A clearing house for diagnostic testing: the solution to ensure access to and use of patented genetic inventions?

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Abstract In genetic diagnostics, the emergence of a so-called "patent thicket" is imminent. Such an overlapping set of patent rights may have restrictive effects on further research and development of diagnostic tests, and the provision of clinical diagnostic services. Currently, two models that may facilitate access to and use of patented genetic inventions are attracting much debate in various national and international fora: patent pools and clearing houses. In this article, we explore the concept of clearing houses. Several types of clearing houses are identified. First, we describe and discuss two types that would provide access to information on the patented inventions: the information clearing house and the technology exchange clearing house. Second, three types of clearing houses are analysed that not only offer access to information but also provide an instrument to facilitate the use of the patented inventions: the open access clearing house, the standardized licences clearing house and the royalty collection clearing house. A royalty collection clearing house for genetic diagnostic testing would be the most comprehensive as it would serve several functions: identifying patents and patent claims essential to diagnostic testing, matching licensees with licensors, developing and supplying standardized licences, collecting royalties, monitoring whether users respect licensing conditions, and providing dispute resolution services such as mediation and arbitration. In this way, it might function as an effective model for users to facilitate access to and use of the patented inventions. However, it remains to be seen whether patent holders with a strong patent portfolio will be convinced by the advantages of the royalty collection clearing house and be willing to participate.

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Voir page 357 le résumé en français. En la página 357 figura un resumen en español. يمكن الاطلاع على الملخص بالعربية في صفحة 357.

Introduction

Scientists, patent attorneys and academics have expressed concerns about the emergence of a "patent thicket" in the biomedical sciences. Many patents have been granted in this specific technical field, leading to concern among researchers and companies that they will encounter serious difficulties cutting through the bulk of patents and paying the associated licensing fees.[1] Heller and Eisenberg developed the idea that such an increase in property rights will ultimately lead to a "tragedy of the anticommons".[2,3] By this, they refer to the situation where there are so many property rights in the hands of various owners — with whom parties must reach agreements to enable them to aggregate the rights they need access to in order to legally perform their activities — that it will prove difficult to bargain licences to the patented inventions successfully. High transaction costs may stand in the way of an agreement.[4] If a high number of agreements with right holders is required, transaction costs may lead parties to decide that the bargaining process is not worthwhile. Hence, a socially optimum level of consumption of the resource may not be achieved, resulting in "under-use" of the property which will have a blocking effect on further innovation.[2,3,5] Moreover, the fact that licensees have to acquire many licences in order to avoid patent infringements may lead to elevated royalty fees, caused by royalty stacking. Because the licensee will usually pass on the cost of these fees to the final consumer, the final development and manufacture of products may be obstructed.

A recent study from the Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation (US National Research Council of the National Academies) shows that at present there is no substantial evidence for the existence of a patent thicket or a patent-blocking problem in genetics.[6] However, we note that this study mainly focuses on the consequences of a potential patent thicket on genetic research. Established companies may be reluctant to pursue active licensing policies or even litigation against universities and research institutes. This may not be the case in more commercially competitive relationships.

Moreover, there are factors that may lead to the emergence of a patent-blocking problem in genetics in the future: increased awareness among researchers; and growing rate of patent enforcement caused by the strategic enforcement of their rights by patent holders and the proliferating complexity of biomedical research requiring a broader range and greater number of

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inputs of which a growing number is patented.[6]

Several studies have, however, highlighted that in the field of gene-based diagnostics, patent holders are already more active in asserting their patents, which seems to be inhibiting research and clinical practice. Indeed, some laboratories have — as a result of such patent enforcement policies — ceased to perform tests and/or refrained from test development.[6–11]

In order to overcome the difficulties created by the overall presence of patents in genetic diagnostics, several national, regional and international organizations together with scientists, the pharmaceutical industry and academics are debating alternative licensing models. These alternative models aim to allow effective access to and use of diagnostic testing services, essential in the light of public health, and to enable further research on related technologies. The two models attracting most interest are patent pools and clearing houses.[12] So far, most contributions have focused on patent pools.[13–16] Patent pools have been in existence for decades in the field of electronics and telecommunications. More recently some pools are being established in biotechnology, such as the Golden Rice-pool,[13] the SARS (severe acute respiratory syndrome) pool[13,16] and the GFP (green fluorescent protein) pool.

The clearing house model, however, is rarely investigated, let alone put into practice. Of the few papers available in this area, Krattiger[17] focused on collaborative and technology transfer mechanisms for biotechnology and Graff et al.[18,19] on an intellectual property clearing house for agricultural biotechnology. In Van Overwalle et al.,[12] we recently reviewed which licensing models might facilitate access to and use of patented genetic inventions for research and public health purposes. The aim of this paper is to further explore the clearing house model, in particular its use in the field of genetic diagnostics. Starting with a description of the concept of the clearing house and a brief survey of the different types of clearing houses, the potential functions, features, advantages and disadvantages of a clearing house for diagnostic testing will be analysed.

What is a clearing house?

The term clearing house is derived from banking institutions and refers to the mechanism by which cheques and bills are exchanged among member banks in order to transfer only the net balances in cash. More recently, the concept has acquired a much broader meaning and is used to describe almost any mechanism whereby providers and users of goods, services and/or information are matched.[17]

Types of clearing houses

The Organisation for Economic Co-operation and Development (OECD),[20] the Human Genome Organisation (HUGO)[21] and the Nuffield Council of Ethics[22] support the idea of a clearing house in order to facilitate access to patented genetic inventions. However, none of these organizations has precisely defined what type of clearing house would be optimal. In view of the previously mentioned broad contemporary interpretation of the term and the clearing houses that currently exist, it is important to be precise about the desirable functions and features of such models.

We have identified five types of clearing houses. The first two models merely provide access to (protected) information. This might be basic information related to the technology, the patents, or claims covering these technologies (information clearing house) and/or lists of technologies available through licensing, thereby providing a platform for technology owners and users to enter into bilateral negotiations (technology exchange clearing house).

The remaining three more advanced clearing house types aim to not only provide access to but also to standardize the use of the (patented) inventions. Access and use can be offered by a clearing house on a royalty-free open-access basis (open access clearing house), or via standardized licences (standardized licences clearing house and royalty collection clearing house). In addition to providing standardized licences, a royalty collection clearing house may offer monitoring of the patents transferred to the clearing house and an independent dispute resolution mechanism.

Facilitating access

The information clearing house provides a mechanism for the exchange of technical knowledge and/or information related to its intellectual property status. Information mechanisms are relatively easy to set up but require constant maintenance and updating.[17–19] Examples include general patent search sites, either freely accessible, such as Espacenet from the European Patent Office (EPO), or fee-based, like Delphion, STN International, Dialog or Micropatent. There are also specific patent biotech search platforms, such as Patent Lens. Patent Lens is established in the framework of the 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.

The technology exchange clearing house is inspired by the basic Internet business-to-business (B2B) model. This type of clearing house offers an information service that lists available inventions. These lists will allow buyers to initiate negotiations for a licence. Furthermore, partnering, mediating and managing facilities may be provided.[17,18]

BirchBob is an interesting example of a global technology exchange model. It is an Internet platform that brings together offers and demands for innovations with services to find and facilitate contacts between technology holders and technology seekers. Specific healthcare technology exchange platforms include Pharmalicensing or TechEx. They provide online partnering support that enables companies in the biopharmaceutical and biomedical industry to find licensing partners and conclude licensing contracts. Specific biotechnology clearing houses include PIPRA (Public Intellectual Property Resource for Agriculture), a collaboration between universities, foundations and non-profit research institutions to make agricultural technologies more easily available for humanitarian use.

The technology exchange clearing house model will, in general, be cheap to maintain and relatively inexpensive to operate. However, it might be difficult to bring together a large enough number of genetic patents to establish the clearing house as a useful tool that ensures effective access to a comprehensive body of patented inventions. At present, most clearing houses only offer a small proportion of the market and a low density of patents, and one has to search several web sites, some of which impose considerable registration fees. Moreover, this model might only be suitable for technologies that can be easily defined and valued: for example, general purpose research methods, such as PCR, and for patents protecting very specific and well defined improvements to familiar

upstream products or processes.[17,18]

It is important to underline that actual access to the patented inventions is not usually granted by the technology exchange clearing house 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 clearing house.

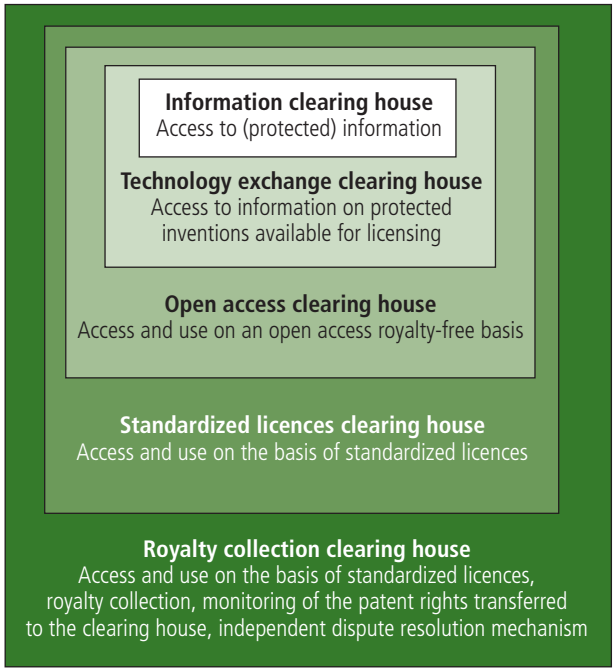
Facilitating access and use

Another type of a clearing house is the open access clearing house. This type of clearing house does not only foster free access to information about inventions, as its name may suggest, but also to standardized free use of inventions. A well known example in the life sciences is the SNP Consortium. 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, in order to enable further drug discovery.

Open access clearing houses may be particularly well suited to sharing and exchanging unpatented inventions. However, most of the genetic inventions are the result of long and expensive research initiatives. Both private enterprises and universities usually seek to recover their investments in such research and, therefore, apply for patent protection. For this reason, apart from situations where the patent rights are extremely fragmented, as illustrated by the SNP Consortium, holders of patents related to genetics will probably not have an incentive to voluntarily cooperate in a scheme where the patented inventions will end up in the public domain. Therefore, the scope of application for this type of clearing house in genetic diagnostics is expected to be rather limited, at least in the near future.

An upcoming model is the clearing house that provides access to and standardized licences for the use of protected inventions, hereinafter called the "standardized licences clearing house". An example of this scheme is Science Commons. This organization aims to encourage data sharing, technology transfer and intellectual property licensing, by stimulating stakeholders to adopt standardized licences in order to create greater transparency. Its sister organization, Creative Commons, 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 literature (e.g. PLoS Biology)) by way of standardized, simplified licences and it has been very successful.

Fig. 1. **Five types of clearing house**



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Finally, the royalty collection clearing house comprises all the functions of the information clearing house, the technology exchange clearing house and the standardized licences scheme (Fig. 1). In addition to these functions, the royalty collection clearing house sets up a mechanism to cash licence fees from users on behalf of the patent holders in return for the access to and use of the inventions.[23] The patent holders will be reimbursed by the clearing house in accordance with a set allocation formula. Well known examples include copyright societies for playing music on air and public performances such as ASCAP (the American Society of Composers, Authors and Publishers), ALCS (the Authors Licensing and Collecting Society in the UK) or JASRAC (the Japanese Society for Rights of Authors, Composers and Publishers) and other national agencies. These copyright collecting societies vary between countries with respect to their make-up, in particular their legal basis, legal structure, decision-making procedures, price-setting procedures, and licensing conditions. In general, however, they are subject to competition law. Therefore, they should refrain from discriminatory practices and set reasonable prices.

An important prerequisite for the royalty collection clearing house to be effective is that there should be a continuous and ongoing demand for patents included in the clearing house. Moreover, the establishment of this type of clearing house is only worthwhile if many patent holders or an entire branch of industry participates. It remains to be seen whether patent proprietors with a strong portfolio would be willing to voluntarily participate in such a clearing house.

At present, no examples of a royalty collection clearing house exist in the field of patents. The Global Bio-Collecting Society (GBS)[24] was a praiseworthy attempt to design a royalty collection clearing house model in life sciences. It was designed to function as an efficient, fair and equitable exchange model of indigenous knowledge between knowledge holders (indigenous groups) and knowledge users (life science industry). The GBS model was never realized, probably because traditional knowledge is a highly sensitive issue, and no consensus could be reached among the stakeholders, nor was there the necessary political support. The GBS model was devised to encourage arrangements between indigenous groups (who generally did not hold any

intellectual property rights) and private and public entities (who did have intellectual property rights) to clear controversies with respect to biodiversity and indigenous knowledge. However, the model might also be applicable to the more classic intellectual property relationship between patent holders (licensors) and users of the patented inventions (licensees).

A royalty collection clearing house in genetic diagnostics?

It has been suggested that a royalty collection clearing house should be set up in the field of patents related to genetic inventions.[12,17,18,20–22,25–27] We take the view that such a clearing house in genetic diagnostics may indeed be able to guarantee both access to and use of patented genetic inventions by serving as a multifaceted platform encompassing as many functions as a clearing house might possibly fulfil.

In a royalty collection clearing house, patent holders would licence their patents to the clearing house in order to enable the clearing house to issue sublicences to the sub-licensees (hereinafter simply "licence" and "licensees"). The clearing house would develop standard licensing agreements in consultation with the patent holders. Such standardized licences could be differentiated in accordance with the nature of the user, the intended use and the profile of the eventual product to be developed by the licensee.

Forms could be drafted with tick-boxes related to the nature of the user, the specific goal of the intended use (such as research, product development (an improvement or a new product), or diagnostic testing), followed by a list of the different patented genetic inventions (such as DNA sequences, mutations, proteins, or technical applications) included in the clearing house. Any potential licensee could tick boxes according to his or her needs, and royalties would be calculated accordingly. Royalty fees would entitle the licensee to access all the essential patents in accordance with the standardized licence drafted for the objective pre-specified by the licensee.

Although the clearing house would facilitate access to and use of multiple patents, the simple "ticking of boxes" related to the relevant genetic inventions by the licensee entails a risk of accumulation of royalties. Such an accumulation may result in a fee that is prohibitively expensive for licensees. To solve this problem, the clearing house might insist on reduced or capped royalties through so-called "royalty stacking clauses" that may be stipulated in the standardized licence.

The clearing house would provide information to the potential licensees on patents and claims relevant to a specific application in genetic diagnostics and indicate to what extent licences are available. Potential licensees would be provided with information about all licences included in the clearing house that might be relevant to their project, much like an information and technology clearing house. It would then "match" licensees and the patented inventions (like a technology exchange clearing house) while at the same time offering the previously mentioned standardized licensing agreements, which could provide flexible yet standardized, reasonable royalties (like the standardized licences clearing house).

Additionally, a royalty disbursement accounting system would be established in the framework of the clearing house. The clearing house would collect the royalties from the licensees and compensate patent holders in accordance with a set allocation formula after deduction of administration costs. Furthermore, the clearing house might also monitor infringements of patents (and notify the patent holder) and provide dispute resolution services by way of mediation or arbitration by a neutral board (Fig. 1).

A royalty collection clearing house in genetic diagnostics could be set up as a neutral, independent agency by a public entity, or as a private initiative by the stakeholders involved who might become members of the collection society. In principle, it might be implemented by a not-for-profit or profit (private) organization as a voluntary scheme or as a statutory framework on a mandatory basis. However, implementation of a statutory organization with an obligation to participate should be a last resort.

Various national or regional clearing houses (North American, Asian, European, etc.) could be set up to identify, match, negotiate, collect royalties, monitor infringements and assist in dispute resolution. All these services could be coordinated by a worldwide, overreaching "umbrella" organization. Such a global approach would not only be cost-effective but could also encourage patent holders to participate in the model by limiting the points of registration yet increasing their visibility for technology users.

Certainly, the global character of the genetics marketplace means that potential licensees would be better served with a global checkpoint for existing patent rights. We note, however, that this suggestion is complicated by the fact that patents operate on a national level. Therefore, standardized licences should be drafted in such a way that the territorial scope of the patents may be taken into consideration. For instance, the licensee would only need to apply for a licence for the countries for which a patent has been granted and for those territories where he wishes to exploit the invention.

Industry standards, which serve as an important incentive for the establishment of patent pools in electronics and telecommunications,[12–14,20] could be another useful tool for managing the royalty collection clearing house. Generally, industry standards are technical specifications related to a product or an operation, and which are recognized by a large number of manufacturers and users.[28] However, a genetic standard should not necessarily be looked at in terms of a technical specification, but could present itself as a set of mutations, recognized by the international scientific community, or reflecting national or international best practice guidelines for genetic testing for a particular disease. Good examples are the standards and guidelines issued by the American College of Medical Genetics for Cystic Fibrosis.[12–14,29]

The rights collected in the clearing house for genetic diagnostics could be identified and grouped on the basis of such best practice guidelines to increase transparency and effectiveness. All the patented products and methods that such guidelines deem to be essential for genetic testing for a particular disease could be made available by the royalty collection clearing house as a bundled set, with a standardized licence at a reasonable royalty fee. In addition to sets of patented inventions, it is very important that the royalty collection clearing house continues to allow scientists, clinical geneticists, laboratories or clinics the option to pick and choose individual licences relevant to their practice. To

limit licensees to buying sets of patents might have anti-competitive effects: users would no longer be free to determine their (competitive) business strategy. Moreover, as the best practice guidelines are subject to continuous review following research and development in the field of genetics, the sets of patented inventions and the related standardized licences should be dynamic as well.

Hence, the clearing house would bridge the gap between patent holders and potential licensees, while at the same time obviating the need for licensees to enter into time-consuming and costly negotiations with the various market players. Thus, transaction costs could be reduced and the potential anticommons effect partly avoided. Because of this collaborative mechanism of centralizing rights, the stacking of royalties could be taken into consideration in the establishment of standardized royalties, and clauses to avoid such stacking could be incorporated into those standardized licences.

Strengths and weaknesses of a royalty collection clearing house

A royalty collection clearing house definitely has certain advantages. From the perspective of a user, such an organization would simplify licensing negotiations in genetic diagnostics and, therefore, facilitate access to and use of the patented inventions. For the patent holder, increased visibility of the patent rights and the streamlining of royalty collection and monitoring, may lead to a rise in licensing and, thus, licensing revenue. At the same time, awareness and respect for intellectual property rights may grow among researchers and their public and private institutions, leading to decreased enforcement costs through fewer infringements. Hence, a reasonable price for licensees (royalties, transaction costs) and licensors (royalties, transaction costs, and enforcement costs) may be achieved.

However, a royalty collection clearing house might have some drawbacks. First, the clearing house might have potential anti-competitive effects, depending on the legal structure chosen for the clearing house. Second, patent holders may be reluctant to voluntarily participate in a royalty collection clearing house. They would have to grant a licence to the clearing house which would then issue licences to all applicants without discrimination and on a non-exclusive basis in accordance with competition law. As a consequence, patent holders would lose some control over their business licensing strategy. Third, unless the clearing house represents a high proportion of all relevant patented inventions, it might not be a viable and effective alternative nor could it prevent the emergence of an anticommons effect. Fourth, royalty clearing houses might be more complicated and costly to set up in comparison with the other clearing house models. Highly educated scientists and experienced lawyers will have to be hired to evaluate the often very complex patents, to match licensees with the patented inventions, to develop standardized licence agreements, and for monitoring and dispute resolution. Fifth, the standardized licences might not allow for measures highly appreciated in commercial licensing practices, such as the setting of milestones, due diligence and the maintenance of long-term business relationships. Sixth, the exchange of relevant technical know-how is often fundamental for the smooth application and further development of the patented invention. Know-how is generally protected as a business secret, but the clearing house will probably not be able to guarantee the exchange of know-how and maintain secrecy. Thus, with respect to complex technologies, direct negotiations between the licensor and the licensee on the issue of know-how may still be required, which might cancel out some of the advantages of the royalty collection clearing house. This drawback might be a reason to advocate the establishment of a royalty collection clearing house that is limited to inventions that do not require the exchange of technical know-how, such as patented DNA sequences and mutations, and a handful of commonly used diagnostic tools.

Admittedly, the analysis we present here is based on preliminary research, and a full economic examination of the model by economists is still required. However, such an examination is beyond the scope of this paper. For now, the leap forward to a royalty collection clearing house may be too big, especially since biotech companies rely heavily on their patent portfolio, and foster what has been called a bunker mentality: that is, a defensive attitude focused on self-protection and secrecy.[30] More realistic might be the emergence of a global technology exchange clearing house for genetic diagnostics that may eventually develop into a royalty collection clearing house when the concept has matured, when economists have delivered favourable reports on the potential efficiency of a royalty collection clearing house and when there is a greater willingness to cooperate within the biomedical industry.

Conclusion

The royalty collection clearing house model could be very useful in providing access to and use of patented inventions in genetic diagnostics. HUGO has already suggested that the clearing house model could also lead to increased levels of licensing and options for researchers to secure licences to sequences and genes at a reasonable cost. HUGO also suggested that these benefits might encourage scientists to pursue research in areas from which they might have been deterred in the past.[21]

Nevertheless, the establishment of a royalty collection clearing house on a national or regional basis covered by a global umbrella organization would without doubt be a complex, time-consuming and costly endeavor. Therefore, before it can be implemented as a workable alternative, it is essential that further exploration and discussion of this model takes place with a wide range of experts (such as economists, lawyers, patent attorneys, social scientists, ethics committees) and stakeholders (such as clinical geneticists, big pharmaceutical companies, biotech companies, and patients' organizations). WHO might play a prominent role in the initiation of this consultation process by organizing and funding workshops of experts to investigate what might be a solution to the patent thicket problem in genetic diagnostics.

Further reading and online links are available from: http://www.who.int/Bulletin ■

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Résumé

Un office central pour les tests diagnostiques : la solution pour que les inventions brevetées dans le domaine génétique soient accessibles et exploitables ?

Dans le domaine du diagnostic génétique, l'apparition de ce qu'on appelle un «taillis de brevets» est imminente. Un tel ensemble de droits de propriété empiétant les uns sur les autres pourrait avoir des effets restrictifs sur la poursuite des travaux de recherche et développement sur les tests diagnostiques, ainsi que sur la prestation de services de diagnostic clinique. Actuellement, deux concepts susceptibles de faciliter l'accessibilité et l'exploitabilité des inventions brevetées dans le domaine génétique sont au centre de bien des débats menés dans les divers forums nationaux et internationaux : la communauté de brevets et l'office central des brevets. L'article explore la notion d'office central et identifie plusieurs types de dispositifs y répondant. Il commence par décrire et examiner deux types d'offices centraux qui permettraient d'accéder aux informations sur les inventions brevetées : un centre d'échange des données et un centre d'échange des technologies. Puis il analyse trois autres types d'offices centraux offrant non seulement accès à l'information, mais également un instrument facilitant l'exploitation des inventions brevetées : l'office central en libre accès, l'office central délivrant des licences normalisées et l'office central de collecte des redevances sur les brevets. Un office central de collecte des redevances sur les brevets relatifs aux tests diagnostiques génétiques constituerait la solution la plus complète dans la mesure où il assurerait plusieurs fonctions : identifier les brevets et les demandes de brevets essentiels dans ce domaine, mettre en relation les octroyeurs et les porteurs de licences, développer et délivrer des licences normalisées, collecter les redevances sur les brevets, veiller au respect des conditions de licence par les utilisateurs et fournir des services pour le règlement des contentieux, tels que la médiation et l'arbitrage. Cet office central pourrait ainsi jouer le rôle de modèle efficace de dispositif facilitant l'accessibilité et l'exploitabilité des inventions brevetées. Il reste cependant à convaincre les détenteurs de gros portefeuilles de brevets des avantages d'un office central de collecte des redevances sur les brevets et d'y recourir.

Resumen

Centro coordinador para las pruebas diagnósticas: ¿la solución para asegurar la accesibilidad y el uso de las invenciones genéticas patentadas?

En el campo del diagnóstico genético, se considera inminente la aparición de lo que se ha calificado como «maraña de patentes». Un conjunto imbricado de derechos de patente puede tener efectos restrictivos en la realización de nuevas actividades de investigación y desarrollo de pruebas diagnósticas, así como en la prestación de servicios de diagnóstico clínico. Dos modelos que pueden favorecer el acceso a las invenciones genéticas patentadas y el uso de las mismas están suscitando actualmente un amplio debate en diversos foros nacionales e internacionales. Se trata de las patentes mancomunadas y los centros coordinadores. En este artículo se analiza el concepto de centros coordinadores y se describen varios tipos de centros con esa función. En primer lugar, describimos y examinamos dos tipos que ofrecerían acceso a información sobre las invenciones patentadas: el centro coordinador de información y el centro coordinador para intercambio de tecnologías. En segundo lugar, analizamos tres tipos de centros de coordinación que no sólo ofrecen acceso a información sino que además brindan un instrumento para facilitar el uso de las invenciones patentadas: el centro coordinador de libre acceso, el centro coordinador de licencias normalizadas y el centro coordinador de percepción de regalías. Un centro coordinador de percepción de regalías para las pruebas diagnósticas genéticas sería el instrumento más exhaustivo pues permitiría asegurar varias funciones: identificación de las patentes y las solicitudes de patentes esenciales para las pruebas diagnósticas, emparejamiento de licenciadores y licenciatarios, desarrollo y suministro de licencias normalizadas, percepción de regalías, vigilancia de la observancia de las condiciones de la licencia por los usuarios, y prestación de servicios de resolución de controversias, como mecanismos de mediación y arbitraje. De esta forma, podría ser un modelo eficaz para los usuarios, que facilitaría el acceso a las invenciones patentadas y el uso de las mismas. Sin embargo, habrá que ver si quienes poseen una buena cartera de patentes reconocen las ventajas de un centro coordinador de esas características y están dispuestos a participar en él.

ملخص

مركز تبادل للمعلومات حول الاختبارات التشخيصية: هل هو الحل لضمان إتاحة واستخدام الابتكارات المسجلة الملكية في الوراثيات؟

لقد أصبح إطباق ((مجالات تسجيل حقوق الملكية)) على المواد التشخيصية في الوراثيات أمراً وشيك الوقوع. وقد يؤدي تراكب مجموعة من حقوق الملكية إلى تأثيرات محددة على زيادة البحوث والتنمية في الاختبارات التشخيصية وعلى إيتاء الخدمات التشخيصية السريرية (الإكلينيكية). ويتعالى الجدل هذه الأيام في مختلف المنتديات الوطنية والدولية حول نموذجين قد يسهلان إتاحة واستخدام الابتكارات المسجلة الملكية في الوراثيات، وأول هذين النموذجين هو مراكز تبادل المعلومات وثانيهما هو مراكز تجميعها. ونستقصي في هذا المقال مفهوم مراكز تبادل المعلومات، ونميز أنماطاً مختلفة لها. وقد قمنا أولاً بوصف ومناقشة نمطين من أنماط إتاحة المعلومات حول الابتكارات المسجلة الملكية، أول هذين النمطين هو مراكز تبادل المعلومات وثانيهما هو تقنيات تبادل المعلومات في تلك المراكز. ثم قمنا ثانياً بتمييز ثلاثة أنماط من مراكز تبادل المعلومات التي تم تحليلها والتي لا تقتصر على تقديم إتاحة المعلومات بل تتعدى ذلك أيضاً لتقديم أداة لتسهيل استخدام الابتكارات المسجلة الملكية؛ وهي مراكز تبادل المعلومات ذات الإتاحة المفتوحة ، ومراكز تبادل المعلومات ذات الرخص (أو الإجازات) المعيارية)، ومراكز تبادل المعلومات ذات مجموعات من حقوق الملكية.

ويعد مركز تبادل المعلومات ذو مجموعات حقوق ملكية الاختبارات التشخيصية في الوراثيات الأكثر شمولاً من بين هذه المراكز، لما يقدمه من

خدمات لوظائف عديدة: التعرُّف على حقوق الملكية المسجلة وطلبات تسجيل حقوق الملكية الضرورية في مجال الاختبارات التشخيصية، ومواءمة الرخص أو الإجازات مع أصحابها، وإعداد الرخص أو الإجازات المعيارية وتقديمها، وتجميع حقوق الملكية ورصد مدى احترام المستخدمين لشروط الرخص أو الإجازات وتقديم خدمات لحل الخلافات مثل التواسط والتحكيم.

وبهذا يمكنه أن يصبح نموذجاً فعَّالاً للمستخدمين لتسهيل إتاحة واستخدام الابتكارات المسجلة الملكية؛ إلا أنه لابد من البحث عمن يحمل حقوق الملكية بشكل شديد الوضوح وإقناعهم بفوائد مراكز تبادل المعلومات التي تجمع حقوق الملكية ولابد من إقناعه بالمبادرة بالمشاركة في هذه المراكز.

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Glossary

Competition or antitrust law: antitrust law is a term primarily used in the United States, while in many other countries the term "competition law" is used. Most antitrust or competition laws have provisions dealing with mergers, abuse of a dominant position and anticompetitive practices.

Industry standard: a norm or a measure that might be the result of a formal consensus-building procedure that is managed by a standardization body (de jure standards) or arise spontaneously owing to the degree of market penetration of a particular technical solution (de facto standards).

Licence: a licence permits the **licensee** to use the patented inventions or product in a defined way and territory for a specific purpose. The use of the patented invention would be unlawful in absence of that permission.

Licensor: the entity that delivers a licence to the licensee, allowing the licensee to use the patented inventions in accordance with the **licensing conditions** (with respect to for instance royalties, territorial restrictions, (non-)exclusivity, obligations to grant back a non-exclusive licence to improvements of the patented inventions). Generally, the licensor will be the **patent holder**, but it may also be a licensee competent to grant sublicences.

Patent: a patent is a right granted by the government to an inventor that confers on that person the exclusive right to prevent others from making, using, selling or importing the invention without his or her permission, for a limited period of time and for a specific (national) territory. For a patent to be granted the invention has to be new, there has to be an inventive step and the invention has to be eligible for industrial application.

Patented genetic inventions: inventions for which a patent has been granted in the field of genetics. These include patents on DNA sequences and mutations, gene-constructs encoding therapeutic proteins, as well as genetic technologies such as amplification or sequencing techniques.

Patent pool: 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 willing to pay the royalties associated with the licence. Licences are provided to the licensee either directly by one of the patentees, or indirectly through a new entity that is specifically set up for the administration of the pool.

Patent thicket: an overlapping set of patent rights, which requires those who seek to commercialize new inventions to obtain licences from many patent holders.

Royalties: fees to be paid in exchange for the use of the licence. Such fees may, for instance, be upfront payments and/or a percentage of the net sale price of any resultant product or invention that results from use of the invention covered by the patent.

Royalty stacking: the accumulation of royalties that have to be paid when several licences must be obtained from many patent holders.

Further reading and online links

- American Society of Composers, Authors and Publishers: http://www.ascap.com/
- Authors Licensing and Collecting Society: http://www.alcs.co.uk/
- BiOS: http://www.bios.net
- BirchBob: http://www.birchbob.com
- Creative Commons: http://creativecommons.org
- Delphion: http://www.dephion.com
- Dialog: http://dialog.com
- Espacenet: http://www.ep.espacenet.com
- GFP-pool: http://www.amershambiosciences.com
- Japanese Society for Rights of Authors, Composers and Publishers: http://www.jasrac.or.jp/ejhp/index.htm
- MicroPatent: http://www.micropatent.com/static/index.htm
- Patent Lens: http://www.bios.net/daisy/bios/patentlens.html
- Pharmalicensing: http://www.pharmalicensing.com
- PIPRA: http://www.pipra.org
- SNP Consortium: http://snp.cshl.org
- Science Commons: http://sciencecommons.org/
- STN International: http://www.stn-international.de
- TechEx: http://www.techex.com