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□ 主编
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Contents

Unblocking Gene Patents: An Antitrust Approach?

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Abstract: Disease gene patents are a serious and sensitive issue. Policy in this area has to be very carefully deliberated upon–as any mistake could have severe consequences for biomedical drug discovery and human health. Literature is replete with concerns that patents over gene sequences would 'block' biomedical drug development. However as Walsh and others warn, before seeking solutions to this blocking impasse, we need to ask ourselves if there is such 'blocking' in the first place.

My paper seeks to demonstrate that antitrust can offer us a good framework to study the blocking issue. By applying the essential facilities doctrine to individual cases where access to a gene patent has been denied, one can assess the existence and maybe extent of blocking in this industry. This data could then be used to assess as to whether the blocking is of such a widespread nature as would warrant a substantial legal and/or institutional response.

With the IMS Health case before the ECJ, the essential facilities doctrine has taken centre stage in Europe. However the parameters of this doctrine are far from settled. Antitrust authorities do not enough guidance on issues such as determining appropriate license fees for access, optimal number of licensees etc. In keeping with my focus on blocking and disease gene patents, I have dealt mainly with one aspect of this doctrine–namely the question of "essentiality". Essentiality would in most cases help in a determination of 'blocking' i.e. if the facility is a non–essential one, then there can possibly be no blocking. However the converse need not always be true–i.e. If the facility is an essential one, but is widely licensed, then it is quite possible that there would be no blocking.

1 INTRODUCTION

By disease genes, I mean not only diseases that have their bases in genetic disorders but also diseases that though 'non–genetic' in origin, could still have genetically based cures. To illustrate this difference, consider Breast Cancer and AIDS. In the case of Breast Cancer, mutated versions of the breast cancer genes (i.e. BRCA 1 and 2) result in the disease. However in the case of AIDS, the disease itself stems from a potentially fatal virus, HIV. The HIV virus enters the cell through certain docking sites or 'receptors', one of which is the CCR5 receptor. A defect in the CCR5 receptor gene could result in a malfunctioning receptor–consequently, the HIV virus would not be able to enter the concerned cell.[2] In this way, the CCR5 gene could offer a poten

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[2] In fact, it was the presence of a class of people that offered strong resistance to the HIV virus (by virtue of not having the CCR5 gene or having a defective version thereof) that prompted scientists to make the nexus between the disease and the CCR5 receptor. For an interesting account of the CCR5 patent saga, see M Waldholz 'Discovery Spurs Some to Challenge: A Patent Filing That Boosted HGS Stock' The Wall Street Journal (16 March 2000): available at http://www.aegis.com/news/wsj/2000/WJ000301.html (last accessed on 24 December 2003)

tial cure for this fatal disease.

As is the case with AIDS, some of these diseases are fatal–unless we find a cure for them in the near future, we are likely to witness an increasing number of deaths each year. The statistics are shocking– in the year 2003 alone, three million people died of AIDS, bringing the total number lost to the epidemic to nearly 32 million, the size of the population of Canada.

The biomedical industry is characterized by the 'cumulative innovation' paradigm, wherein the discovery of a gene sequence is only the first step; vast amounts of additional time, effort and money will have to be spent turning such sequence information into viable products, tests and cures for genetic conditions and diseases. Nonetheless, those who patent such 'raw data' will find themselves in a strong bargaining position and will undoubtedly be able to secure for themselves significant financial return, quite often at the cost of holding up further downstream research. This potential 'blocking'[1] or 'access' issue could adversely impact upon drug discovery, as many diseases today are known to be gene based.

Multiple patents over such raw data could also result in what Heller and Eisenberg refer to as the 'tragedy of the anticommons'.[2] This impending tragedy refers to a situation where there are numerous property right claims over the building blocks necessary for research and development. If property rights over such building blocks are held by multiple owners, the negotiations necessary to bring these blocks together can fail, thus stifling follow–on innovations. In contrast to this prospect of an anticommons, the 'blocking' or 'access' issue is not a problem of accessing multiple rights but one of accessing relatively few patents—or perhaps even one patent on a key upstream invention. Rather than concerning itself with the anticommons issue, the focus of this paper will be on the 'blocking' or 'access' issue. In terms of the structure of this paper:

(1) In the first chapter, I will introduce the 'blocking' or 'access' issue, as thought to be prevalent in the biomedical arena; with a special focus on the Breast Cancer gene and HIV/AIDS related gene controversies. I will however caution that before we seek to redress this blocking impasse, we need to ask ourselves as to whether there is a 'blocking' in the first place.

(2) In the second chapter, I will explore the evolution of the Essential Facilities Doctrine (EFD) by the European commission/courts and its application to intellectual property. I will also briefly discuss Japan's recent move to integrate the EFD in a more substantial manner within its antitrust regime.

(3) In the third chapter, I deal with the core concept underlying the EFD i.e. the question of 'essentiality'. I will explore the viability of various alternatives to patented 'genes'.

(4) In the fourth chapter, I will highlight the local nature of 'essentiality'–arguing that it varies depending on the level of technological sophistication and/or legal protection available to an invention in each country.

(5) I will then conclude, drawing on the key points stressed in the earlier chapters.

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[1] Note that this term is of wider import than the term 'blocking patents'. 'Blocking patents' has a specific legal connotation and signifies instances where one patent holder holds a broad patent over an invention (the dominant patent) and another patent holder holds a narrower patent over an improvement to that invention, or a new invention (the subservient patent). The holder of the subservient patent requires a licence from the holder of the dominant patent, and the holder of the dominant patent would be precluded from exploiting the improvement without a licence. However, I have tried to use the term 'blocking' in a wider manner, to include all instances of where downstream research was blocked by patents on upstream inventions.

[2] See MA Heller and RS Eisenberg 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' 280 Science 698–701 (1998).

2 UNBLOCKING GENE PATENTS: IF IT AINT BROKE, DON'T FIX IT!

The prospect of 'blocking' by broad patents on upstream inventions in a cumulative industry is not merely anecdotal but has some historical basis. In a path-breaking paper, Merges and Nelson argue that the refusal of the Wright brothers to license their patent significantly retarded progress in the aviation industry.[1] The biomedical industry seems an ideal target for blocking problems to occur, given the fact that:

(1) Patents were granted at the initial stages on mere DNA sequences, with no other known function than their mere use as probes.[2] Inherent in these grants was the potential for blocking any further research on these protected sequences.

(2) Genes are finite in number. It is also extremely difficult to invent around gene patents. Because of these factors, gene patents grant real monopolistic power in a market already fraught with inefficiencies.[3]

(3) A single gene may have more than one function. For example, mutations in the RET (REarranged during Transfection) gene are responsible for two different disorders, Multiple Endocrine Neoplasia, which includes thyroid cancer and Hirschsprung disease, a disorder of the intestinal tract. A single patent over the sequence would give the patent holder potential control over two very different disorders.[4] It is important to note that most patent regimes stipulate that a patent over a novel product would entitle the patentee to not just the use identified in the patent application but to all its uses, even those that that may be discovered in future by third parties.

Two of the most controversial gene patents that have raised concerns of blocking in a stark manner are the patents on the CCR5 gene and the BRCA genes.

2.1 CCR5 Patent

In 2000, the USPTO (United States Patent and Trademark Office) granted a patent to Human Genome Sciences Inc (HGS) covering the nucleotide sequence of CCR5.[5] The utility of the invention was defined, among other things, as a tool for screening for receptor agonists and antagonists, and as a diagnostic tool for detecting mutations in the gene itself. A utility in HIV research was not mentioned– as admitted by HGS; no such utility

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[1] RP Merges and RR Nelson 'On the Complex Economics of Patent Scope' 90 Colum LR 839

[2] See S Basheer 'Patenting Genes And Gene Sequences: The Next El Dorado' Electronic Database of Intellectual Property (EDIP) Oxford (2002) 16: Available at users.ox.ac.uk/~edip/student_index.htm (last accessed on 20 January 2004). Between 1992 and 1996, Human Genome Science Inc. (HGS) of Rockville, Maryland launched a factory like effort to sequence gene fragments and thereafter applied for scores of patents on these fragments (EST's). Incyte Pharmaceuticals Inc., of Palo Alto, California, set up a similar project. In another development, Lexicon Genetics Incorporated applied its 'gene trapping' technology (which helps to rapidly and efficiently obtain gene sequence information from thousands of human genes) to human cells and discovered more than 50,000 partial human gene sequences. Patent applications have been filed for all these partial gene sequences. (Press Release in Yahoo Finance on May 1st 2001. See http://biz.yahoo.com/prnews).

[3] Statement of Jon F. Merz 'Oversight Hearing on Gene Patents and Other Genomic Inventions' The Subcommittee on Courts and Intellectual Property (US House of Representatives) July 13, 2000. The Nuffield report also stresses the difficulty of inventing around gene patents, particularly in the case of diagnostic tests. See Nuffield Council on Bioethics 'The Ethics of Patenting DNA: A Discussion Paper' (Nuffield Council on Bioethics: London): Available at http://www.nuffieldbioethics.org/patentingdna/index.asp (last accessed on 26 February 2004).

[4] See Cornish et al 'Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector' (PHGU Cambridge 2003) 33: Available at www.phgu.org.uk (last accessed on 10 January 2004).

[5] US Patent No. 6,025,154 (2000).

was contemplated at the time.[1] Other researchers subsequently discovered that the CCR5 receptor was the 'docking receptor' used by the HIV virus to infect a cell; the gene therefore came to promise significant utility in AIDS research and the possibility of a cure.[2] However, the patent grant meant that HGS could exclude all such researchers from using the CCR5 gene in their research. It was feared that this patent would have a 'blocking' effect on AIDS research. However HGS's promise to grant the requisite licences for research into new drugs and to permit academics from undertaking unlicensed research with the CCR5 gene ensured that such apprehensions of blocking soon subsided.[3]

2.2 BRCA Patents

In much the same way, Myriad Genetics, a corporation headquartered in Utah, USA has been accused of stifling research because it has been unwilling to broadly license the diagnostic use of its patents on the breast cancer genes, BRCA1 and 2.[4] Myriad's exorbitant demands for royalties put its test out of the reach of clinics and hospitals and it was feared that Myriad's actions could have the effect of preventing the emergence of new and improved tests. This fear became even more real when researchers at the Institut Curie, a French research institute, used their own test to demonstrate a shortcoming in the Myriad test.[5] This indicated that Myriad's tests were far from perfect and that their approach to testing (which involved full DNA sequencing of the two BRCA genes) could only detect small–scale deletions and re–arrangements. Myriad's patents however ensured that it could stunt the emergence of any such tests.

Quite apart from high licensing fees that discouraged the procuring of licences by third party researchers, Myriad went to the extent of insisting that all samples
be sent to its headquarters in Utah, stating that this was necessary to ensure safety in testing. It is feared that this 'compulsory' sending of DNA samples will help Myriad build up a genetic data bank, and enable it to further monopolise all future discoveries using this material.[6]

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[1] E Marshall 'Patent On HIV Receptor Provokes An Outcry' Science Now, 23 Feb 2000: Available at http://bric.postech.ac.kr/trend/science/2000/00_2now/000223a.html (last accessed on 17 January 2004).

[2] One such researcher was Professor Marc Parmentier who applied for a patent as well. The patent in the name of 'Euroscreen' (of which Marc Parmentier is the founder and CSO) was recently granted. This patent (US Patent No. 6,448,375) covers a protein containing a specific portion of CCR5 and therefore the full–length wild–type amino acid sequence of CCR5. See 'Euroscreen awarded US patent covering key HIV target' Patent Café International (12 September 2002).

[3] Apart from the licensing deal announced in early 2000 with Praecis Pharmaceuticals (for the development of HIV therapy based on the CCR5 gene), the author was unable to find any other documented evidence of licensing by HGS. The author is of the view that even absent such licensing, research in this direction continues unhindered. Given the tenuous nature of the patent grant to HGS (there is near consensus from all quarters that the utility cited by HGS was a highly speculative one) as also the fact that a conflicting patent seems to have been granted to Euroscreen (see n 11 above), HGS may be intentionally turning a blind eye to infringements for fear of risking an invalidity attack.

[4] Myriad owns patents on the genes, certain mutations of the genes and on tests to detect mutations in these genes. Such mutations are thought to account for a sizeable number of breast cancer cases. Many claim that not only are the licence fees sought by Myriad exorbitant but also that Myriad is abusing its monopoly by preventing the emergence of better and cheaper tests. The US patents include numbers: 5,654,155, 5,747,282, 5,710,001, 5,693,473 and 5,837,492. European patents include numbers: 699754 and 705903. Apart from this, patents have also been granted in Australia, Canada and New Zealand.

[5] Institut Curie used one of their patented technologies, called combed DNA colour bar coding– to identify a 3 exon deletion in BRCA1 in a patient who had received a negative result (no mutations detected) when tested by Myriad. See BW Jones 'History of a Gene Patent: Tracing the Development and Application of commercial BRCA Testing' 10 Health LJ 123 (2002) 139.

[6] M Rimmer Myriad 'Genetics: Patent Law And Genetic Testing' 25 EIPR 1 (2003) 27

However with the recent grant of a European wide patent to the charity, Cancer Research (UK) on the BRCA2 gene[1], it is hoped that the monopoly of Myriad will be curbed.

Various solutions have been proposed to tackle the blocking issue. Some have recommended patent law reform, such as ensuring that only 'use patents' are granted for inventions claiming DNA sequences. Thus for example, the Nuffield Council on Bioethics recommends in its report as follows: 'we recommend…. limiting the scope of product patents that assert rights over naturally-occurring DNA sequences to the uses referred to in the patent claims…' [2]

Similarly, in France, concern about Myriad's patents led to a controversial bioethics bill that sought to broaden compulsory licensing of patented diagnostic tests, and to even ban the patenting of human genes.[3]

Some others have sought to redress these issues outside the confines of patent law[4]. However, before weighing up the pros and cons of such proposed solutions, one has to take a step backward and ask the question: "Is there a 'blocking' in the biomedical industry in the first place?"

2.3 Walsh and OECD

Despite initial concerns echoed by many that the biomedical industry would be characterised by a severe 'blocking' issue, Walsh et al[5] demonstrated that the theoretical possibility of such blocking concerns may have been offset by certain 'working solutions' adopted by the industry:

Moreover, although we do not have comparably systematic evidence on projects never undertaken, our interviews suggest that IP on research tools, although sometimes impeding marginal projects, rarely precludes the pursuit of more promising projects. Why? Industrial and university researchers have been able to develop "working solutions" that allow their research to proceed.[6],

These 'working solutions' include taking licences, inventing around patents, infringement (often informally invoking a research exemption), going offshore, developing and using public tools, and challenging patents in court.

Walsh's conclusions[7] were broadly reflected in an OECD report as well which stated:

The few examples used to illustrate theoretical economic and legal concerns related to the potential for the over-fragmentation of patent rights, blocking patents, uncertainty due to dependency and abusive monopoly po-

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[1] S Mayor 'Charity wins BRCA2 patent: Genetics researchers welcome a decision that will make the gene freely available in Europe' 13 February 2004: Available at http://www.biomedcentral.com/news/20040213/02 (last accessed on 28 February 2004)

[2] Nuffield (n 7) 87

[3] Jones (n 14) 139

[4] For example, SJR Bostyn proposes that 'If DNA patents lead to excessive prices of health care, then governments should take price measures instead of prohibiting patentability of DNA sequences', SJR Bostyn 'The Prodigal Son: The Relationship between Patent Law and Healthcare' Medical Law Review 11 Spring 2003 (54).

[5] J Walsh, A Arora and W Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W.M. Cohen and S.A. Merrill (eds.) Patents in the Knowledge-Based Economy (Washington: National Academies Press 2003) at 287. This report dealt with whether the prospect of an 'anticommons' as feared by Heller and Eisenberg had been realized as also whether the restrictions on access to upstream discoveries had impeded biomedical innovation. As noted earlier, the 'anticommons issue' is quite different from the 'blocking' or 'access' issue and my focus will be on the latter

[6] Ibid 331

[7] Arrived at after conducting 70 interviews with IP attorneys, business managers, scientists (from 10 pharmaceutical firms and 15 biotech firms), university researchers and technology transfer officers (from 6 universities), patent lawyers and government and trade association personnel.

sitions appear anecdotal and are not supported by existing economic studies[1]

Notwithstanding the general finding that there is no evidence of systematic or large scale blocking in this industry, one–off instances do exist. Myriad's licensing practices could perhaps be considered a good example in this regard.[2] Maybe there will arise more such instances in future. Walsh et al warn that the present evidence may not hold good for all time to come and that access could become an issue in future.[3] It is therefore important that we constantly monitor this industry and assess individual blocking situations as they arise to determine the need for a broader and more systematic response to concerns of blocking.

It is in this regard that antitrust offers a good structural framework to help us determine the existence and extent of blocking in each individual case. I will show in this paper how the EFD helps us achieve this. Underlying the very essence of this doctrine is the concept of 'essentiality'. Essentiality would in most cases help in a determination of 'blocking' i.e. if the facility is a non–essential one, then there can be no blocking. However the converse need not always be true–i.e. if the facility is an essential one, but is widely licensed, it is quite possible that there would be no blocking. In this way and perhaps paradoxically, the very application of an antitrust remedy would help us determine if there is a 'blocking' in the first place.

3 THE ESSENTIAL FACILITIES DOCTRINE

The 'Essential Facilities Doctrine' (EFD) is designed to deal with the danger that a monopolist in control of a scarce resource will extend its monopoly power vertically from one level of production to another. The 'scarce resource', which may range from a physical bottleneck (such as a telecommunication network or a port) to an Intellectual Property Right (IPR), would qualify here as the 'Essential Facility'. A denial of access to this facility would then qualify as an abuse of dominant market power, and the dominant undertaking would be forced to grant 'access' on fair and reasonable terms. Thus, for example, this doctrine would specify when a railroad must be made available on 'reasonable' terms to a rival rail company or a patent licensed to a competitor.

The EFD has its origins in the US[4] and has been most widely applied in regulating access to physical infrastructure such as transport facilities (notably, ports) or utility networks (e.g. pipelines, energy networks).

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[1] See Organisation for Economic Co–operation and Development (OECD) 'Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies' (OECD Berlin 2002) 78: Available at http://www.oecd.org/dataoecd/42/21/2491084.pdf (last accessed 20 February2004). This report stemmed out of a workshop (held by the OECD Working Party on Biotechnology on 24–25 January 2002), in which several experts, including Dr Walsh presented their findings

[2] The licensing practices of the owners of patents for other genetic tests – for example, Athena's Alzheimer's (ApoE) test, and the test owned by Miami Children's Hospital for Canavan's disease – have also raised concern about high costs and limited access to genetic tests. A 1999 survey of the licensing practices of holders of patents that cover the diagnosis of genetic disorders showed that almost all the patents were being licensed exclusively; in theory, this could allow the monopolisation of genetic testing services. See Schissel et al 'Survey Confirms Fears about Licensing of Genetic Tests' Nature 402 November 118 (1999). The OECD report also cautions that 'empirical studies have shown problems arising over access to diagnostic genetic tests, although the exact cause of these problems has not been fully elucidated' (n 23).

[3] 'We cannot, therefore, rule out future problems resulting from patents currently under review, court decisions, new shifts in technology, or even assertions of patents on foundational discoveries. Therefore, we anticipate a continuing need for the active defense of open science.' Walsh (n 20) 335.

[4] United States v. Terminal Railroad Association, 224 U.S. 383 (1912). However with the Supreme Court's recent expression of hostility towards this doctrine in Verizon Communications Inc. v Law Offices of Curtis V. Trinko LLP 540 U. S. 1 (2004) the extent of applicability of this doctrine in the US is not clear.

3.1 European Position

The EF Doctrine derives from Art. 82 of the EC (European Community) Treaty, which prohibits the abuse of a dominant position.[1] As evident from this article, 'dominance' per se is not prohibited under Article 82; rather, it is only when such dominance is abused that Article 82 springs into operation. An examination of some of the 'essential facilities' cases would help us understand the parameters of this doctrine better.

3.2 Volvo vs Veng

In terms of the application of EFD to intellectual property cases, the best starting point is AB Volvo v. Eric Veng (UK) Ltd[2]. The case concerned the front wings of Volvo 200 cars, on which Volvo held a registered design. Veng imported these products, manufactured reproductions of them, and marketed them in the United Kingdom without authority from Volvo, who instituted proceedings for an infringement of its registered design. Veng argued that by refusing access to their designs, Volvo committed an abuse of its dominant position.

The court stressed that a mere refusal to grant a licence to a third party would not by itself constitute an abuse of a dominant position. Rather, Article 82 requires factors over and above a mere refusal to license. The European Court of Justice (ECJ) endorsed three examples that had been suggested by counsel when a refusal to license might be abusive. A refusal to license might be abusive if coupled with:

(1) an arbitrary refusal to supply spare parts to independent repairers;

(2) overcharging for spare parts, or

(3) ceasing to produce spare parts for a particular model when there were many vehicles of that model still on the road, i.e. despite an objective demand.[3]

The crucial point in this case was that Veng merely wanted to copy Volvo's design to make cheaper spare parts for Volvo cars – it had no intention to innovate, but was merely trying to 'free ride' on Volvo's efforts to develop an original design for its cars.

3.3 RTE v. Magill[4]

Magill is the first EC case in which the refusal to license an intellectual property right (IPR) was held to constitute an abuse under Article 82. Consequently, the IPR holder was ordered to compulsorily license the right invoked.

Magill published a weekly TV Guide containing programme schedules for all the television channels available in Ireland. At that time, the broadcasting and TV stations RTE, BBC and ITV each published separate weekly guides to their own programmes. All of them supplied programme information free to daily newspapers, which were allowed to publish one day's listings (or two days' at weekends or where the following day was a public holiday). However, publication of the weekly listings was not authorised – the broadcasters had reserved this for themselves relying on Irish copyright rules. The broadcasters successfully sought an injunction to prevent the continued publication of the Magill comprehensive weekly guide on the basis that, as literary works and compilations, the schedules were entitled to copyright protection.

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[1] However Article 82 envisages several other forms of abuse as well, such as excessive pricing, selective licensing etc.

[2] [1988] ECR 6211

[3] Para 9 of the judgment.

[4] [1995] ECR 1–743. For a discussion of this judgment, see IS Forrester 'Compulsory licensing in Europe: A Rare Cure to Aberrant National Intellectual Property Rights?': Available at http://www.ftc.gov/opp/intellect/020522forrester.pdf (last accessed 14 December 2003).

Magill lodged a complaint with the Commission alleging that the broadcaster's refusal to license the weekly listings amounted to an abuse within the meaning of Article 82. The Commission found that the broadcasters had abused their respective dominant positions on the market for their weekly listings: their refusal had prevented the introduction onto the market of a new product for which there was "substantial potential demand". It ordered that the broadcasters license each other and third parties on a non–discriminatory basis, a decision confirmed by the Court of First Instance (CFI). [1]

The ECJ upheld the Commission decision. It appeared to approach the case as an instance of a refusal to supply. In coming to the conclusion that there was abuse of a dominant position, the Court noted that the broadcasters were "the only sources of the basic information on programme scheduling which [was] the indispensable raw material for compiling a weekly television guide"

The Court then took three elements into consideration:

(1) The broadcasters' refusal to provide 'basic information' prevented the emergence of a new product, "which the broadcasters did not offer and for which there was a potential consumer demand." (Para 54)

(2) There was "no justification for such refusal either in the activity of the television broadcasting or in that of publishing television magazines" (para 55), and

(3) The broadcasters, by denying access to "the raw material indispensable for the compilation" of a TV guide, "reserved to themselves the secondary market of weekly television guides by excluding all competition on that market" (para 56)

Therefore, the refusal was an abuse under Article 82(b).

The Court's approach verges on an essential facilities analysis, but there is no discussion of an essential facilities doctrine, despite the Commission's increased reliance on it in the years preceding the ECJ judgement. By labelling Magill as a refusal to supply case, the ECJ managed to side step the argument on the relationship between nationally granted intellectual property rights and the Treaty rules on competition that had generated so much controversy in the earlier stages of the case.

It may be suggested that implicit in the Magill judgement was a belief that a copyright in a television list did not deserve extensive intellectual property protection.[2] This was hinted at by Advocate General (AG) Jacobs, who had occasion to remark about Magill in Oscar Bronner:

'the provision of copyright protection for programme listings was difficult to justify in terms of rewarding or providing an incentive for creative effort.'[3]

It must also be remembered that in Magill, the weekly listings were not reasonably and practically replicable – they were very 'essential' and no amount of innovation could produce an alternative. This separates them from the vast majority of intellectual property rights cases and clearly informed the courts decision to order a licence.

3.4 Oscar Bronner v. Mediaprint[4]

In Bronner the issue before the ECJ was whether the defendant newspaper's nation–wide home–delivery

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[1] Para 53 of the judgment.

[2] Para 55 of the judgment. See also IS Forrester (n 29) who states "The low intrinsic value of the right was not expressly mentioned in the Magill case by the Courts (their role is not to comment on the appropriateness of national copyright rules)….It was, however, clearly part of the equation"

[3] Oscar Bronner v. Mediaprint 4 CMLR 112, 63.

[4] Ibid.

network constituted an essential facility. Bronner sought an order that Mediaprint cease abusing its dominant position by including his publication in its distribution network in return for fair remuneration.

The ECJ emphasised that the essential facilities doctrine applies only in 'exceptional' circumstances. The Court stated that it would only be an abuse of Article 82 of the EC Treaty for Mediaprint to refuse Bronner access to its home-delivery system if three conditions were satisfied:

(1) The refusal to give Bronner access to Mediaprint's home-delivery system would be likely to eliminate all competition in the daily newspaper market on the part of Bronner;

(2) such refusal could not be objectively justified; and

(3) the home-delivery service, in itself, was indispensable to carrying on Bronner's business inasmuch as there was no actual or potential substitute in existence for that home-delivery service. (para 41)

The ECJ did not regard these conditions as being satisfied in this case. Other methods of distribution, such as by post and by sale in shops or kiosks, were available, even if they constituted less advantageous means of distribution. The ECJ also stated that there were no technical, legal or economic obstacles making it impossible, or even unreasonably difficult, for a publisher of papers to establish, possibly in co-operation with other newspaper publishers, its own nation-wide home-delivery service. The ECJ specifically rejected Bronner's argument that the small circulation of his newspaper made it economically unviable for him to develop his own nation-wide home-delivery scheme. The ECJ held that such an argument is not enough to demonstrate the lack of a realistic potential alternative to access to the home-delivery scheme. It would be necessary to show objectively that the establishment of an alternative home-delivery system was not economically viable – that is, not just that Bronner could not develop an alternative home-delivery system, but that an alternative home-delivery system was not a realistic option for any of Mediaprint's actual or potential competitors in the daily newspaper market.

The ECJ expressly stated that Magill was an exceptional case and affirmed that the starting point in all such cases is that firms are free to decide who is to have access to their facilities and assets, and that it is only as a last resort that EC competition law will intervene, with the burden of proof being on the alleged victim of the refusal of access in the first instance.[1]

3.5 IMS Health[2]

This case involved a series of proceedings, some before the European institutions and some before the national authorities. The key issues were recently referred to the ECJ, and the Advocate General (AG) handed down his opinion late last year.

IMS Health is a world leader in data collection on pharmaceutical sales and prescriptions. It has copyright over its 1860 brick structure, which segments Germany into sales zones or bricks. The concept behind the brick structure is to partition Germany into the maximum number of geographical units that permits data collection without the ability to match the data to a specific pharmacy-as this would contravene German data protection rules. The 1860 brick structure soon developed into a de facto industry standard for sales data collection and analysis. It came to be widely used by German pharmaceutical companies to analyse sales trends, measure market shares, and gauge the performance of sales representatives. IMS successfully brought actions for breach of

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[1] See V Korah 'The Interface Between Intellectual Property and Antitrust: The European Experience' 69 Antitrust Law Journal 801 (2002) 820.

[2] IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG (C418/01)

copyright against competitors using the copyrighted brick structure and refused to grant them licences. One competitor, NDC complained to the European Commission.

The European Commission found that the refusal by IMS to grant access to the brick structure was likely to eliminate all competition, and therefore ordered IMS to grant a licence to competitors.

The Commission's decision in large part turned on the fact that the copyrighted 1860 brick structure was in effect a de facto industry standard and that competitors were effectively 'locked in' to this standard. Certain 'technical and legal constraints' (such as data protection law) made it near impossible for competitors to create a new structure for regional sales data in Germany that could effectively compete with the 1860 brick structure.

The President of the CFI suspended the Commission decision on the ground that the Commission seemed to take a fairly liberal view of the notion of 'exceptional circumstances' as stressed in Magill. In particular, the CFI was concerned that the Commission regarded the Magill conditions as non–cumulative i.e. it did not regard it as necessary that the refusal to license should prevent the emergence of a new product or service for which there is potential consumer demand. The Order of the President of the CFI was then confirmed by the President of the ECJ.

In his opinion delivered on October 2, 2003, AG Tizzano suggested that the ECJ deliver the following preliminary ruling on the questions posed by the Landgericht Frankfurt am Main on the interpretation of Art.82 EC:

Article 82 EC must be interpreted in the sense that the refusal to grant a licence to use an intangible good protected by copyright constitutes an abuse of a dominant position according to the meaning of that Article if:

a) there is no objective justification for such a refusal; and

b) the use of the intangible good is indispensable in order to operate on a downstream market and, as a result of such refusal, the owner of the copyright can eliminate all competition on the said market.

3.6 Broad Conclusions

Although the parameters of the EFD have still not been worked out fully in the EU, some broad conclusions can be drawn from case law.

1. A mere refusal to license is not sufficient to invoke the EFD. Rather, as stressed in Volvo v Veng, there have to be 'exceptional circumstances', beyond a mere refusal to license. Although the nature of such 'exceptional circumstances' has not been clearly articulated, it can be broadly culled out from case law such as Magill and IMS.[1]

2. The three criteria developed in Magill, Bronner and IMS to determine whether a refusal to license constitutes an abuse may serve as a starting point to determine the existence of 'exceptional circumstances':

a. New Product: The refusal to grant access to the facility is likely to prevent the emergence of a new product for which there is potential consumer demand;

b. Essentiality: The facility itself is indispensable to carrying on business, inasmuch as there is no actual or potential substitute in existence for that facility; and

c. Objective Justification: The refusal is not capable of being objectively justified.

Of all these factors, the one that will be focussed upon in this paper is 'essentiality'. Needless this say,

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[1] AG Tizanno's opinion in IMS however moves away from the notion of 'exceptional circumstances'. Rather, it attempts to define the conditions under which a refusal constitutes an abuse of a dominant position. See Bruno Lebrunims 'IMS V NDC : Advocate General Tizzano's Opinion' 26 (2) EIPR 84 (2004)

this factor underpins the very essence of the EFD i.e. if the facility is non-essential, then presumably, a competitor need not have access to it in order to compete effectively.

'Essentiality' formed a significant portion of the underlying judicial reasoning in Magill Bronner and IMS. In Magill, the weekly listings were not reasonably and practically replicable – they were very 'essential' and no amount of innovation could produce an alternative. In Bronner, the ECJ applied a seemingly high test of essentiality holding that a mere inconvenience in duplicating the 'essential facility' in question was not sufficient. In IMS, the Commissions found that the copyrighted 1860 brick structure had acquired the status of a de facto industry standard and this precluded the creation of a viable substitute by a competitor.

It is important to note that the question of essentiality becomes relevant at two stages of the application of the essential facilities doctrine:

1. When determining the issue of 'dominance'.

2. When determining the issue of 'abuse'.

To elaborate:

(1) EFD is not a stand-alone concept. Rather, it is a subset of the wider mandate to refrain from abusing a dominant position. Prior to a finding that there has been an abuse, 'dominance' in a given market has to be established. In most cases, 'market power' (determined in turn by factors such as market share) will determine 'dominance'. Market power will in turn significantly hinge upon how "essential" the facility itself is.

(2) The doctrine becomes important at the stage of determining 'abuse' as well. One of the three criteria developed in Magill, Bronner and IMS that inform the 'exceptional circumstances' equation (as highlighted above) is a determination that the facility itself is indispensable to carrying on business, inasmuch as there is no actual or potential substitute in existence for that facility.

4 ESSENTIALITY AND INVENTING AROUND: GET CREATIVE!

As has been stressed in the earlier chapter, one of the essential prerequisites for an application of EFD is a determination that the facility is an essential one. The question of 'essentiality' would in large part turn upon the availability of substitutes available for inventing around the patent. In the case of patents on human genes, substitutes/alternatives do exist, at least theoretically. Let's explore some of them:

4.1 Animal genes:

Since animal genes share a striking similarity to human genes, it may be theoretically possible to substitute an animal gene for a human one. In a recent BBC report[1] it was stated that scientists discovered a gene, in the nematode worm, that was quite similar to the human breast and ovarian cancer gene BRCA1. It was hoped that this gene could offer some clues for the development of breast and ovarian cancer. Given Myriad's heavy-handedness in enforcing its patents on the breast cancer genes, researchers keen on working on these genes without paying the exorbitant royalties demanded by Myriad could consider using the nematode gene instead.

4.2 Muteins:

Another interesting area that could throw up potential substitutes is 'protein engineering'. This involves the artificial modification of genes to yield new proteins or 'muteins'. Examples of successful muteins include

[1] See 'Primitive Worm Gives Cancer Clue': Available at http://news.bbc.co.uk/1/hi/health/3368685.stm (last accessed on 19 February 2004).