

Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling

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Abstract Patent applications that incorporate the genomic sequence of the severe acute respiratory syndrome (SARS) coronavirus, have been filed by a number of organizations. This is likely to result in a fragmentation of intellectual property (IP) rights which in turn may adversely affect the development of products, such as vaccines, to combat SARS. Placing these patent rights into a patent pool to be licensed on a non-exclusive basis may circumvent these difficulties and set a key precedent for the use of this form of mechanism in other areas of health care, leading to benefits to public health.

Keywords SARS virus/genetics; Severe acute respiratory syndrome/immunology; Viral vaccines; Patents/legislation; Licensure/legislation (source: MeSH, NLM).

Mots clés Virus du SRAS/génétique; Syndrome respiratoire aigu sévère/immunologie; Vaccin antiviral; Brevet/législation; Autorisation exercer/législation (source: MeSH, INSERM).

Palabras clave Virus del SARS/genética; Síndrome respiratorio agudo grave/inmunología; Vacunas virales; Patentes/legislación; Licencias/legislación (fuente: DeCS, BIREME).

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يمكن الاطلاع على الملخص بالعربية في صفحة 710.

Background

In late 2002 an outbreak of severe atypical pneumonia was reported in patients from China's Guangdong province. Over the following few months, the disease spread to other Asian countries, Europe and North America (1–5), where it had a dramatic impact on people and economies. The disease was named severe acute respiratory syndrome (SARS).

In March 2003, WHO enlisted a network of laboratories from around the world to identify the etiological agent of the disease and to help contain it. This led to the rapid isolation of a new coronavirus (SARS-CoV) (2), the sequencing of its genome (6, 7) and the demonstration that this coronavirus was the causative agent of the disease (8). Since then, research on SARS has continued rapidly.

Several of the groups that were involved in the sequencing of SARS filed patent applications that incorporated either parts, or the whole, of the genomic sequence of SARS. The impacts of these patent applications have been widely discussed and some commentators have suggested that such applications act as a defensive measure to reduce the possibility that the putative patents of others could be used to gain exclusive access to essential products such as vaccines (9).

The containment of SARS is an example of the effectiveness of active scientific collaboration in isolating and containing a disease outbreak, and WHO deserves much credit for its role

in organizing the SARS network, disseminating clinical samples and ultimately controlling the outbreak. Following WHO's announcement in July 2003 that the SARS outbreak was over, there have been a few isolated cases that were traced back to exposure of laboratory personnel to the virus. It is not known whether there will be further outbreaks of SARS. The effect of patent rights incorporating the SARS genomic sequence on the development of products to combat SARS now needs to be addressed.

The social benefits and costs of patents that incorporate genetic sequences is the source of much debate and is beyond the scope of this article. Rather, this article seeks to explain how the SARS patent applications may adversely affect the development of technologies, such as vaccines, that will be covered by them. Furthermore, it proposes a way in which careful application of existing regulations would circumvent such an impact, might set an important precedent for biotechnology and be beneficial to public health.

Impact of patent applications on stakeholders

Given that groups from several institutions, including the Bernhardt-Nocht Institut (BNI), the British Columbia Cancer Agency (BCCA), the Centers for Disease Control and Prevention (CDC), Erasmus Medical Centre (EMC) and Hong Kong

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University (HKU), were simultaneously involved in the sequencing of SARS-CoV, it is likely that patent rights incorporating the SARS genomic sequence will be fragmented across several different groups. Sorting out these rights will be complex and may require the intervention of the law courts. Furthermore, many additional patent applications on SARS have been filed (more than 160 hits in a recent database search), which complicates the issue. SARS intellectual property (IP) rights are a source of considerable uncertainty for all stakeholders, including putative patent owners and their potential licensees, and ultimately will affect the consumer and public health.

In the case of SARS, a major uncertainty faced by owners of patent applications stems from the sequencing of the virus having been conducted simultaneously by the different groups. In the United States, if a patent application is filed that would interfere with either a pending patent or an unexpired patent, an interference proceeding may be called. These proceedings aim to determine who has priority for the claim, and may lead to long courtroom battles and large legal fees for the owners of such patents. An acrimonious dispute over who first discovered the human immunodeficiency virus (HIV), and who owned the commercial rights to a blood test, was settled only after an agreement was reached between the presidents of France and the USA; a similar dispute must be avoided in the case of SARS. What makes matters worse for owners of SARS patent applications is that it is as yet unknown whether a market for products covered by their applications is likely to develop, so a decision to prosecute and maintain their putative patent rights may prove to be costly.

Firms that wish to develop products such as vaccines against SARS form the second group of stakeholders — the potential licensees of the SARS patents. These firms face the unenviable task of deciding whether to invest potentially many years' of effort and hundreds of millions of dollars into developing a vaccine without knowing whether there will be a market for it. The uncertainty over patent rights makes this decision even more difficult, because it is neither possible to determine the future cost of licensing the patent rights, nor whether all necessary patents will be available for licensing: in the case that a single essential patent for vaccines against SARS is licensed on an exclusive basis, the firm with the exclusive licence would be able to exclude competitors from selling their SARS vaccines. The incentive for vaccine manufacturers is therefore to delay the decision to invest in vaccine development for the time being, or to use grants from public funding bodies to initiate a vaccine programme and defer the decision on whether or not to invest significant amounts of the firm's own money until there is less uncertainty.

The net result is a scenario in which patent owners, putative licensees and consumers may lose out by incurring increased costs, risks and potential delays to product development, which in turn will have an impact on public health.

Patent pooling as a potential solution

The health care sector is not alone in facing issues relating to fragmentation of patent rights, and lessons may be learned from looking at how other industries have resolved similar problems. So-called "patent pools" have dealt with fragmentation of patents rights for the past century and a half. Patent pools are formed when owners of complementary patents, all of which are necessary to sell a particular product, aggregate their patents and license them as a group to third parties. Such patent pools

offer benefits to the owners of patents and to their putative licensees through reduced administrative costs — all patents in a pool are licensed simultaneously from one entity — and decreased risk that an essential patent will be offered for license either at exorbitant rates or exclusively, which would affect both the owners of other patents and the putative licensees. For example, in 1997 some 27 Motion Pictures Coding Experts Group technology (MPEG-2) patents owned by seven commercial firms and one university, were aggregated into the MPEG Licensing Administrator LLC (MPEG LA®) to enable the licensing of the whole group of patents in a "one-stop shop".

Many patent pools have been formed to set standards for a particular technology, enabling its wide dissemination and the establishment of a robust market. The electronics industry provides several examples of such patent pools and their benefits: the adoption of DVDs expanded rapidly following the formation of two patent pools that covered DVD-Video and DVD-ROM standard specifications (1998) and products manufactured in compliance with that format (1999).

Regulatory requirements for patent pools

Patent pools must address regulatory requirements. The main aims of antitrust laws and IP laws are to promote innovation and enhance consumer welfare, albeit through different mechanisms which appear to be at odds with each other. Whereas antitrust laws promote competition, patent laws confer rights to exclude competitors from making use of an invention. The justification for conferring such enforceable proprietary rights on inventions is that this creates economic incentives to invest in innovative research.

Antitrust authorities have examined patent pools closely as, by placing several patents together, such pools might be a mechanism through which patent owners could collude to the detriment of the consumer. To guard against this, the US Department of Justice and Federal Trade Commission have defined guidelines for patent pools (10) that aim to ensure that the competitive benefits of such pools outweigh the competitive harm by achieving:

- integration of complementary technologies;
- clearing of blocking patents (blocking patents are patent(s) that would be infringed when practising another patent(s));
- dissemination of technology;
- reduction of transaction costs (e.g. licensing costs); and
- reduction of infringement litigation and associated costs.

Government-mandated compulsory access

There are several precedents for governmental intervention to make patents either more widely or more cheaply available. A classic example is that of the Manufacturers' Aircraft Association (MAA) formed during the First World War. The exorbitant royalties charged for use of patents owned by the companies of the Wright brothers and Glenn Curtiss paralysed the aircraft industry as the United States was about to enter the First World War. Following the recommendation by an advisory panel that a patent pool be formed, the Naval Appropriations Act of 1917 forced the formation of the MAA and a drastic decrease in the royalties payable.

More recently governments have used, or contemplated using, compulsory licensing or similar government use provisions, to deal with specific health situations. For example, the

US Government publicly contemplated the use of these powers in the wake of the anthrax attacks of October 2001, in the course of negotiations with Bayer for the use of its antibiotic, Cipro®. In the end agreement was reached with Bayer through negotiation (11). The International Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS) permit compulsory licensing, or government use, under a wide range of circumstances. In the case of public health emergencies, or public non-commercial use, prior negotiations with the patent holder on voluntary arrangements are not required.

As mentioned above, patent law was developed to drive innovation through providing economic incentives for inventors to invest in high-risk research. Should governments interfere with this system in any but the most severe of emergencies, they risk undermining trust in the patent system with resultant detrimental effects on investment in innovative ideas. It would be better to set up market-driven mechanisms to resolve issues where possible.

The case for using severe acute respiratory syndrome as a key precedent in health care

The recent explosion in genomics-related patents has led to fragmentation of IP rights and the potential for obstacles being created to the research and development of products that would be of benefit to public health. This has led to an examination of whether patent pools might enable broader access to patents that are key to the development of such products (12). However, to date, no precedent exists for a patent pool in the life sciences, thus preventing the routine use of such mechanisms. Might the SARS situation be used to set such a precedent?

A pool comprising patents incorporating genomic sequences of SARS, licensed out on a non-exclusive basis, would comply with regulatory requirements and benefit all stakeholders. It would enable wide access to the genomic sequence of SARS — a key building block for the development of vaccines — driving competition away from accessing such IP rights to areas downstream in development, resulting in more innovative products. Furthermore, the formation of such a patent pool would send a powerful signal to putative licensees (e.g. vaccine manufacturers) that patent owners mean to make their IP rights available from standard rates, reducing IP risks and licensing costs, and in turn potentially stimulating greater and/or earlier investment in product development.

The net effect would be of great value to public health because the formation of such a patent pool would not only aid development of vaccines against SARS, but would also

set the precedent that may help the formation of analogous pools in other areas of the life sciences that face similar issues, such as malaria, tuberculosis and avian influenza, and lead to increased dissemination of key technologies that might help combat disease.

The SARS situation is an ideal one to set such a precedent, because of its relative simplicity.

- The patent applications are at a similar, early stage of prosecution, so formation of a pool is not complicated by these patent applications being entangled in many third-party agreements.
- Only four parties are currently known to hold the key patent applications that would form part of such a pool: CDC, Health Canada (holds BCCA's application), Versitech Ltd — the technology transfer office of HKU, and CoroNovative BV — a company spun out of Erasmus MC.
- As yet there is no significant market for SARS-related products covered by the patents, providing a powerful incentive to contain costs.
- The parties are either public health organizations, or are closely linked to such organizations, and the public health implications of SARS provide a strong drive to move forward.

Furthermore, the concept has gained support from the WHO SARS Consultation Group, which issued a recommendation to develop these ideas further, and from the National Institutes of Health Office of Technology Transfer in the USA, which is backing this concept and helping to develop the operating model for such a pool. In addition, two major law firms expressed their support for the concept and are providing a pro bono service to evaluate the suitability of each patent application for incorporation into a patent pool (Drinkier Biddle & Reath LLP), and for discussions with antitrust authorities (Morgan Lewis and Bockius LLP).

Most importantly, CDC, Health Canada, HKU/Versitech and Erasmus MC/CoroNovative have not only stated their willingness to test this model, but have initiated discussions with US regulatory agencies to determine how such a pool might be formed and comply with regulations. Should a pool be formed in the USA, the parties hope to roll out the model to other regions. ■

Competing interests: JHMS, EC, CEC, & ADMEO are employed by, and shareholders of, CoroNovative BV. This study was funded by CoroNovative BV.

Résumé

Gestion des droits de propriété intellectuelle liés au syndrome respiratoire aigu sévère : possibilités offertes par la mise en commun des brevets

Un certain nombre d'organismes ont déposé des demandes de brevet contenant la séquence génomique du coronavirus provoquant le syndrome respiratoire aigu sévère (SRAS). Cette démarche est susceptible de conduire à une fragmentation des droits de propriété intellectuelle qui, à son tour, pourrait nuire au développement de produits destinés à combattre le SRAS, tels que

des vaccins. Placer ces droits de propriété dans une communauté de brevets pour qu'ils soient exploités sur une base non exclusive permettrait éventuellement de contourner ces difficultés et de créer un précédent important pour le recours à cette forme de mécanisme dans d'autres domaines des soins de santé, ce qui servirait les intérêts de la santé publique.

Resumen

Gestión de los derechos de propiedad intelectual en relación con el síndrome respiratorio agudo severo: posible función de las patentes mancomunadas

Varias organizaciones han depositado solicitudes de patentes que incluyen la secuencia genómica del coronavirus del síndrome respiratorio agudo severo (SRAS). Esto podría dar lugar a una fragmentación de los derechos de propiedad intelectual, que a su vez podría perjudicar al desarrollo de productos contra el SRAS, por ejemplo vacunas. Si esos derechos se refirieran a patentes

mancomunadas que sólo pudieran explotarse mediante licencias no exclusivas, se podrían soslayar esas dificultades y se sentaría un importante precedente para utilizar dicho mecanismo en otros ámbitos de la atención sanitaria, con el consiguiente beneficio para la salud pública.

ملخص

إدارة حقوق الملكية الفكرية في السارس: الدور الممكن لتجميعه لبراءات الاختراع

الرئوي الحاد الوخيم أو سارس. إن وضع هذه الحقوق الخاصة ببراءات الاختراع في تجميعه للبراءات يمكن الحصول على ترخيصات لها على أسس غير حصرية قد يسهل هذه الصعوبات ويسجل سابقة لاستخدام هذه الآلية في مجالات أخرى للرعاية الصحية تؤدي إلى منافع في الصحة العمومية.

لقد تم اعتماد التطبيقات الخاصة ببراءات الاختراع التي تتضمن تعيين سلاسل المجموع الجيني (الجينوم) للفيروسات الإكلينيكية التي تسبب متلازمة الالتهاب الرئوي الحاد الوخيم (سارس) لدى عدد من المنظمات، مما أدى إلى تبعثر في حقوق الملكية الفكرية، وهو أمر قد يؤثر تأثيراً ضائراً على إعداد بعض المنتجات مثل اللقاحات التي تستخدم لمكافحة الالتهاب

References

1. World Health Organization. Severe acute respiratory syndrome (SARS). *Weekly Epidemiological Record* 2003;78:81-3.
2. Peiris JS, Lai ST, Poon LL, Guan Y, Yam LY, Lim W, et al. Coronavirus as a possible cause of severe acute respiratory syndrome. *Lancet* 2003;361:1319-25.
3. Lee N, Hui D, Wu A, Chan P, Cameron P, Joynt GM, et al. A major outbreak of severe acute respiratory syndrome in Hong Kong. *New England Journal of Medicine* 2003;348:1986-94.
4. Tsang KW, Ho PL, Ooi GC, Yee WK, Wang T, Chan-Yeung M, et al. A cluster of cases of severe acute respiratory syndrome in Hong Kong. *New England Journal of Medicine* 2003;348:1977-85.
5. Poutanen SM, Low DE, Henry B, Finkelstein S, Rose D, Green K, et al. Identification of severe acute respiratory syndrome in Canada. *New England Journal of Medicine* 2003;348:1995-2005.
6. Rota PA, Oberste MS, Monroe SS, Nix WA, Campagnoli R, Icenogle JP, et al. Characterization of a novel coronavirus associated with severe acute respiratory syndrome. *Science* 2003;300:1394-9.
7. Marra MA, Jones SJ, Astell CR, Holt RA, Brooks-Wilson A, Butterfield YS, et al. The genome sequence of the SARS-associated coronavirus. *Science* 2003;300:1399-404.
8. Fouchier RA, Kuiken T, Schutten M, van Amerongen G, Van Doornum GJ, van den Hoogen BG, et al. Aetiology: Koch's postulates fulfilled for SARS virus. *Nature* 2003;423:240.
9. Gold ER. SARS genome patent: symptom or disease? *Lancet* 2003;361:2002-3.
10. US Department of Justice & Federal Trade Commission. *Antitrust guidelines for the licensing of intellectual property*. Washington, DC: US Department of Justice & Federal Trade Commission; 1995. Reprint available from: URL: <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>
11. Resnik DB, DeVille KA. Bioterrorism and patent rights: "compulsory licensure" and the case of Cipro. *The American Journal of Bioethics* 2002;2:29.
12. Clark J, Piccolo J, Stanton B, Tyson K. Patent pools: a solution to the problem of access in biotechnology patents? Alexandria (VA): United States Patent and Trademark Office; 2000. Reprint available from: URL: <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>