to recapture the spirit of the open science tradition. Such initiatives take many forms and “open access” initiatives to copyrighted scientific literature is one of them. This explains why open access and open science are sometimes used as synonyms.

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176 See for example in the definition provided by Science Commons (http://sciencecommons.org/resources/readingroom/principles-for-open-science/).
Linking the findings in the present essay with the open biotechnology discourse, leads us to conclude that (individual and multiple) ownership of knowledge may contribute to the accomplishment of open biotechnology, if well crafted (individual, collaborative or collective) license models are put to work, taking the form of licenses of right, open source licenses, patent pools and standard or royalty collecting clearinghouses.177

5. Final conclusion

The debate on the role of knowledge and IP protection in genetics has been very intense over the past decade, as concerns have deepened over access and use in the field of human genetics and health care. Individual ownership of gene patents is cumbersome for it may result in blocking patents. Multiple ownership of gene patents is disquieting as it may lead to hindering patent thickets. Blocking patents and patent thickets may ultimately frustrate research and development instrumental to public health, restrict clinical access and decrease the availability of therapies for patients.

The alleged detrimental impact of individual and multiple ownership may be mitigated by the use of creative individual licensing regimes and the establishment of collaborative and collective platforms facilitating the fluid exchange of patents from patent holders to third party users. The effect of blocking patents and patent thickets may be attenuated by well tailored individual and collaborative/collaborative licensing mechanisms.

The experience with special license regimes in the life sciences is fascinating because it depolarizes the debate around proprietary and non-proprietary regimes.178 In cases of individual and multiple IP ownership, formal rules of contract179 taking the form of licenses of right, open source licenses, pools and clearinghouses, create (quasi-)total openness. Through the shaping of license policies, exclusive or proprietary rights are used to leverage access, to promote dissemination, and to safeguard downstream use rights. Imaginative and solid IP license

177 Public domain knowledge may also contribute to the set up of open biotechnology projects, assuming it is not appropriated and then licensed restrictively. An in-depth discussion of the contribution of public domain to openness is beyond the scope of the present paper.
178 Cf. Taubman, supra note 33.
179 For the distinction between formal legal rules and formal rules of contract, see Dedeurwaerdere, supra note 155, at 365.
management is a powerful tool for advancing both private and public interest.\textsuperscript{180} The notion of promoting access through rights that exclude is indeed the underlying paradox of IP law and policy.\textsuperscript{181}

The paradoxical effect of collaborative and collective mechanisms on private entitlements was suggested by Robert Merges as early as 1996.\textsuperscript{182} He found that these organizations ease some of the tensions created by strong IP rights and may play a valuable role in facilitating transactions in IP rights.\textsuperscript{183} However, his efforts (as well as later writings from other scholars\textsuperscript{184}) have mainly focused on collaborative and collective measures, such as patent pools and copyright collecting societies, in specific industries such as ICE and music. The present chapter has aimed at carrying the debate further by reflecting upon the potential role of both collaborative/collective and individual licensing measures in different technological areas, such as genetics. Both individual license schemes, taking the form of a license of right or an open source license, and collaborative/collective license structures, taking the form of patent pools, standardized clearinghouses or royalty collecting clearinghouses, moderate the effect of IP exclusivity and turn the individual and multiple IP ownership regime into (semi-)open infrastructures.

Recent studies have tried to recast the debate on managed-access property initiatives and develop a theoretical framework based on the work of Elinor Oström.\textsuperscript{185} These scholars take up the challenge of better understanding the governance of environments where the resources to be produced are pieces of information – cultural and scientific knowledge – which are distributed through institutions supporting pooling and sharing of knowledge, and lead to “constructed cultural commons”. They anticipate that social ordering both depends on and generates a wide variety of formal and informal institutional arrangements and that the logical and normative priority assigned to proprietary rights and government intervention may turn out to be misplaced. Further reflection is needed on the concept of “reconstructed”\textsuperscript{186} or “positive commons”\textsuperscript{187} as well

\textsuperscript{180} Cf. Sam Dryden, in his foreword to Intellectual Property Management in Health and Agricultural Innovation, (XIX), XIX.
\textsuperscript{181} Cf. Taubman, supra note 33.
\textsuperscript{182} Merges, supra note 68.
\textsuperscript{183} Merges, supra note 87.
\textsuperscript{185} Michael J. Madison, Brett M. Frischmann & Katherine J. Strandburg, Constructing Commons in the Cultural Environment, 95 Cornell L. Rev., 658 (2010).
\textsuperscript{186} The term “reconstructed commons” is drawn from Reichman & Uhlir, supra note 116, at 315. Also see Van Overwalle, supra note 180.
as the way in which individual and collaborative/collective licensing measures reshape the patent and exclusive ownership regime into such a reconstructed commons, and on the validity of arguments fully dismantling proprietary rights.

Another issue meriting further attention relates to the ‘sustainability’ of openness, established by special licensing regimes. Most totally open regimes – created through licenses of right, compulsory licenses, patent pools or clearinghouses – only establish ‘first generation’, ‘one shot’ or ‘relative’ openness: openness is established towards a first subsequent user, after which openness comes to an end. Yet, one open regime – namely the regime created through open source – has the capacity to warrant openness towards ‘further generations’ and constructs a ‘chain’ of openness: openness towards the first subsequent user, the second follow-on innovator, etc. So, openness does not end with the first subsequent user but is being ensured to all downstream users. Can licensing scenarios, other than open source, also enforce a chain of openness? How can follow-on openness be secured, and can first and later subsequent users be prevented from prohibiting further use? Can such sustainable openness be crafted by formal rules of contract or is a legislative intervention, establishing formal legal rules, necessary?

Further research is also called for to investigate the economic viability of open biotechnology infrastructures in a for-profit context. Recent experiences in the genetic sector suggest that collaborative/collective models are more easily established in genetics when they serve social and humanitarian motives in a not-for-profit context. Can open licensing models be efficient and adequate enough to deal with knowledge production, protection, exchange and translation, in markets served by the profit motive? Can licensing regimes fostering openness be viable in a for-profit context? Can such models be crafted in a way that they are not only economically viable, but also yield socially acceptable outcomes? The introduction of open patent regimes in a for-profit context should only be contemplated, to the extent that such regimes prove to be economically viable without overriding social motives.

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188 See Van Overwalle et al., supra note 86. Also see Verbeure B. et al., supra note 86.
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<th>Number of inventors</th>
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* access means: access and (legitimate) use
** monetary condition: payment of fee; non-monetary condition: sharing behaviour
*** shared use (points to relation between owner and user): use shared between the legal owner and licensee(s), whereby the licensor and the licensee(s) can exert their right independently; collective use (points to relation between users): use shared between connected licensees, whereby the licensees exert their right as a group

Table 1. Overview of different forms of ownership in patent law, and their constituting elements (number knowledge holders, number of attributed rights). Overview of differing licensing strategies (number of recipients) and their effect on openness.