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Alternative approaches to IP management: One-stop technology platform licensing

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Abstract

As a pioneering, one-stop technology platform licensing enterprise, MPEG LA is presented as a template for patent pooling. By providing the marketplace with fair, reasonable, non-discriminatory access to a portfolio of worldwide essential patents under a single licence, this example of a one-stop technology platform licensing programme enables widespread implementation, interoperability and use of fundamental broad-based technologies covered by many patents owned by many patent owners. This paper will: (1) present observations from MPEG LA's unique experience and perspective including a description of the necessary elements and principles on which such efforts are based, what works and why; and (2) describe efforts to apply this innovative licensing model to the biotechnology and pharmaceutical industries within the larger context of historical patent pooling as a solution to biotechnology bottlenecks.

Keywords: *patent pools, intellectual property, one-stop*

INTRODUCTION

In today's biotechnology and pharmaceutical markets, battle lines are often drawn between those who have strong intellectual property (IP) positions and those who do not. Those with strong IP positions choose either to retain the technology exclusively for their own use or transfer it under exclusive bilateral licensing arrangements and strategic alliances – in either case resulting in limited access. Those with weak IP positions may favour placing the fruits of biotechnology research in the public domain,[1] but the results are mixed since this runs counter to the incentives that fuel research and development by entitling IP owners to the fruits of their inventive labours. There is another way. By preserving the incentives that drive commercial investment and technology development, one-stop technology platform licensing balances a patent holder's expectation of a reasonable return on its IP with the market's interest in the widespread availability of technology while encouraging technological innovation through vigorous marketplace competition. It may not be the right fit in all cases or for all parties, but it can work with any technology and where it fits, does not preclude independently negotiated bilateral licensing arrangements for those who want them.

This innovative patent licensing model has been successfully employed by the electronics and video content industries since 1997. By providing access to essential IP on fair, reasonable, non-discriminatory terms to all users under a single licence, the one-stop technology platform licence (or 'patent pool' as it is often called) enables widespread implementation, interoperability and use of fundamental broad-based technologies covered by many patents owned by many patent owners. One reason for its success is that the electronics and video content industries are accustomed to the use of standards. Development costs are high and product manufacturers and content providers have rallied around the use of standards in order to foster compatibility that encourages both industry and

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consumers to invest in new products. But, products and the standards on which they are based increasingly rely upon many patents owned by many patent owners. Therefore, if the 'thicket'[2] of essential IP rights underlying their use cannot be accessed under reasonable terms and conditions (eg cost) applied evenly to all similarly situated competitors, the best of standards often go unused.

In their use of fundamental diagnostics and drug development technologies involving numerous patent holders, the biotech/pharma industry faces the potential for confusion, conflict, uncertainty and costs

In their use of fundamental diagnostics and drug development technologies that employ many patents owned by many different patent holders, the biotechnology and pharmaceutical industry ('biotech/pharma'), like the electronics and video content industries, also faces the potential for confusion, litigation conflict, uncertainty and cost. But what are the conditions and incentives that would lead biotech/pharma to employ the patent pool solution? This paper presents observations and case studies from the unique experience and perspective of one-stop technology platform licences that have been employed successfully in the electronics and video content industries, examines the marketplace issues and conditions unique to biotech/pharma that may affect the use of this innovative new licensing model in that industry and offers some thoughts for resolving them.

MPEG LA: A BUSINESS MODEL

MPEG LA, LLC, pioneered one-stop technology platform licensing starting with the core international digital video compression standard known as MPEG-2.[3] The single biggest challenge to MPEG-2's adoption was dealing with the essential IP rights in an orderly, cost-effective way. Many patents owned by many patent holders created the potential for confusion, litigation conflict, uncertainty and cost. MPEG LA provided the solution.

Transaction costs required to identify blocking patents and conclude negotiations for a licence under each of them are too costly for the average user

MPEG LA was organised as a licensing administrator company in 1996 and in July 1997, following issuance of a Business Review letter from the US Department of Justice's Antitrust Division,[4] began licensing the MPEG-2 Patent Portfolio License. Since the programme's inception, 14 new patent owners and more than 425 essential patents have been added. The MPEG-2 Patent Portfolio License has grown from the original 8 patent owners and 100 essential patents (25 patent families) to include more than 525 essential patents (111 patent families) in 54 countries owned by 21 companies and a leading university.[5] There are now almost 500 Licensees to the MPEG-2 License.[6] As the legal and business template for one-stop technology platform licensing, MPEG LA also provides an innovative way to achieve fair, reasonable, non-discriminatory access to patent rights for other technology standards.[7–10]

WHAT PROBLEM DOES IT SOLVE?

Expansion of broad standards and fundamental platform technologies means a growing interdependence among complementary patents necessary to implement them. In addition, there has been enormous growth in the number of issued patents containing progressively narrower claims. Therefore, licences under multiple patents owned by multiple patent owners are required. In the absence of a patent pool, the transaction costs required to identify the blocking patents and conclude negotiations for a licence under each of them (assuming the patent owners are even willing to enter into licence negotiations), to say nothing of paying multiple royalties, are too costly for the average user – with the result that technological advancement, adoption and use are impeded; freedom of technological movement is restricted; the potential for conflict is increased; and traditional one-on-one licensing arrangements fall short.

As Garrard Beeney noted in testimony before the US Department of Justice Antitrust Division and the Federal Trade Commission:[11]

> . . . product standardization and joint product development naturally and inescapably lead to a proliferation of IP held by numerous companies covering a single product – a phenomenon Professor Shapiro has referred to . . . as the 'patent thicket.'[2]

In addition, as further noted by Mr Beeney:

> The growth of patent thickets has been fueled not just by product standardization and joint development, but also by the explosion in the number of patent applications and patent grants. The United States Department of Commerce reports that both patent applications and grants doubled between 1988 and 2000.[12]

Certain legal, marketing and organisational elements are necessary to ensure (a one-stop technology platform licence product's) success

In the case of MPEG-2, however, where the MPEG-2 Patent Portfolio License enables users to acquire patent rights necessary for compliance with the standard in a single transaction rather than through separate licence agreements with multiple patent owners, wide acceptance of the licence across all market sectors[13] has enabled the worldwide technological implementation, interoperability and use of digital video across myriad applications.[14] Like the MPEG-2 Standard that it covers, the MPEG-2 Patent Portfolio License encourages technological improvement, competition and innovation in and outside of the Standard. Not only are licensees free to develop competing products within or outside of the standard, but in addition to the variety of products that use MPEG-2, the marketplace in fact utilises many different video compression standards.

'Essentiality' and a defined field of use communicate clearly to both licensors and licensees the rights granted by the licence and why patents are included or excluded

WHAT WORKS AND WHY

In addition to the market conditions that create the appropriate incentives and need for a one-stop technology platform licence product, certain legal, marketing and organisational elements are necessary to ensure its success. Apart from the fact that these elements promote the pro-competitiveness of an IP pool, most of them are determined and assured by the marketplace itself.

First, the legal and marketing elements:

- **Fair, reasonable, non-discriminatory access to essential IP** – patent holders grant the licensing administrator a non-exclusive right to license their essential patents over their useful life. The licensing administrator offers the same licence agreement to everyone and is empowered to sign up licensees and take necessary actions to achieve compliance with the licence terms.

- **'Essentiality' and a defined field of use** – a patent may not be included unless it is infringed by use of ('essential' to) the defined technology. To ensure fair, reliable results, independent patent experts in various jurisdictions are employed to evaluate patents for their essentiality. In general, 'essentiality' and a defined field of use communicate clearly to both licensors and licensees the rights granted by the licence and why patents are included or excluded. As a legal matter, this is necessary to ensure that the licence is specific enough to include what a licensee needs to practise the particular technology and that competitive implementation options are neither favoured nor foreclosed.[15] Since each patent is essential, the royalty rate and thus the value is the same whether a licensee uses one or more patents, and the licence, in effect, conveys the IP rights necessary to enter the field. As a marketing matter, unless a licence is well defined, the customer will not know what it is buying and will be reluctant to sign up. Similarly, if the licence requires a royalty for non-essential patents, the customer who does not need them will not agree to pay for them. Further, a licence with patents that have not been evaluated by an independent patent expert will lack credibility and be difficult to sell.

To the extent that a licensee independently negotiates a licence directly with a patent owner, that is a matter to be worked out directly between them

- **Non-exclusive** – other (eg bilateral) licensing options are not foreclosed either to licensers or licensees. To the extent that a licensee independently negotiates a licence directly with a patent owner, that is a matter to be worked out directly between them. The licensing administrator does not become involved in such negotiations, and any adjustments the parties may wish to make as a result of their bilateral licence is a matter between them not involving the licensing administrator. Although not legally mandated, this policy is important to licensees to know that they will be treated the same and pay the same royalties to the licensing administrator as any other similarly situated licensee (whether or not a patent holder). If the licensing administrator is hesitant to provide that assurance, prospective licensees are reluctant to sign.

Licensees are assured most favourable royalty rates and pay the same royalties to the licensing administrator whether or not they are patent owners

- **Licensee protections** – the typical licence agreement contains numerous provisions to assure that licensees are treated fairly and reasonably. Among them are the following: (a) Licensees are assured most favourable royalty rates and pay the same royalties to the licensing administrator whether or not they are patent owners.[16] (b) To ensure complete coverage, patent holders are required to include all of their essential patents worldwide. (c) Licence grants are clear in scope. (d) To ensure, for the benefit of all licensees, that a licensee does not take advantage of the licence, on the one hand, yet refuse to license its own essential patents on fair and reasonable terms, any licensee is free to add essential patents to the licence that it or an affiliate may own on the same terms and conditions as the licensors, but if a licensee chooses not to do so, it agrees to grant back a licence similar in scope to the licence granted to the licensee on fair and reasonable terms under any essential patents it may own. (e) Licensee sales data is protected as confidential from patent holders and licensees. (f) A clear up-to-date list of licensed patents is maintained.

A fair, unbiased process, for the continuing evaluation of patents for their essentiality and inclusion must be provided

- **The objective of the licence is to include as much essential IP as possible** for the convenience of the marketplace, although no assurance is or can be made that a pool licence includes every essential patent. Therefore, a fair, unbiased process for the continuing evaluation of patents for their essentiality and inclusion must be provided. Any patent owners that believe they own an essential patent is welcome to submit it for evaluation of essentiality and inclusion in the licence on the same terms as the other patent holders following successful evaluation. Not only does this ensure the openness of the licence to the inclusion of as much essential IP as possible, but it also enhances the credibility, value and marketability of the licence.

- **Licensor protections** – among other things, licensors share in a reasonable allocation of royalties commensurate with their contributions to the licence. In addition, to prevent licensees from using the licence to protect themselves from lawsuit in order to sue others on their own patents and to encourage negotiation and innovation in support of the technology platform, a patent holder may remove its patents from coverage as to a particular licensee if the licensee brings a lawsuit or other proceeding for infringement of an essential or related patent against the licensor and has refused to grant the licensor a licence on fair and reasonable terms and conditions under such patents on which the lawsuit is based.

Now turning to the organisational elements:

- **Professional management** – the Licensing Administrator provides a

seamless worldwide connection among patent owners, users and technology. This requires a financially sound and motivated organisation with expertise in joint licensing administration; building consensus among fiercely independent patent holders each with its own expectations of value; the development of joint licence products that meet patent holders' interest in a reasonable return and the interest of the marketplace in access to fundamental technology under fair, reasonable terms; IP, anti-trust, contract drafting and administration and taxation; licensing and marketing; web site management; transaction fulfilment and auditing; and international tax mitigation and reconciliation.

- **Independence** – the licensing administrator is neither a licensor nor a licensee. Its allegiance is to fair, impartial administration of the licensing programme, each administered separately from others.

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- **Openness to new business models** – business models should be determined by market needs, and driven by the desire to create a positive economic opportunity for both licensors and licensees and should balance the interest in realising a reasonable return on IP with the interest in providing reasonable access.

Each licence must be priced to sell

- **Emphasis on marketability and integrity of the licensing product** – each licence is based on value given for value received. Therefore, it must be responsive to the marketplace and priced to sell. Since both buyers and sellers are necessary, royalties must be fair and reasonable, and prospective users, like all customers, should be engaged in dialogue leading to the formation of the licence.

- **Legal tenability** – The licensing programme must be in compliance with antitrust laws.

BIOTECH/PHARMA: PROBLEMS IN COMMON

The problems – expansion of broad standards and fundamental platform technologies leading to a growing interdependence among complementary patents necessary to implement them; enormous growth in the number of issued patents containing progressively narrower claims; need for licences under multiple patents owned by multiple patent owners; increasingly burdensome transaction costs; impairment of technological advancement, implementation and use; restricted freedom of movement, increased potential for litigation conflict and uncertainty; and the inability of one-on-one licensing arrangements to respond[17,18] – are no less present in biotech/pharma than they are in the electronics and video content industries. But, unlike the electronics and video content industries, it is not as clear that the biotech/pharma industry views these as problems to be immediately overcome.

BIOTECH/PHARMA: WHAT'S DIFFERENT?

Biotech/pharma differs from the consumer electronics, computer and content industries in ways that may limit the feasibility of one-stop technology platform licensing:

- Biotech/pharma is not standards-driven.

- Interoperability may be desirable in research, discovery and diagnostics but not at the outer edge of the therapeutic product development chain.

- Many companies are founded and funded on the basis of their proprietary technologies and are, therefore, unwilling to part with them.

- Given the differences among products and technologies, biotech/pharma has a bunker mentality focused on self-protection.

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- There is a greater likelihood of disagreement over patent values.[18]
- Platform technologies and fields of use are difficult to define in the absence of standards.

BIOTECH/PHARMA: BARRIERS TO ADOPTION

To address these differences, the following barriers need to be overcome in order for one-stop technology platform licences to be adopted in the biotech/pharma industry:

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- Finding the incentive – it is easy to imagine the incentive for licensees but finding the incentive that will cause patent holders (licensors) to include their patents in a one-stop technology platform licence may be more difficult.
- Defining essentiality/setting field of use boundaries.
- Determining what the market needs.

OVERCOMING THE BARRIERS

Finding the incentive

A one-stop technology standards licence must benefit the public interest, address the need for interoperability and access, provide a means of reducing the potential for litigation conflict, enhance the freedom to operate and reduce the costs of negotiating licences with many parties for many patents. However, none of these factors in and of themselves may be enough to provide the necessary incentive that will persuade patent holders to contribute their IP. For many patent holders, patent infringement is a cost of doing business. But, as noted by Marks *et al.*[18] 'there are forces and factors at work that make pooling biotech patents more attractive than ever before.' Among them are new revenue streams from joint licensing outside of the patent holder's primary business focus and more remotely, the threat of compulsory licences.[19] A strong endorsement for patent pools is that they provide a way for patent holders as well as licensees to minimise risk. As proffered by Grassler and Capria,[1] 'it is likely that the combined factors of the price, the volume of licensees, and the low cost of out-licensing for the contributing members would be sufficient encouragement for sufficient numbers of patentees to participate in the pool'.[20] This is especially true where one patent is indistinguishable from another in its ability to block implementation of the subject technology, and where, as Grassler and Capria point out, the patents 'do not provide strong market differentiation to the dominating patent owner's product.'[20]

Defining essentiality/setting of field of use boundaries

While the lack of standards in the biotech/pharma industry may present a problem of desire and familiarity, it should not be a problem of construction for a biotech/pharma patent pool. Standards are a helpful way of ensuring that the element of 'essentiality and a defined field of use' can be satisfied, but they are not the only way. As long as the licence grant is defined with the precision necessary to ensure that the licence is specific enough to include what a licensee needs to practise the particular technology and to communicate clearly to both licensors and licensees the rights granted by the licence and why patents are included or excluded, then the absence of an official standard is of no consequence.[1] For example, in lieu of a standard, the creation of a *de facto* or quasi-standard bounded by a definable 'four-sided' limitation or box consisting of complementary patent rights that are essential to the use of the defined field of use will suffice. The challenge is to identify those areas where interdependent patents are necessary to practise a technology that can be defined as a platform in lieu of an existing standard. This will likely be at the research, discovery and diagnostics or lowest

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Areas of interest will likely be at the research, discovery and diagnostics level rather than at the outer edge of the therapeutic product development value chain, thereby enabling a patent owner to provide non-exclusive access while retaining exclusivity over its proprietary birthright

common denominator level rather than at the outer edge of the therapeutic product development value chain, thereby enabling a patent owner to provide non-exclusive access while retaining exclusivity over its proprietary birthright in its area of focus.[1] Like MPEG-2, it will be a technology platform that does not establish end product requirements but is flexible within a broad functional range, thereby encouraging the creation of myriad applications. In their article Grassler and Capria[1] suggest 'libraries of targets' or 'high-throughput screening' as one possibility. Other possibilities include broad diagnostic (eg mass spectrometry), drug discovery and design (combinatorial or structure-based drug design techniques) or drug structure (eg therapeutic antibody) platforms.[21]

Determining what the market needs

The lowest common denominator will provide technology users with the freedom to operate with reduced risk

The lowest common denominator will be a point which satisfies the need for interoperability and access, provides a means for reducing the potential for litigation conflict and reduces the costs of negotiating licences with many parties under many patents. It will provide technology users with the freedom to operate with reduced risk in otherwise uncertain areas.[21] Consistent with the above discussion, this is likely to be a drug discovery tool or development platform readily used by a broad cross-section of research laboratories and pharmaceutical companies willing to pay a reasonable price for risk avoidance that frees them to focus their full-time effort on competing vigorously to develop new drugs.

CONCLUSION

The need for one-stop technology platform licensing in the biotech/pharma industry is apparent, and its impact on life-enhancing benefits could be profound

The need for one-stop technology platform licensing in the biotech/pharma industry is apparent, and its impact on life-enhancing benefits could be profound. Based on the foregoing analysis of the relevant issues, a one-stop technology platform licence is foreseeable in the near future. A competitive marketplace, healthy business climate, enhanced quality of life: one-stop technology platform licences will be good for consumers and business alike.

References and notes

1. The SNP consortium is one example. See Grassler and Capria (2002), 'Patent pooling: Uncorking a technology transfer bottleneck and creating value in the biomedical research field, *J. Comm. Biotechnol.*, Vol. 9(2), 15–22.
2. Shapiro, C. (2001), 'Navigating the patent thicket: cross licenses, patent pools and standard setting' (URL: http://haas.berkeley.edu/~shapiro/thicket.pdf).
3. MPEG-2 refers to a fundamental technology underlying the efficient transmission, storage and display of digitised moving images and sound tracks on which high definition television (HDTV), digital video broadcasting (DVB and ATSC), direct broadcast by satellite (DBS), digital cable television systems, multichannel-multipoint distribution services (MMDS), personal computer video, digital versatile discs (DVD), interactive media and other forms of digital video delivery, storage, transport and display are based. MPEG-2 is an open technology, giving users a wide interoperable range of cost and quality options within the computation that compresses data to produce an MPEG-2 video stream. The MPEG-2 standard does not set hardware requirements; it is flexible within a broad functional range, thereby ensuring the interoperability of myriad applications. For more information, see URLs: http://www.cselt.it/mpeg and http://www.mpeg.org
4. Business Review Letter from Hon. Joel I. Klein to Garrard R. Beeney (26th June, 1997), available at URL: http://www.usdoj.gov/atr/public/busreview/1170.htm. The European Commission issued a comfort letter in December 1998 (Case No IV/C.3/36.849).
5. Current patent holders include Canon, Inc., Columbia University, France Telecom R&D, Fujitsu, GE Technology Development, Inc., General Instrument Corporation, Hitachi, Ltd, KDDI Corporation, Matsushita, Mitsubishi, Nippon Telegraph and Telephone Corporation (NTT), Koninklijke Philips Electronics NV, US Philips, Robert Bosch GmbH, Samsung Electronics Co., Ltd, Sanyo Electronic Co., Ltd, Scientific Atlanta, Sharp Kabushiki Kaisha, Sony, Thomson Licensing S.A., Toshiba Corporation, and Victor Company of Japan, Ltd (JVC).
6. URL: http://www.mpegla.com
7. A licensing programme for the high-speed transfer digital interconnect standard known as IEEE 1394 was organised in November 1999. The 1394 Patent Portfolio License includes essential patents owned by Apple Computer,

Inc., Canon, Inc., Compaq Computer Corporation, Hitachi, Ltd, Koninklijke Philips Electronics, NV, Matsushita Electric Industrial Co., Ltd, Sony Corporation, STMicroelectronics NV and Toshiba Corporation; it now has more than 170 Licensees (URL: http://www.1394la.com).

8. In July 2001 MPEG LA launched a licensing programme for the terrestrial digital television standard used in Europe and Asia known as DVB-T. Current patent holders include France Telecom, Koninklijke Philips Electronics NV, Matsushita Electric Industrial Co., Ltd, US Philips Corporations and Victor Company of Japan, Ltd (URL: http://www.dvbla.com).

9. In autumn 2002, MPEG LA will offer the MPEG-4 Visual Patent Portfolio License and the MPEG-4 Systems Patent Portfolio License for use of the MPEG-4 Visual and Systems standards, respectively. MPEG-4 Visual Patent holders will include Canon Inc.; France Télécom; Fujitsu Limited; GE Technology Development, Inc.; General Instrument Corp.; Hitachi, Ltd; Hyundai Curitel, Inc.; KDDI Corporation; Matsushita Electric Industrial Co., Ltd; Microsoft Corporation; Mitsubishi Electric Corporation; Oki Electric Industry Co., Ltd; Philips Electronics; Samsung Electronics Co., Ltd; Sanyo Electric Co., Ltd; Sharp Kabushiki Kaisha; Sony Corporation; Telenor AS; Toshiba Corporation; and Victor Company of Japan, Limited. MPEG-4 Systems patent holders will include Apple Computer, Inc.; Electronics and Telecommunications Research Institute (ETRI); France Télécom; Mitsubishi Electric Corporation; Philips Electronics; Samsung Electronics Corporation, and Sun Microsystems, Inc. (URLs: http://biz.yahoo.com/bw/020715/150498_1.html; see http://www.mpegla.com/mpeg4).

10. MPEG LA continues to work on the development of joint licences in connection with other emerging technologies, including biotech/pharma in which it has been promoting the concept of a patent pool licence and working to create one since July 1997. See also Marks, M. S., Schmickel, D. B. and Bednarek, M. D. (2001), 'Unity in the gene pool', *Intellectual Property*, 8th October.

11. Beeney, G. (2002), 'Pro-Competitive Aspects of Intellectual Property Pools: A Proposal for Safe Harbor Provisions', United States Department of Justice Antitrust Division and the Federal Trade Commission Joint Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, 17th April (URL: http://www.ftc.gov/opp/intellect/detailsandparticipants.htm#April%2017). Mr Beeney, a partner with the law firm of Sullivan & Cromwell in New York City, is a leading authority on patent pools. He has participated with the Antitrust Division in two of the three principal Business Review Letters that address patent pools and also with the European Commission.

12. US Department of Commerce, Patent and Trademark Office (2001), '2001 TAF Special Report – All Patents, All Types, January 1972–December 2000', US Government Printing Office.

13. MPEG LA's MPEG-2 licensees, now almost 500, make most of the MPEG products in the current world market. See URL: http://www.mpegla.com/Licensing/Licensees.

14. As noted by Baryn S. Futa, Chief Executive Officer of MPEG LA, in testimony before the US Department of Justice Antitrust Division and the Federal Trade Commission

> Today MPEG-2 video technology is used in some 300 million decode, encode and transport product units – and by 2006 is expected to increase by more than six-fold. Included are cable, satellite and terrestrial digital set-top boxes; digital television sets; DVD players; video game systems; personal computers; digital video recorders, encoders and multiplexers. And that doesn't even count the billions of DVD discs being produced. All told, through 2006, the estimated value of MPEG-2 products in the world market is projected to exceed half a trillion dollars – and that doesn't even begin to measure the materials that go into the products, the services that surround them or the content that comes out. This is a vigorous market. Thousands of companies employing countless people in the US and around the world make products using or relying on MPEG-2 technology. MPEG-2 has made video communication interoperable, global, competitive, innovative and efficient.

Futa, B. (2002), 'Statement of Baryn S. Futa, CEO and Manager, MPEG LA, LLC', The US Department of Justice Antitrust Division and the Federal Trade Commission Joint Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, 17th April (URL: http://www.ftc.gov/opp/intellect/detailsandparticipants.htm#April%2017).

15. See US Department of Justice & Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (1995) (URL: http://www.usdoj.gov).

16. In fact, patent holders to MPEG LA's Patent Portfolio Licenses that make products covered by the applicable licence are also licensees and subject to the same terms as non-patent holder licensees.

17. See Clark, J., Piccolo, J., Stanton, B., Tyson, K., Critharis, M. and Kunin, S. (2000), 'Patent Pools: A Solution to the Problems of Access In Biotechnology Patents?', US Patent and Trademark Office, 5th December (URL:

http://www.uspto.gov/web/offices/pac/dapp/opla/patpool.htm).

18. Marks, M. S., Schmickel, D. B. and Bednarek, M. D. (2001), 'Unity in the gene pool', *Intellectual Property*, 8th October.
19. As pointed out in Clark *et al.*,[17] the demand for access to research data could be among the factors that compel the granting of a compulsory licence under certain circumstances. For example, countries that are reluctant to grant patents in such areas as genomics may find that the granting of a patent subject to compulsory licence would help reconcile their concern that certain intellectual property does not constitute patentable subject matter with their domestic interest in encouraging intellectual property ownership. See also Marks *et al.*[18]
20. The authors go on to say that all relevant patent owners will be encouraged to contribute because 'If the pool is of a sufficient and significant number of relevant patents, the ''industry standard royalty rate'' is *de facto* set by the pool and could put downward pressure on damage calculations that would negatively affect a patentee's claim . . .' They also suggest that the desire to perform research in countries without basic research exemptions might provide an additional incentive for licensees.
21. It may be that the full uncertainty and therefore the true value of a patent pool may not be appreciated by the marketplace until such time as products using these technologies generate significant revenues and patent holders seek their share through patent litigation and licensing. For example in the area of drug structure platforms, it has been estimated that in the USA since 1994, monoclonal antibody based therapeutics make up about 22 per cent of the approved biopharmaceutical drugs; Reichert, J. M. (2002), 'Therapeutic monoclonal antibodies: Trends in development and approval in the US', *Curr. Opinion Mol. Therapeut.*, Vol. 4(2), pp. 110–118. Further, between a quarter and a third of the biopharmaceuticals currently in clinical trials are monoclonal antibody-based drugs; J. M. Reichert, personal communication. Similarly, in the area of diagnostic platforms, mass spectrometry is employed in many of the mandatory newborn screening tests for genetic and metabolic disorders (URL: http://www.yale.edu/opa/newsr/02-06-13-04.all.html).