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LICENSING INFORMATION ASSETS IN THE NEW ECONOMY: A PRO-RIGHTS PERSPECTIVE

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ABSTRACT

Transactions in the twenty-first century are no longer restricted to just transactions of goods. The digital age has brought with it a boom in transactions in information, and licensing of information assets is often seen as the best way to permit and control the use of the information in question by mutual agreement. However, given the rapidity of technological advances and the corresponding changes in the nature of licensing transactions, an economy is not best served by a static legal system that continues to treat information licensing in the same manner as a hire, rent or lease of goods. This article therefore examines the nature of licences as well as the market and legal rationales behind licensing in an effort to depict the impact of these transactions and the importance of having dynamic legal systems enforcing and protecting them.

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I. INTRODUCTION

Modern information processing and communications systems have fundamentally changed the ways in which we interact and do business, and even the subject matter of substantial parts of modern commerce. With these changes have come corresponding changes and diversification in the transactional frameworks in which commerce occurs, both in mass-market environments and in environments involving more tailored transactions between two or more businesses. Commercial practice is a fluid and evolving phenomenon, and both commercial practice and the law related to it have adapted to the new technologies and new opportunities grounded in them.

This paper focuses on one form of that adaptation: licensing transactions. Licensing of information assets has been a commercial practice for generations. Modern information industries and their related technology, however, have vastly expanded the use of licensing, brought licensing transactions into the mass-market environment, and expanded the types of assets to which licensing concepts are applied. Throughout the world, licence agreements have become an important aspect of modern practice and reality. The reason is simple: the structure of a licence and its focus allows commercial practice to tailor assets to markets and the interests of the parties therein in ways that suit both sides of a deal, which could not as readily be attained under other forms of traditional commerce. In both law and practice, it is important to accommodate and provide support for this type of commercial relationship. The law and policy issues associated with licensing in the international environment, even as between developed and developing countries, are not issues of taking advantage or withholding assets, but of enabling and supporting transactions in which assets and rights are made available in ways tailored to both current and future needs.

I will not survey in detail the broad area of the law associated with licensing here – that is a task for a different venue.[1] My focus here is primarily on the digital or computer information industries (including the software and online information industries) and on licensing as an aspect of broad marketplaces that often include consumer licensees, since digital industries initiated the

[1] *See generally* RAYMOND T. NIMMER & JEFF C. DODD, MODERN LICENSING LAW (2006).

modern explosion of licensing practice in broad or mass-market practice. The value of this transactional framework can now be seen in how it has spread throughout the economy, even in industries that seemingly focus on transactions in ordinary goods, but are actually grounded in more sophisticated matrices of intellectual property rights.[2]

Licensing is, and has always been, an important means of allocating rights or their use in respect to intellectual property and ownership of other sources of control over informational assets and intellectual property rights. This type of transaction has been an integral part of the information industry almost since the origins of information as a form of commercial value and a focus of commerce. The expansion of this format into broader mass markets corresponded with the explosion of growth in software and other digital industries, creating the most vibrant, competitive and rapidly growing sector of commerce in the global economy.

Although some academics argue that licensing contracts, along with strong intellectual property rights, create risks of suppressing innovation and the availability of information,[3] the digital information industries and their licensing practices have had a startling *positive* impact on consumer services, opportunities and products. Consumer choices have expanded, along with the richness of the consumer marketplace. There has been an explosion in the availability of information, in the options by which consumers obtain information, and in the types of information or functionality they acquire. In short, this is not an era in which the use and availability of information has been restricted or constrained, but an era in which the opposite has occurred.

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[2] *See, e.g.*, LG Electronics, Inc. v. Bizcom Electronics, Inc., 453 F.3d 1364 (Fed. Cir. 2006) (microprocessors); Arizona Cartridge Remanufacturers Ass'n v. Lexmark Int'l, Inc., 2005 WL 2077641 (9th Cir. 2005) (printers and cartridges); Jazz Photo Corp. v. U.S., 439 F.3d 1344 (Fed. Cir. 2006) (cameras); Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004) (seeds); DSC Communications Corp. v. Pulse Communications, Inc., 170 F.3d 1354 (Fed. Cir. 1999) (telecom routers); Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 704 (Fed.Cir.1992) (medical devices).

[3] *See, e.g.* Yochai Benkler, *Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain*, 74 N.Y.U. L. Rev. 354 (1999); Niva Elkin-Koren, *Copyright Policy and the Limits of Freedom of Contract*, 12 Berkeley Tech. L. J. 93 (1997); Neil Weinstock Netanel, *Locating Copyright Within the First Amendment Skein*, 54 Stan. L. Rev. 1, 34-35 (2001).

Stagnant markets and economies are characterized by rigidity. Dynamic markets are characterized by vibrant change and fluidity in market and business structure. The digital information economy epitomises a dynamic market, as does the increasing use of licensing arrangements tailored to particular market demand. It is important that this dynamic market not be constrained for policy reasons based on preconceived notions grounded in the economy of the pre-information age.

II. WHAT IS A LICENCE?

There are numerous ways to answer this question. Fundamentally, however, for our purposes, a licence is a contract that sets out a limited or conditional grant or permission to use an informational or other asset.[4] While most licences deal with numerous other issues (as do most sales agreements), the core of a licence delineates limited rights or permissions in the licensee to use information that is otherwise controlled by the licensor.

Licences have long been used in commerce, both with respect to information that is covered by valid intellectual property rights and with respect to information that is not (such as mere data).[5] What is new in modern commerce, however, is that licensing has come to dominate several aspects of commerce and that licence arrangements are used extensively in the mass market, including in transactions involving consumers. This reflects a market-supported decision to use contractual arrangements to apportion, by granting or withholding, rights given to the transferee to use information or related products.

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[4] Some, especially in the open-source software community, argue that at least some licenses are non-contractual permissions to use an intellectual property asset subject to limits or conditions. *See* RAYMOND T. NIMMER, THE LAW OF COMPUTER TECHNOLOGY, ch. 11 (1997, 2006 Supp.). That type of relationship can be created, but in general commercial contexts where a transaction occurs because of an agreement and typically involves an exchange, the mere permissive image is typically submerged in the contractual relationship itself. Indeed, there is both historical and recent authority in the United States to the effect that, if the license is not contractual, its limitations are ineffective, at least in some cases. *See, e.g.*, Jazz Photo Corp. v. U.S., 439 F.3d 1344 (Fed. Cir. 2006),

[5] *See, e.g.* ProCD, Inc. v. Zeidenberg, 86 F.3d 1447 (7th Cir. 1996) (contract limits use of database to consumer purposes only); Register.com, Inc., v. Verio, Inc., 356 F.3d 393 (2d. Cir. 2004); Siedle v. National Ass'n of Securities Dealers, Inc., 248 F. Supp.2d 1140 (MD Fla. 2003).

In intellectual property practice, a licence is often described as being no more than a mere 'covenant not to sue' for conduct that would otherwise infringe the intellectual property of the licensor.[6] The connotations of this characterisation are numerous, but the most important is that it suggests that the licensor gives no implicit promise that the licensed subject matter will be effective. For any such obligations or promises to arise for either party in a normal non-exclusive licence, there must be an affirmative undertaking to that effect.[7] Indeed, from this perspective, even seemingly express terms may not be enough to eliminate aspects of the covenant-not-to-sue characterisation.[8]

While this concept shapes the law and practice in the United States, many licence agreements go beyond that and expressly or implicitly state various commitments made by both the licensor and the licensee. In this more complex commercial context, however, the core focus on limited rights or permissions in the use of information or intellectual property distinguishes a licence from other types of transaction. In the United States, the Uniform Computer Information Transactions Act defines a 'license' as:

> *a contract that authorizes access to, or use, distribution, performance, modification, or reproduction of, information or informational rights, but expressly limits the access or uses authorized or expressly grants fewer than all rights in the information, whether or not the transferee has title to a licensed copy. The term includes an access contract.*[9]

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[6] *See, e.g.* US Phillips Corp. v. International Trade Comm'n, 424 F3d 1179 (Fed. Cir. 2005); Spindelfabrik Suessen-Schurr v. Schubert & Salzer, 829 F.2d 1075, 1081 (Fed.Cir.1987), *cert. denied* 484 U.S. 1063 (1988); General Talking Pictures Corp. v. Western Electric Co., 304 U.S. 175, 181 (1938) (patent licence "a mere waiver of the right to sue"); Cohen v. Paramount Pictures Corp., 845 F.2d 851 (9th Cir 1988); MacLean Assocs. Inc. v. William M. Mercer-Meidinger-Hanson, Inc., 952 F.2d 769 (3d Cir. 1991) (non-exclusive license is not a transfer of ownership).

[7] For a discussion of the distinction between an exclusive and a non-exclusive license, see RAYMOND T. NIMMER & JEFF C. DODD, MODERN LICENSING LAW, ch. 5 (2006).

[8] *See* Spindelfabrik Suessen-Schurr v. Schubert & Salzer, 829 F.2d 1075, 1081 (Fed.Cir.1987), *cert. denied* 484 U.S. 1063 (1988) ("[A] patent license agreement is in essence nothing more than a promise by the licensor not to sue the licensee [even] if [the promise is] couched in terms of '[L]icensee is given the right to make, use, or sell X.'").

[9] U.C.I.T.A. § 102(a)(41). The reference to an 'access contract' picks up the variety of contractual relationships in which the essence of the arrangement is to allow the licensee access to an online or similar asset. *See* U.C.I.T.A. § 102(a)(1).

If one were forced to draw an analogy to the world of goods, a licence resembles a lease more than a sale.[10] The person who acquires the licensed information (or the leased car) does not own that information, but has certain rights to possess and use it. Those rights are defined by the contract. The analogy between a licence and a lease breaks down, not because of the similarity of a licence and a sale, but because the subject matter of a licence is intangible and because a greater array of use-related provisions are common in licensing (either increasing or decreasing the licensee's permission to use the information).

One issue that has arisen as licensing transactions have proliferated in broader markets, including in consumer transactions, concerns the extent to which a limited view of qualitative or other assurances implicitly given to a licensee should continue to prevail in these markets and for new products. One difficulty in answering this question involves the fact, discussed below, that the subject matter of a licence differs fundamentally from the subject matter of other mass-market and similar transactions: licences deal with information, not goods. As a consequence, different expectations are reasonable and different obligations should be invoked in the absence of express language setting out the obligations in a particular transaction.

III. CONTEXT: TRANSACTIONS IN INFORMATION, NOT GOODS

A licence deals with rights or privileges to use information and not with goods. In its simplest form, even in the mass market, the contract does not primarily concern what one can do with the plastic diskette on which information may have been delivered, but with whether the licensee can copy, modify or distribute the copyrighted or other information contained on the diskette. (The distinction between the tangible material and the information and associated rights is specifically recognised in U.S. copyright law.) The software and other information industries do not deal in goods and their focus

[10] In U.S. law, the difference between a sale and a lease of goods lies in the fact that a sale conveys title to the goods, while a lease merely conveys a right to possession of the goods for a particular time. *See* U.C.C. § 2-106 ("A 'sale' consists in the passing of title from the seller to the buyer for a price."); U.C.C. § 2A-103(1)(p) (" 'Lease' means a transfer of the right to possession and use of goods for a period in return for consideration").

is not on transactions in tangible property. They deal in information and focus on transactions in intangibles. The primary value sought and obtained by the consumer or business licensee lies in the intangibles and in the contractual right that the transferee obtains to use them. The tangible items do not define the product, even when the transaction involves delivery of the information in the form of a copy of it.

In the U.S. and elsewhere, consumer protection laws have generally focused on tangible products and associated services, or on credit and monetary transactions.[11] The focus on goods was not a random decision. In the U.S., Congress did so because the then-proven abuses with which it dealt concerned sales of manufactured consumer goods and the warranties associated with them. The legal policies and social balance associated with consumer protection change when one moves to information and services contracts. We traditionally treat providers of information differently from the way in which we treat sellers of goods: the information providers are less subject to liability for defects (i.e. errors in the information) unless provable fault is involved.[12] This distinction is not made because of arbitrary tradition, but rather because what the information and services industries provide is different from goods, and retaining it as a central feature of commerce and culture requires a more protective approach.

The fundamentals of an economy do not often change, but when change occurs there is a predictable response from some brought up in the former economy that the new economy should be viewed solely in terms of the past and that change should be reversed or restrained by law in order to retain the formerly comfortable patterns of economic exchange. Such a response is both wrong and impractical. In fact, one of the leading documents on contract law in the United States, the Uniform Commercial Code, states as one of its primary purposes that it "must be *liberally construed and applied* to promote its underlying purposes and policies, which are: [...] to permit the continued expansion of commercial practices through custom, usage, and agreement of the parties".[13] The contrary view is quite incorrect. It either argues (or assumes) that nothing

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[11] *See, e.g.*, Magnuson-Moss Warranty Improvement Act, 15 U.S.C.A. § 2301.

[12] *See, e.g.*, Winter v. G.P. Putnam's Sons, 938 F.2d 1033, 1035 (9th Cir. 1991). *See* U.C.I.T.A. § 404 (1999); Gilmer v Buena Vista Home Video, Inc., 939 F. Supp. 665 (W.D. Ark. 1996).

[13] U.C.C. § 1-103 (a)(2) [emphasis added].

has changed when, in fact, very much has changed, or it ultimately argues that law should act to preserve old economic patterns, rather than allow the economy to embrace new patterns. Like those who argue for restricting the ability to license in the mass market, it argues from a position of fear even though we are in a world of growth and expansion where the positive benefits of change for everyone, including consumers, are demonstarted on a daily basis.

Over sixty years ago, Karl Llewellyn denounced the lawyers and legislators of that time in the U.S. who thought in terms of the prior economy, rather than focusing rationally on the new economy.[14] He was describing a change in the U.S. from an agrarian economy to a manufactured, mass-produced goods economy. Over several decades, his arguments eventually resulted in adoption of U.C.C. Article 2 on the sale of goods, a creature of the goods economy and a statute consciously tailored to deal with transactions involving the sale of manufactured goods. Were he alive today, Llewellyn would argue just as strongly against any belief that the digital information commerce of today should be treated under rules developed decades ago for sales of goods.

The change experienced in the modern economy is even more profound than the shift from an agrarian to a manufactured goods economy. Much of our current global economy is dominated by transactions in intangibles, services, information, knowledge and digital systems. Viewing word-processing software as equivalent to a toaster, a transaction for a multimedia product as equivalent to the purchase of a refrigerator, or an online access contract for research information as equivalent to buying a book – in fact, equating most other digital information or services contracts to purchasing manufactured hard goods – is a fundamental mistake. The transactions differ in many fundamental ways and call into play entirely different social values, marketplace dynamics and opportunities for a vibrant, diversified and responsive consumer marketplace that enhances opportunities and benefits for everyone.

In the U.S., except for some software licences, most licences are routinely dealt with under laws separate and apart from the law of goods for the purposes of general contract law. While some U.S. courts have held that software licences should be handled under contract law relating to the sale of goods, most of

[14] *See* Karl Llewellyn, *The First Struggle to Unhorse Sales*, 52 HARV. L. REV. 873, 880 (1939).

these decisions involve cases where goods (not software) predominated in the overall transaction.[15] The courts in those cases used standard rules to hold that the entire transaction (including the software) should be brought into Article 2 because goods dominated that transaction. In contrast, in cases dealing with software alone, the decisions split in terms of what law governs. More importantly, after years of independent debate and discussion involving diverse constituencies and interest groups, *three* different uniform state law projects have concluded that software and other information are not goods:

- U.C.C. Article 9 treats software and intellectual property rights as a general intangible.[16] Article 9 has been adopted throughout the United States.

- Proposed revisions of U.C.C. Article 2 treat information as being different from goods.[17]

- U.C.I.T.A. develops a separate body of contract law applicable to transactions in computer information. U.C.I.T.A. has been adopted in two states.

When one considers all three projects and the massive, diverse public involvement and detailed consideration of policy that has gone into them, the judgement of the various committees drafting these statutes establishes an impressive and uniform conclusion: transactions concerning computer information are not transactions in goods. Both a major uniform state law in the United States and significant federal case law and legislation acknowledge that computer software is properly characterised as 'information'.[18]

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[15] *See, e.g.*, BMC Indus., Inc. v. Barth Indus., Inc., 160 F.3d 1322 (11th Cir. 1998) (contract to "design, fabricate, debug/test and supervise field installation and start up of equipment to automate [production of eyeglass lenses]" was more a contract for goods than one for services); Neilson Business Equip. Ctr., Inc. v. Italo V. Monteleone, M.D., P.A., 524 A.2d 1172 (Del. 1987) (turnkey hardware and software system was contract for goods); Advent Sys., Ltd. v. Unisys Corp., 925 F.2d 670 (3d Cir. 1991) (article 2 applied to a software distribution contract). *C.f.* Architectronics, Inc. v. Control Sys., Inc., 935 F. Supp. 425 (S.D.N.Y. 1996) (predominant purpose of software license was the intellectual property rights, not goods): Fink v. DeClassis, 745 F. Supp. 509, 515 (N.D. Ill. 1990) (trademarks, tradenames, advertising, artwork, customer lists, sales records, unfulfilled sales orders, goodwill and licenses are not "goods").

[16] U.C.C. § 9-102(a)(42).

[17] U.C.C. § 2-103(k).

[18] *See, e.g.*, Electronic Signatures in Commerce Act (E-Sign), 15 U.S.C.A. § 7006(7); Uniform Electronic Transactions Act § 2(10) (1999) (" 'Information' means data, text, images, sounds, codes, computer

IV. THE RATIONALE FOR LICENSING

The subject-matter focus of a licence is different from that of a sale of goods. The point of this paper, however, is not to continually state the obvious (that information is not goods), but to discuss the question of why licensing exists and what rationales support its explosive growth into a major factor in the global economy.

One might begin by asking: "What is the rationale for characterising a transaction as a licence?" However, while some phrase the issue this way, the word 'characterising' connotes an artificiality and lack of substance that is not present in fact. It thus illustrates a substantively important and common mistake. The question implies that licensing (a major type of modern transaction) differs from transactions in the prior economy (e.g. copies sold to customer) merely because of a 'characterisation'. That is not true. In fact, licences differ from sales in fundamental ways. The choice of a licence rather than a sales model reflects judgments about how best to commercially distribute digital and other information in the current economy in light of market interests, legal risks, and other factors.

There are several ways to understand the rationale for choosing to license rather than sell (or give away) copies. We will discuss two of these.

One concerns an *economic* or *market* rationale for licensing. Licensing provides significant diversification in the market that goes well beyond the opportunities involved in mere sales of copies. Some describe this as *mass customisation.*[19] Others describe the licence as the *informational product* itself.[20] Under any terminology, this refers to a characteristic of digital and online information systems that helps shape vibrant markets, the achievement of which

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programs, software, databases, or the like."); 15 U.S.C.A. § 7706(7) (" 'information' means data, text, images, sounds, codes, computer programs, software, databases, or the like."); Green v. America Online (AOL), 318 F.3d 465 (3d Cir. 2003) (Section 230 barred a claim that AOL was negligent in not preventing the use by a third party of a so-called "punter program" that briefly shut down the plaintiff's computer. The program was within the definition of "information.").

[19] *See* Raymond T. Nimmer, *Licensing in the Contemporary Information Economy*, 8 WASH. U. J. L. & POL'Y. 99 (2002). *See also* STAN DAVIS & CHRISTOPHER MEYER, BLUR: THE SPEED OF CHANGE IN THE CONNECTED ECONOMY 38 (1998).

[20] *See* Robert W. Gomulkiewicz & Mary L. Williamson, *A Brief Defense of Mass Market Software License Agreements,* 22 RUTGERS COMPUTER & TECH. L.J. 335 (1996).

often requires contractual licence provisions. I will discuss this in greater detail below, but one way of seeing the significance is to compare two hypothetical licences: in one, the licensee obtains a copy of the software with a right to make and use copies for its personal use so long as only one copy is in use at any time. In the other, the transferee acquires the same software under a licence that allows it to make copies for all ten thousand of its retail stores and to use the copies in all of the stores. In each case, the software is identical, but the contract terms for and the value of the two transactions are entirely different. The difference resides in the terms of the licence. The licence, in effect, defines the product.

A second way to understand the rationale for choosing to license focuses on the rationale in *law* for licensing. One part of this lies in simple contract law: the right to agree to terms and to promises that define the scope of conduct expected or permitted with respect to a particular subject matter. In addition, the legal rationale includes the right of an owner of property (including of a patent or a copyright) or other value to shape the terms *and the extent* to which it makes that value available to others by contract. Unlike in goods, in reference to information, mere possession of a copy, access to a system, or knowledge of a fact does not necessarily give a person full rights to use the copy, exploit the system, or disclose the fact. The information transferor often retains dominant rights to use copyrighted, patented or other value. A licence provides a contractual basis by which the transferor and transferee establish to what extent those rights are granted or withheld.

A. The Market Rationale: Diversity and Tailoring

When we look at modern commerce in information, one clear fact emerges: the information economy entails a burgeoning diversity in what information and services can be obtained by consumers and by businesses, and how they can be obtained. These new services, resources, business models, functionality, and the like reflect vibrant competition and a dynamic open market. There is an expanding and shifting array of options, products and services. Businesses that have a chance of surviving in the modern economy must understand and react to this.[21]

[21] *See generally* STAN DAVIS & CHRISTOPHER MEYER, BLUR: THE SPEED OF CHANGE IN THE CONNECTED ECONOMY (1998).

On what basis are these diverse products and services differentiated? There are numerous answers, but one important part of the overall answer is that the differentiation is often based on contracts and that these contracts often involve a licence.

As a practical matter, of course, the basis for being able to make a differentiation lies in the response of the market. Sustainable distinctions in information products ultimately depend on whether the products attract a positive market response. In the information economy, the fact that the value does not lie in tangible assets amplifies the capability to tailor products by contract because doing so does not necessarily require physical modifications. An automobile, once built, can be significantly modified for distribution only with substantial, costly and skilled effort. A computer database, on the other hand, ordinarily carries within it the ability to be altered with relative ease to react to a different market (or individual) demand either by contract or by technological means.

There are many different ways on which information or information-based services are differentiated in the information economy. Some lie in the nature of the information. However, even for identical information, differentiation occurs through contractual terms,[22] technology controls,[23] and the ability to deliver similar information in different ways that fit different value configurations. The difference between the books I purchase that summarise an area of law and the online services that are updated continually and available under a licence is vast and fundamental. I may still buy books, but the online licence gives an entirely different functionality as an information product. The difference between word-processing software and the typewriter I once used is equally, if

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[22] *See, e.g.,* ProCD Inc. v. Zeidenberg, 86 F.3d 1447 (7th Cir. 1996); Register.com, Inc., v. Verio, Inc., 356 F.3d 393 (2d Cir. 2004); Frontline Test Equipment, Inc. v. Greenleaf Software, Inc., 10 F. Supp.2d 583 (W.D. Va. 1998).

[23] Technological controls shape the scope and nature of uses of, or access to copyrighted and other types of information products. This was recognised in the Digital Millennium Copyright Act with the exception of some uses that qualify as fair use under applicable copyright law. *See* 17 U.S.C. § 1201 (1998). *See also* Davidson & Assoc. v. Jung, 422 F.3d 630 (8th Cir. 2005) (combination of technology and contract limits use of Internet version of game); Storage Technology Corp. v. Custom Hardware Engineering & Consulting, Inc., 2005 WL 3411773 (Fed. Cir. 2005) (combination of contract and technology limit access to diagnostic software; but no DMCA violation in circumventing the technology).

not more, fundamental. For the same word-processing software, the difference between acquiring a copy for personal use in a single desktop and acquiring a copy for use throughout a seven-hundred-lawyer firm is just as fundamental. That latter difference often rests entirely on the terms of the licence.[24]

1. The Myth and Limits of the Idea of 'First Sale'

It would take a stark leap of intentional disregard to ignore the fact that the information economy is different from the goods-based economy. Similarly, the contemporary information market vastly differs from the pre-digital information world. It is much more diverse and much more active. The availability of information and functionality is much more extensive. Consumers and businesses clearly benefit from this. In this new environment, it is clear that any legal response to it *cannot* simply transport old ideas to new commerce, hoping to force it back into old moulds allegedly dominated by sales of copies of books, records, and the like. Even more importantly, the law *should not* do so even if it *could* do so.

Even though it is transformed in character in many respects, the contemporary economy still comprises numerous markets. Thus, publishers often still sell books and magazines today not because the law mandates that they do so, but because of a marketing choice made by owners of copyrighted works in that marketplace. The fact that some mass-market distribution of DVDs involves a sale of a copy similarly results from a marketplace choice and not a legal mandate. No rule in copyright or patent law requires intellectual property owners of works reproduced in books, videocassettes, or diskettes solely to sell copies, rather than distributing them in other ways, including by licence.

Some might argue that distribution methods from the older era were good enough then and they should be kept or mandated for all transactions today. However, this entirely fails to account for the diversity of the modern information market and ignores the huge social and economic benefits that diversity has produced and continues to produce.

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[24] *See, e.g.* Wall Data Inc. v. Los Angeles County Sheriff's Department, 447 F.3d 769 (9th Cir. 2006) (where the licence limits the number of copies or sites, the creation of copies in more sites is infringement).

In any event, any assertion that the sole manner in which information was made available in the mass market to consumers in the 1960s and 1970s was through so-called 'first sales' of copies is an over-simplification. Even before the advent of Internet systems, a broad variety of different distribution systems existed. Should we retreat from or stifle expanding diversity? We should not. Even if we assumed that all mass-market information transactions were first sales before the emergence of the digital industries, does that mean that we should mandate that this be the sole model available in the future? Again, the answer is no.

In many criticisms of mass-market licensing as a commercial model, the critics' preferred alternative and ideal model involves sales of copies governed by intellectual property 'first sale' doctrine. However, this is simply a judicial or a legislative statement of limited protections from claims of infringement that a buyer receives if the rights-owner chooses to authorise unrestricted sales of copies of its work.[25] U.S. courts have consistently held that the doctrine does not apply when the rights-owner explicitly restricts the terms under which a transfer of a copy or of a patented machine can occur and does so in a manner inconsistent with the idea that it authorised a simple sale.[26] A sale is a relatively sterile transaction of fixed contours that, in the diverse marketplace for digital information, does not accommodate the numerous ways of doing business and the numerous ways in which productive markets are beneficial to consumers and business.

There is an underlying element of confusion associated with the aura that some, for political reasons, construct around the idea of first sale. That aura implies that first sale is grounded in concepts related to First Amendment free

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[25] *See* 17 U.S.C. §§ 109, 117.

[26] *See, e.g.* DSC Communications Corp. v. Pulse Communications, Inc., 170 F.3d 1354 (Fed. Cir. 1999); Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992). The latter case dealt with application in patent law of a doctrine similar to the 'first sale' doctrine in copyright law. In patent law, the concept refers to 'exhaustion' of the patent rights by an authorised first sale. However, the conceptual premise and the court's approach in each case is consistent. By authorising only a restricted or limited transfer of rights, the copyright or patent owner and the transferee are not governed by first sale concepts *as a matter of property rights law. See also* LG Electronics, Inc. v. Bizcom Electronics, Inc., 453 F.3d 1364 (Fed. Cir. 2006); Jazz Photo Corp. v. U.S., 439 F.3d 1344 (Fed. Cir. 2006); Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004); Arizona Cartridge Remanufacturers Ass'n v. Lexmark Int'l, Inc., 2005 WL 2077641 (9th Cir. 2005).

speech, while licensing is inconsistent with those concepts. In fact, the 'first sale' concept only provides that a buyer can distribute a copy (or do other designated acts) without infringing the copyright or an applicable patent. It is quite clear that freedom of speech provides a background in which the information economy functions in the United States. In cases of allegedly abusive governmental regulation, First Amendment concepts provide constitutional restrictions or indirectly define independent public policy restrictions on contract terms.[27] That is not a feature of 'first sale' doctrine, but a feature of U.S. law in general. Whether a term in a particular contract is invalid under the First Amendment or fundamental public policy of a state has nothing to do with whether there was a 'first sale' or a licence. Indeed, courts that have addressed the issue routinely conclude that contractual terms can waive first sale and associated rights, including the privilege to engage in fair use such as reverse engineering of computer software.[28]

2. Licences Creating Differentiated Markets

Especially when intellectual property rights are involved, virtually all commercial transactions in information entail restrictions on the transferee's use of the information rather than conveying an unlimited right of use. In fact, a first sale, even when it occurs, does *not* give the transferee full rights in the information. It does not transfer the copyright to the buyer. The copyright or patent owner still controls the vast majority of all rights to use the intangible work.[29] An unrestricted first sale merely gives the buyer of a book the ability to use the information in ways that do not involve making copies or otherwise infringe the copyright, and the right to resell the book if the buyer chooses. A similar doctrine gives the owner of a copy of a computer program limited rights with respect to that copy and limited copies made from it.[30]

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[27] For a detailed discussion, see the comments to U.C.I.T.A. § 105(b). U.C.I.T.A. is the first uniform law in the U.S. that expressly recognises the power of a court to invalidate a contract term if the court finds that the term offends fundamental public policy and that this policy clearly outweighs the policy of enforcing contracts.

[28] *See, e.g.* Davidson & Assocs. v. Jung, 422 F.3d 630 (8th Cir. 2005) (shrink-wrap license waived fair use rights and was not preempted).

[29] 17 U.S.C. § 109.

[30] 17 U.S.C. § 117.

In this context, a licence, when compared with a first sale, merely entails a transactional decision to place different restrictions on the transferee than would occur under a first sale. Are there cases in the mass market where it might be desirable and important to alter these rights by contract? Clearly, the answer is yes. Just as clearly, licence agreements are the manner in which a different permitted range of uses can be efficiently established in mass markets and elsewhere. These differences established by contract may increase or decrease what the transferee purchases and receives in contrast to a simple sale.

By way of illustration, consider the following:

> Illustration 1: Consumer Product. *A publisher creates a digital work that appeals to consumers and to commercial entities. Rather than distributing the work online via an access licence, the publisher distributes it in copies in a retail market. The work contained in each copy is identical. Some, however, are subject to a licence that restricts use to 'consumer purposes', while others are subject to a licence that permits commercial use. The consumer licenses are made available for $10, while the commercial licences cost $10,000.*[31]

As the Seventh Circuit Court of Appeals emphasised in *ProCD, Inc.* v. *Zeidenberg,*[32] being able to make this type of price and product differentiation creates huge benefits in the marketplace and directly benefits consumers. Under this arrangement, a consumer can obtain an attractive information product for a fraction of the cost it would otherwise be required to pay. Yet, a mere first sale would not involve contractual differentiation based on the type of use. A single or set price would be charged since all products would have the same use conditions. As a result, consumers would pay a substantially higher price, subsidising commercial users. The licence here efficiently establishes a basis to differentiate prices based on type of intended use, in a manner that clearly benefits consumers.

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[31] One might express concern about consumer fraud (paying $10,000 for a work that is subject to a consumer-use-only licence). That risk is like any risk of fraud in the modern marketplace and is met by various statutes, regulations and common law rules giving remedies for fraud. Also, when U.C.I.T.A. is adopted nationally, it provides a direct response to this problem. Under U.C.I.T.A. § 209, the terms of a mass market licence cannot alter the terms expressly agreed to between the parties. An agreement to provide a commercial use licence is not overridden by a consumer use licence.

[32] 86 F.3d 1447 (7th Cir. 1996).

Of course, the publisher could offer a different product. It could strip out the 'commercial' features of the product and offer to consumers a minimal version at a low price, with functions limited to those perceived as conducive to typical consumer use, *i.e.* limited functions that justify the low price. Yet that would create a market differentiated by the actual functionality of the software, bringing into play all of the inefficiencies associated with similar differentiation in sales of goods. It would also yield a result that is exactly what most consumers do not want: for example, a survey reported in the July 2000 issue of PC Magazine revealed that the respondents preferred more advanced tools to simpler and less feature-rich alternatives. The licence allows publishers to offer supply feature-rich products to consumers, differentiating between customers and pricing based on contractual use restrictions.

Consider another illustration that carries a certain fondness for those in legal or other educational fields:

> Illustration 2: Database software. *The publisher develops database processing software. It distributes the software: (1) by allowing it to be accessed and downloaded from the publisher's website, or (2) through distributors who distribute the software in copies. In both contexts, some distributions are licensed for 'educational use only', while others permit 'commercial or any other use'. The license fee for educational use is $1000, while the general (commercial) use license fee is $75,000. The software is identical in both cases.*

Again, differentiation based on the terms of the licence enables a price differentiation that permits the publisher to respond separately to two active markets and, in consequence, allows end users to acquire software capability tailored to their needs. In fact, major online databases have made this distinction for years, with huge cost savings to educational users. On the other hand, a simple first sale would not entail restrictions. A change to a first sale would alter both the marketplace and the price of the software. The ability to enforce the use restriction comes from both contract law and intellectual property law. As the court in *Adobe Systems Inc.* v. *One Stop Micro, Inc.*[33] observed, if a person

[33] 84 F. Supp. 2d 1086 (ND Cal. 2000) (distribution agreement held to be a licence, rather than a sale conveying ownership).

acquires software under an educational-use restriction, but violates that restriction in making or distributing copies of the software, copyright infringement occurs. In addition, there is a breach of contract if the person breaching the restriction is bound by the contract.

3. Licences that Create Products and Expand Rights

The foregoing illustrations involve licences that restrict the end user's rights to use in a manner that prevents uses permitted in an unconditional sale. In my view, these restrictions do not harm the market for information. In fact, they clearly contribute to establishing a vibrant and diverse market. They take an otherwise monolithic environment and provide a diversity of value and functionality tailored to particular consumer or business markets.

Yet, there is a more important reality: while some mass-market licences give less authority to a transferee to use the information than would a first sale, many mass-market licences give *greater* rights than would pass to the buyer at a first sale. Unlike what might be the practice with mass-market contracts for the sale of goods which focus on narrowing warranties, a mass-market licence defines the product. Depending on the market being targeted by the publisher, those product definitions may, and often do, exceed the authority given to a buyer at a first sale.

To see this side of licensing, consider the following:

> Illustration 3: Word-processing software. *The publisher distributes a word-processing program through retail stores. In some cases, the program is subject to a licence that allows the program to be copied into and used only in a single user machine owned by the licensee, and that allows making a back-up copy or selling the licence if the licensee transfers all its copies. In other cases, the program is subject to a licence that permits use of the software in a computer network with copies sufficient for use by persons at the site up to a total of one thousand simultaneous users. The program is identical in all cases, but the site licence costs $2000 and the single-user fee is $200.*

The rights under the site licence far exceed the rights that a buyer at a first sale would obtain. The single user licence parallels the terms of a first sale. The

site licence, on the other hand, entails an efficient means of contracting *beyond* the terms of a first sale and, of course, an efficient response to a commercial market via retail outlets. Under that licence, the licensee obtains rights to make many more copies than would be permitted in a sale.[34]

There are many instances of licences in the mass market that give greater rights to the licensee. The buyer at a first sale does not have the right to make and distribute copies or to publicly display the work without risk of infringement. Some such uses might be treated as fair uses that, in the event of litigation, would not infringe the copyright, but the licence makes clear the enhanced rights of the licensee. In many cases, however, the product would have no value unless the expanded rights could be granted. In effect, the licence creates a new product and, in practice, creates new fields of commerce.[35]

4. Mass Customisation

The digital information marketplace enables mass customisation of products through the terms of their licences. Mass customisation means that a product is distributed on a mass basis but is still customised to particular users. In such a scenario, a digital information provider may be able to publish a single work (either online or in copies), but customise it to fit narrow markets or market niches *without changing the work itself*. As we have seen, that capacity flows from the licence. For example, the difference between a single-user word-processing program and a 100-person product rests in the terms of use in the licence. In both cases, the program itself is identical. What differs is the scope of authorised use.

Consumers benefit from such market differentiation, as do commercial entities. In the world of goods, in contrast, the difference between a commercial-use product and a personal-use product will often lie in the physical character of the product itself. If, for example, I acquire a coffee-maker for my apartment, I am very likely to buy a physically different product than if I were to acquire a coffee-maker for use in my restaurant. The difference in physical character presents a sharp difference in the marketing channel and in the opportunities

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[34] *See, e.g.* Wall Data Inc. v. Los Angeles County Sheriff's Department, 447 F.3d 769 (9th Cir. 2006).

[35] *See* Green Book Int'l Corp. v. Inunity Corp., 2 F. Supp.2d 112 (D. Mass. 1998).

that can be readily provided in the mass-market. That does not mean that commercial coffee-makers are never distributed in the mass market, but it does mean that there are various costs and other consequences of a decision to do so.

The licence, then, often defines the product in the digital information industries. This makes the importance of the mass-market licence much greater for all parties than the far less significant warranties that some manufacturers use in mass-market sales of manufactured goods. In all of the illustrations we discussed above, the licence arises between the publisher (e.g. copyright or patent owner) and the licensee, rather than between the end user and a retailer. In fact, if there is a retailer involved, its rights to distribute the product are often limited. The retailer does not own the informational rights in the work and *cannot* grant a licence to use it except as permitted by the rights owner.[36]

In some cases, the mass-market licensee deals directly online with the publisher. In current commerce, however, there are many cases where the end user does not deal directly with the publisher but obtains the software from a computer manufacturer or from a retail store. Here, achieving the market benefits of licensing requires that a means exist by which the licensee and the publisher establish a contractual relationship – which has historically been the function of the so-called 'shrink wrap' licence. The terms of the licence run directly from the licensor to the licensee, and that licence implements the various market effects we noted above and establishes the right to use, whether in a broader or a narrower manner than would be allowed under a first sale.

B. The Legal Rationale for Licensing

What legal rationale exists for licensing transactions in the information industries?

Actually, there are many rationales. Most are grounded ultimately in the role of contract in a free-market economy. One party owns or controls something

[36] *See* LG Electronics, Inc. v. Bizcom Electronics, Inc., 453 F.3d 1364 (Fed. Cir. 2006); Microsoft Corp. v. Harmony Computers & Electronics, Inc., 846 F. Supp. 208 (E.D.N.Y. 1994); Microsoft Corp. v. Grey Computer, 910 F. Supp. 1077 (D. Md. 1995).

of value; another party may desire to acquire access to, or use of, that valuable subject matter. The terms of any transaction that ensues are shaped by the market and by the individual choices of the parties; they are implemented by the contract. The rationale for enforcing that contract in law rests simply in the assumption of a market economy supported by numerous individual contracts.

Assuming that a licence *contract* is formed, is further legal justification required for enforcing the licensing contract? No. Most reported decisions in U.S. case law enforce mass-market and other digital information licences.[37] The few that do not do so typically refuse enforcement because in the particular case, contractual assent was not properly obtained.[38] As the Seventh Circuit Court of Appeals suggested when presented with this question: a contract is a contract, and the U.S. system of law assumes that contracts should be enforced in the absence of fraud, duress, criminality, unconscionability or similar problems.[39] Licences of digital information serve many positive functions and there is no basis in policy to preclude them.

Yet, if one needed a further rationale to support the practice of licensing, in the vast majority of cases that rationale can readily be found in the property rights that law gives to licensors under copyright, patent, other intellectual property law, and other law relating to the control of access to computer and other systems owned by a party. Unlike with goods, when one deals with information and rights in it, the mere fact of possession of a copy does not necessarily give the possessor broad rights in that copy. Rather, the person who owns the intellectual property right or who controls the system to which access

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[37] *See, e.g.* ProCD Inc. v. Zeidenberg, 86 F.3d 1447 (7th Cir. 1996); i.Lan Systems, Inc. v. Netscout Service Level Corp., 183 F. Supp.2d 328, 338 (D. Mass. 2002) ("*Step-Saver* once was the leading case on shrinkwrap agreements. Today that distinction goes to a case favoring NextPoint, *ProCD, Inc. v. Zeidenberg*"); M.A. Mortenson Co., Inc. v. Timberline Software Corp., 970 P.2d 803 (Wash. 1999); Hill v. Gateway 2000, Inc., 105 F.3d 1147, 1148 (7th Cir.1997). *See generally* Robert A. Hillman & Jeffrey J. Rachlinski, *StandardForm Contracting in the Electronic Age*, 77 N.Y.U. L. Rev. 429, 491 (2002) ("U.C.I.T.A. maintains the contextual, balanced approach to standard terms that can be found in the paper world.").

[38] *See, e.g.*, Specht v. Netscape Communications Corp., 306 F.3d 17 (2d Cir. 2002) (no assent manifested in this case).

[39] ProCD Inc. v. Zeidenberg, 86 F.3d 1447 (7th Cir. 1996).

was conditionally given retains broad rights *as a matter of property law* to control the other person's activities regarding the information. In effect, all mass-market transactions involving information are conditional or limited in the sense that the transferee receives less than all rights to use the information. A licence is a contract that deals directly with that conditional or limited rights aspect of the deal and, as we have seen before, either expands or contracts the transferee's rights when compared to a transaction where the provider merely sells a copy.

In federal copyright law, for example, the owner of the copyright has various exclusive rights. The basis for a licensing arrangement thus rests in part on the licensor's right to transfer, license, or withhold any of these rights, in whole or in part, as a part of the commercial deal in which it engages. The circumstance is like that of an owner of a desk who has the right to sell it, lease it, allow use of it, or simply to not transfer or allow access to it at all.

In online licences, one basis for licensing stems from the online provider's right to control access to and use of the computer system that holds the information, and from a desire to use contractual terms to allocate rights of access and use associated with building different informational products associated with that system and the information it contains. This right does not necessarily depend on intellectual property interests. It comes from control of the system and the fact that *unauthorised* use is an illegal act.[40]

By contractually regulating use, copying, and quality commitments, these contracts allow providers to make available a resource that had never before existed in the mass market. The consumer benefits are enormous. Contracting for access to digital information resources in the mass market accounts for billions of dollars of commerce annually as well as a massive expansion in information readily available to consumers. It is a form of mass-market commerce that could not exist in paper-based media or in sales of goods that cannot be accessed and used by remote electronics.

Because of its commercial and social significance, it is not surprising that reported cases in the U.S. uniformly enforce such contracts if assent to the

[40] Register.com, Inc., v. Verio, Inc., 356 F.3d 393 (2d Cir. 2004).

contract was obtained.[41] The approach in these cases is generally consistent with the standards set out in the U.C.I.T.A. (e.g. there must be a manifestation of assent to the terms with reason to know assent is being inferred and occurring after having had an opportunity to review them).[42] If an opportunity to review and an expression of assent did not occur, the contract may be unenforceable. If the contract is unenforceable, however, that leaves the question of whether the user's access to and use of the information was authorised or constitutes trespass or infringement.[43]

V. CONCLUSION

Licensing computer or digital information and intellectual property rights in the mass-market and elsewhere is not a mere re-characterisation of commercial practice with respect to sales of goods. On the contrary, licensing is the legal structure that supports the unique and diverse range of information products and establishes a functional, efficient distribution channel, allowing wide distribution of computer information to consumers and others. It has thus become a method of doing business used throughout a multi-billion-dollar industry that leads the modern economy. Numerous illustrations from the marketplace show this as a practical matter and also document that the effect of licensing in consumer and other markets is diverse, productive and efficient. The practical and legal roles of a licence go far beyond the issues for goods. In the consumer market and elsewhere, the licence is the product and its description, because the licence defines what uses the licensee may make of the licensed information. Mass-market licensing allows publishers, often by exercise of their property rights, to facilitate and establish a vibrant market for digital information, which benefits

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41 *See, e.g.*, Caspi v. The Microsoft Network, L.L.C., 323 NJ Super. 118 (N.J. Super. A.D. 1999) (click agreement enforced); Hotmail Corp. v. Van$ Money Pie, Inc., 47 U.S.P.Q.2d 1020 (N.D. Cal. 1998) (online terms of service enforceable); Rudder v. Microsoft Corp., 1999 CarswellOnt 3570 (Ontario Superior Ct. J. 1999) (click agreement enforced); Jessup-Morgan v. America Online, Inc., 20 F. Supp.2d 1105 (E.D. Mich. 1998) (enforced); Groff v. America Online, Inc., 1998 WL 307001 (R.I.Super. 1998); CompuServe, Inc. v. Patterson, 89 F.3d 1257 (6th Cir. 1996); *In re* RealNetworks, Inc., Privacy Litigation, 2000 WL 631341 (N.D. Ill. 2000).

42 *See* UCITA §§ 208, 112.

43 Micro Star v. Formgen, Inc., 154 F. 3d 1107 (9th Cir. 1998) (lower court enforced online license; appellate court held that either the licence barred the conduct or there was no license to prevent claim of infringement).

consumers, both as consumers and as members of an economy. This in turn provides a means to efficiently allow mass availability of customised information and services.

The legal justification for licensing is also very clear. The vast majority of all courts that have addressed the question have held that licences of digital information under standard form contracts are enforceable, whether the contracts are made online, in direct contact between the publisher and the end user, or through so-called shrink-wrap licences where the end user and publisher do not directly deal with each other. In many cases, an additional property-rights basis for enforcing these contracts comes from the fact that the provider controls the computer resource from which the information is made available and the contract gives the consumer necessary but conditional authorisation to access that system. In still other cases, an additional property-rights basis comes from intellectual property law under which mere possession of a copy of information does not give the possessor rights to use the information in a manner that violates the retained exclusive rights of the copyright or patent owner, unless the owner grants it permission to do so. Given that this is a complex and important area in commerce, it is vital that any fears of the future and images of the past do not lead us to act in a way that wrongly encumbers and constrains one of the true sources of innovation and economic growth that has been fuelling the modern economy and generating formerly undreamed-of benefits to consumers.

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IT OUTSOURCING AND GLOBAL SOURCING: A COMPARATIVE APPROACH FROM THE INDIAN, U.K. AND GERMAN LEGAL PERSPECTIVES

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ABSTRACT

Businesses today have been able to take advantage of technology in order to use models such as offshoring in order to reduce their costs without a corresponding decline in quality. However, concerns such as data confidentiality and security issues have emphasised the need for businesses to take considerable care when dealing with cross-border transactions, especially since some knowledge of the needs of different jurisdictions is necessary. This article examines the outsourcing model in the context of the information technology industry and looks at the most important clauses and legal issues in such contracts in the light of Indian, English and German law.

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I. BASIC SUMMARY OF OFFSHORING AND GLOBAL SOURCING

A. Introduction

Businesses are constantly being driven to reduce costs and enhance productivity in order to increase shareholder value. Many business models have

been adopted to achieve these goals, and for many years outsourcing has been seen as one of the proven solutions. Businesses have also been taking advantage of global sourcing opportunities, and nowadays going offshore is hardly novel. Venturing offshore can offer the opportunity of cost arbitrage by using equally qualified, but cheaper, employees and lower-cost resources and services from offshore locations. Originally a trend led by manufacturing, offshoring is now also a concept readily deployed for providing services via call centres and back-office service centres.

However, offshoring is not necessarily the same as outsourcing, as any of a wide range of business models may be adopted. One option is to set up and manage the business's own offshore operations as a 'captive' organisation. Companies such as SAP, Hewlett-Packard, Accenture, Siemens and Microsoft are following this model. Another model is third-party outsourcing, in which the customer utilises the services of an external service provider. Yet another option used frequently in India is the BOT (Build-Operate-Transfer) model, a hybrid model in which the customer initially uses an external service provider but reserves the right to operate the service later on (e.g. a joint venture with a call option).

Outsourcing comprises the following services and models:

1. *Outtasking*: sourcing certain tasks, such as payroll services, to an external service provider

2. *Selective Outsourcing*: sourcing a selected part of a larger business unit (e.g. sourcing of maintenance services)

3. *Transitional Outsourcing*: sourcing in the context of a technology upgrade

4. *Complete Outsourcing*: sourcing an entire business unit

5. *Business Transformation Outsourcing (BTO)*: a combination of business consulting and outsourcing (e.g. the reorganisation of a business unit, followed by the sourcing of the reorganised business unit)

6. *Business Process Outsourcing (BPO)*: sourcing an individual business process (e.g. sales, accounting, human resources) to a third party

7. *Out-servicing*: sourcing business processes that are organised pursuant to the Service-Oriented Architecture (SOA)

8. *Managed Services*: offering services in the areas of information/ communication that can be sourced by the client on a case-by-case basis (similar to Application Service Providing, or ASP)

Sourcing offshore is not without its risks and disadvantages. For an offshoring project to be successful, it is important for a business to understand its reasons for offshoring as well as why it has selected and how it can manage a certain offshoring model. Offshoring is about more than just saving costs. Issues such as control, core competency, provider capability and reputation are also highly relevant.

As with any business solution, there are always advantages and disadvantages to the eventual model that is adopted by the business user. The following table sets out some of the pros and cons in the context of the three typical offshoring models (captive, third-party and hybrid).

MODEL	THIRD-PARTY	CAPTIVE	HYBRID
CONCEPT	Subcontracting work to a third party to provide services or products	Establishing and running an offshore operation to carry out business functions	Any combination of onshore, offshore, captive or third party operations
PROS	Time to solution can be shorter than other models Customer can rely on contractual rights to ensure satisfactory performance Service flexibility Access to expertise	Customer has direct control Can reduce costs by avoiding third-party profit margins and ongoing savings IPR vests within the group and can easily be monitored and controlled	Each function can be sourced to the operation best suited to perform it Better risk management through diversification Flexibility to transfer functions between operations when needed

The Table continues

MODEL	THIRD-PARTY	CAPTIVE	HYBRID
	Value for money	Captive's employees can be part of the customer's corporate culture	
CONS	Loss of control Harder to incentivise provider's personnel Potential IPR issues, such as contamination and security Business risk because function taken outside the corporate boundary Enforcement issues where provider is offshore	Time to solution often slower than third-party model Higher setup costs Potential difficulties with bureaucracy Direct exposure to local risks Customer responsible for ongoing compliance with local laws and regulation	Requires increased resources to manage each relationship and delineate responsibilities Can be more costly
USE	Growing trend towards partnership models such as Build-Operate-Transfer and Build-Operate-Manage	A joint venture can be established to exploit shared resources and experience (compulsory in some countries and circum stances) Increasingly popular with multinational corporations	Certain services can be provided globally from a single location on an Application Service Provider basis

B. Sourcing Models and Analysis of the Utilisation of the Various Models

The usage of the various service delivery models outlined above varies around the globe, as does the degree to which outsourcing and offshoring has been adopted successfully. India has dominated the world market as the supplier to the global outsourcing market since the trend to seek offshore services first emerged in the late 1990s. This is principally thanks to the size of its skilled English-speaking workforce, low-cost bases and understanding of the need for flexibility and culture of learning.

India's pre-eminence may now be working against it, however, as cost inflation fuels growing competition from China, Eastern Europe and South America (particularly Brazil), amongst others. China has already established itself as the number two outsourcing destination and, with its phenomenal economic growth, massive workforce, and strong government backing, there is a good chance that it will overtake India in coming years. The outsourcing industries of Eastern Europe and South America are still in the early stages of development but look set to benefit from their proximity to Western Europe and the U.S. respectively.

C. India

There has been a resurgence of interest in the Indian IT sector in the recent past, along with an increased focus on the movement of work to India. In the late 1990s, many U.S. and British companies turned to Indian IT professionals for help in dealing with the threat of the Y2K bug. It was at this time that Indian IT professionals became a sought-after resource, and many Indian IT professionals shifted to the U.S. and U.K. as a result. However, the subsequent bursting of the dotcom bubble forced many Indian IT professionals to head back to India, and IT companies in the U.S. also started looking at means to cut costs without having to compromise on the quality of the services they offered. Many looked at India as a viable option, since they found an abundance of IT professionals who had worked in the U.S. and were acquainted with the American work ethic and culture. The movement of work to India thus began for a number of reasons, including the following:

1. *Language*: English became an official language in India as a result of the country having been a British colony until 1947. There is thus no dearth of talented and educated people who are highly fluent in English. This attracted most nations to India for outsourcing, putting India ahead of China in tapping the IT outsourcing market.

2. *Culture*: Another advantage is the perceived adaptability of Indian workers. Their fluency in English also enables them to meet cross-cultural requirements when delivering to international clients.

3. *Market domination:* Global companies have realised that outsourcing to India can offer numerous potential benefits focused on the economic, strategic and IT expertise of the Indian vendors. IT revenues in the Indian market by the foreign companies have been growing at quite a rapid pace.[1]

D. The United Kingdom

In the U.K., outsourcing has been a popular business solution for many years. The industry has evolved from the early bureau service models to a diverse and rapidly growing market sector. The outsourcing market has become a mature market supported by specialist providers (from all over the world), consultants, lawyers and other specialists.

Today, U.K. business uses all the models of outsourcing detailed above. However, according to the predictions of IT services exporter Luxoft, no single model is likely to gain supremacy over the others in the near future.[2] It is believed that each company will assess its available global resource and skills pool and choose a combination of in-house teams and outsourced services in order to attempt to reach its desired business and technical goals. The U.K. seems to be following the U.S. in this trend towards smaller multi-sourcing deals. As Phil Morris, Morgan Chambers' CEO, put it: "The [U.K.] outsourcing market has matured and clients are becoming smarter in the way they contract. Businesses are beginning to drop the 'offshore' or 'nearshore' labels, moving instead to

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[1] NASSCOM, *Indian IT Software and Services Revenues to Reach U.S. $50bn mark in FY 07-08*, *at* http://www.nasscom.in/Nasscom/templates/NormalPage.aspx?id=51734.

[2] Dmitry Loschinin, *Luxoft: Outsourcing Predictions 2007*, *at* http://www.noa.co.uk/index.php?option=com_content&task=view&id=274&Itemid=85.

'global sourcing', with no geographical boundaries. This opens up the market to a new wave of providers and contracting models."[3]

1. Language

With English as the international business language of choice, the U.K. has found it very easy to leverage world resources and various low-cost countries as the outsourcing offshoring market has matured. The British population and workforce are far less advanced in other languages than their European counterparts. This makes it an easy market to serve, but a difficult supply hub for international service provision. India has been a particular and dominant beneficiary, having been a British colony and thus sharing colonial, linguistic and legal ties with the United Kingdom. China's current shortage of sufficient English-speaking workers is one of the major challenges in the growth of international service provision in China (though this is rapidly changing).

2. Culture

Despite the trend for U.K. businesses to outsource offshore, the culture in the U.K. still has a lot to offer. The English workforce has extensive exposure to global sourcing compared to continental Europe and its ability to combine knowledge of IT domains with the realities and imperatives of real-world business challenges is a real advantage. For this and other reasons, the British have freely adopted the outsourcing model across many industries (and in recent years, the public sector outsourcing market's growth has been particularly strong). In a now mature market, it can certainly be said that there is a British outsourcing culture. The savings, efficiencies and business successes to be gained from outsourcing and offshoring frequently speak volumes to those tasked with the sourcing decision, and the change and effort required is usually justified at the Board level, though there is sometimes debate further down the line about whether all the benefits promised by a discrete project are ever fully realised.

From time to time, there is substantial hype when a business advocates and implements an 'insourcing' program, bringing solutions back in-house or back

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[3] Press Release, Morgan Chambers, UK Faces 'Outsourcing Turmoil' (Dec. 12, 2006), http://www.morganchambers.com/press_office/41.

onshore. In other instances, outsourcing is resisted from the outset as some maintain their philosophical objections. At times, in some industries, there can be significant union objection and resistance to offshoring plans, and from time to time such pressure has influenced the nature of the solution eventually delivered.

3. Market Domination

The forecast for the U.K. software and IT service market is one of slow growth. A June 2006 study by Ovum for the Department of Trade and Industry stated that the market is looking to increase by a modest 5.5% in 2007 and 4.9% in 2008.[4] The U.K. IT industry is becoming more heavily reliant on global sourcing, with many companies expecting to increase offshore capabilities. The business processing market is stronger.

According to outsourcing advisory service TPI, the average value of outsourcing contracts was at its lowest in five years in the last quarter of 2006, with a decrease of 8% in the value of new outsourcing deals compared to 2005 levels.[5] This may be due to client companies in large continental agreements being less satisfied with what they are getting than those in smaller contracts.[6] This means that IT managers are no longer flocking to the six largest outsourcing companies (Accenture, ACS, CSC, EDS, HP and IBM) and the U.K. market for outsourcing deals is being opened up to the smaller players.

Outsourcing, for many, has been an unnecessary risk from the perspective to data security. In particular, financial services companies have historically preferred to manage their own data centres internally. This fear has been heightened by a number of stories of data security breaches in India.[7] However,

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[4] David Bradshaw et al., *The Impact of Global Sourcing on the UK Software and IT Services Sector* 10, *at* http://www.berr.gov.uk/files/file32496.pdf.

[5] Press Release, TPI, Tighter Times for Outsourcing Providers (Jan. 11, 2007), http://www.tpi.net/newsevents/news/releases/070111-UK.html.

[6] *See* Morgan Chambers, *Outsourcing Service Provider Performance Study 2007: A Morgan Chambers Management Summary*, *at* http://www.morganchambers.com/downloads MorganChambers_Outsourcing_Study_BeLux_2007_ManagementSummary.pdf.

[7] *See, e.g.*, Ed Frauenheim, *Insecurities over Indian Outsourcing*, *at* http://www.news.com/Insecurities-over-Indian-outsourcing/2100-7355_3-5685170.html .

it is fast approaching the situation where such companies will start to outsource due to the increasing need for power, cooling and storage of these systems that they simply cannot meet internally. Global publicity for these breaches can only assist institutions when deciding whether to send contracts offshore, and security is set to be an important factor, rivalling costs and deliverability.

Overall, it seems that the market will continue to grow in the U.K., if only modestly, but that large single-provider contracts will fragment into multi-source, increasingly specialised deals.

E. Germany

In Germany, the outsourcing models described above are all used in practice. The German market is a difficult one to crack for outsourcing service providers. This is due to many reasons, especially the following:

1. *Language:* Although English is the international business language of choice, and global companies such as Siemens have already adopted English as their first language, many German companies still prefer to operate in German. Service providers have to cater to this and prepare all documents, contracts, and services in German. Also, some outsourcing services, such as BPOs and BTOs, require consulting services, which must be provided in German. Therefore, it is easier for international service providers in India to cater to American or British customers.

2. *Market domination:* The German market for outsourcing services has historically been dominated by the four top providers, T-Systems, IBM, Siemens Business Services and EDS, although the recent spate of captive takeovers offers a threat to that dominance. It is a challenge for Asian service providers to break this market dominance and the 'old boys' network' of the established market players, and this is a contributing factor to the lead that nations such as the U.K. and U.S. have over Germany. Nevertheless, the market is likely to grow dramatically in coming years, and the value of outsourcing in Germany is expected to hit 60 billion euros by 2010.[8]

[8] Ulrich Bäumer, Jame Mullock & Mark Webber, *Offshoring and Global Sourcing* 16, http://www.osborneclarke.de/publikationen/Offshoring%20and%20global%20sourcing.pdf.

II. A CLOSER LOOK AT THE OUTSOURCING MODEL

As discussed above, outsourcing can offer real benefits; but the impact and potential consequences for the business undertaking outsourcing must be properly evaluated. Among the advantages of outsourcing are cost savings (through factors such as economies of scale and reduced overseas costs and overheads); access to cutting-edge technology, processes and skills; the ability to focus internally on core competencies and objectives, access to flexible; adaptable and scalable solutions; more efficient management of workloads; and decreased product development cycle/speed to solution. However, there are also the risks of loss of control (including loss of quality control), adverse public opinion (especially where there is a loss of domestic jobs or a negative impact on the local economy), scope creep leading to cost increases, problems with security/confidentiality, retransition issues and cultural and communication difficulties.

One way to understand outsourcing is to think of it in terms of a cycle going through four initial stages preceding operation (and subsequently retransition): self-assessment, choosing a provider, negotiation and implementation.

A. Self-Assessment

Before a company embarks on any outsourcing project, it needs to make a full and frank assessment of its current business and any anticipated impact on the way the sourcing is structured. This will typically involve a statement of requirements or service/solution specifications based on its own internal due diligence and the knowledge it has of its existing solution, often using the assistance of specialist advisers. In the case of second-generation outsourcing this can be a harder task, and a well-advised user will build in certain contractual rights to elucidate the information and any support that it may require in these circumstances from the incumbent supplier.

This self assessment should include technical, commercial, and legal analyses. For example, questions would have to be raised as to the severability of the processes, whether the processes require proximity, whether they can be standardised, whether they are of sufficient scale, and whether there are any legal or regulatory impediments. Aside from this, questions will also be raised as

to what the management and shareholders would want from the strategic sourcing programme, what the impact on existing personnel would be, whether the union (if one exists) should be consulted, and also as to what the market's perception of these changes would be.

This statement of requirements is then often used to approach potential suppliers to market-test and sometimes to commence a selective procurement process. Such a selective process is frequently driven by an all-encompassing invitation to tender (ITT) which outlines the potential outsourcing in hand and invites prospective suppliers to bid for the project at the same time as providing further information about their specific recommended solution. It is essential to communicate the rationale for the sourcing and then identify the objectives and instill them in the project team. It is often prudent for a customer embarking on offshoring for the first time to first outsource a small-scale non-critical project before exporting any business critical operation. Providers offering the most attractive solutions may be short-listed by the user, and a specific solution and provider then chosen. At times, a 'preferred supplier' and reserve may be selected and a competitive negotiation created by the user allowing him to extract maximum gain from each of the providers in a competitive situation. However, such a process is time-consuming, only justified in some situations, and can be a significant cost of bid for the suppliers in question (costs which can eventually be passed on to the unwitting user).

In other circumstances, the user may simply select a certain provider without recourse to an ITT or competitive tender. Selection can be made based upon alternative reasoning or because the provider (or a third party consulting provider) has consulted with that user and recommended or sold certain services. In certain public sectors or in the case of specifically regulated industries such as water supply, the project may be subject to the national public procurement rules applicable to that business depending on the nature and value of the project in hand. This can significantly affect the way potential providers are sought as well as the timing and manner in which a potential contract with a provider is offered.

The impact of offshoring on external sources should not be underestimated. There are many current examples of businesses trying to distinguish themselves

in the marketplace by emphasising the fact they do not offshore.[9] It is increasingly common for 'thou shalt not offshore' clauses to be negotiated into agreements with the chosen provider. In trying to reach into the service delivery methods of their contractors and prohibit them from utilising offshore services in the delivery or subcontracting of services, the customer can frustrate real savings. While one might consider this approach prudent, a blanket dismissal of the opportunity is perhaps a little naïve.

B. Choosing a Provider

A customer can maximise its options and benefit from competition among providers in tendering for its work. The ITT should clearly specify the customer's requirements in order to increase its prospects of attracting suitable providers and accurate proposals. It is also important to examine the size and capability of the provider, whether the provider uses its own employees or subcontractors, what processes and operational procedures are deployed to protect confidentiality and intellectual property rights, and what other customers the provider is supplying (in case of a conflict of interest).

If a decision has been made to go offshore, the location of the offshoring service also needs to be considered. Naturally, there are many factors to consider: time zones, languages, product localisation needs and synergies with exiting or potential markets or users all need to be considered when making a decision on location. This may be compounded if multiple locations are to be used. The choice of country ought to be influenced by factors such as the expected role of the country in the global economy in the long-term, the talent pool and experience available (including language ability), the legal controls and export

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[9] *See, e.g.*, LetsTalk, *Why Buy from LetsTalk*, *at* http://www.letstalk.com/promo/whybuy/whybuy2.htm ("Buy from fellow Americans. We're proud of our Dallas, Texas-based customer sales representatives, and we do not offshore customer care outside our country to save money at the expense of good service. Your business is handled here in the U.S.A. from start to finish."); Travel Sciences, Inc., *About Us*, *at* http://www.travelsciences.com/AboutUs.asp ("Our solutions are designed and built in the United States of America. We do not offshore to third world countries for cheap engineering labor and profit on their labor without telling you like other companies do. Your technology and proprietary information is safe with us, and any proprietary innovations that you want us to custom develop for your company will not show up with your competitors through some unknown company operating in a country where you are not protected."); ActionMedia,net, *ActionMedia.Net*, http://www.actionmedia.net/ ("All of our technicians are ranked as TIER 3 engineers, and are located in the USA. You will never have to rely on India for support, **NEVER**.").

controls applicable, the scalability of operations and potential speed to operations, the availability of governmental incentives (such as the software technology parks in India), the country's infrastructure and potential risks; and the overall effect on cost (including domestic management costs).

C. Negotiation

An outsourcing contract should be a 'living' document that can evolve and be actively managed by the parties, helping to sustain and build the relationship by providing practical solutions to identify and resolve issues at an early stage. The contract should incorporate a clear definition of each party's responsibilities, along with service level agreements, as well as contract management procedure with co-operation, monitoring and reporting procedures, and procedures to identify and deal with changes to the agreement. It should also incorporate an escalation and business continuity procedure, and a clear retransition/exit strategy.

D. Implementation

This stage of the life cycle — when the project goes live — is the one that most commonly causes problems. Success often depends on good preparation, and it is therefore important to have a well-developed implementation plan that includes project managers with clearly defined roles and responsibilities, a defined and clear timetable, a milestone process, and acceptance testing procedures for deliverables.

E. Summary and Recommendations

Outsourcing, and especially offshore outsourcing, has its advantages and disadvantages. The risks are inherent and obvious when one considers that every project involves many parties from all corners of the world, working in various languages and time zones. However, the advantages can far outweigh the risks if the project has been prepared thoroughly, and if the customer outsources certain business operations to the right service provider for the right reasons.

One particularly important aspect is the organisational and legal framework of such IT projects. Typically, outsourcing and offshoring projects are long term

commitments for the customer, and the service provider and the duties and rights of the partners need to be defined. Therefore the outsourcing contract (framework or master services contact and statement of works) needs to address all relevant aspects of the project. The contract also needs to include exit scenarios and exit clauses that assist the parties from the beginning with the retransition of the application. The application must then be backsourced to the customer or transferred to another service provider, and the parties must know their rights and duties during that phase of the contractual relationship as well.

Therefore, it is imperative for both parties to think about and negotiate a contractual framework for the outsourcing project that takes into consideration all material aspects of such a long-term business relationship. This article goes on to describe important legal clauses under Indian, British and German law in a comparative analysis. Please take note that the following list is not exhaustive, and that there are many more legal and commercial issues (such as tax, human resources and real property) that need to be addressed in a framework agreement.

III. A COMPARATIVE LEGAL ANALYSIS OF THE MOST IMPORTANT CLAUSES AND LEGAL ISSUES

Every offshoring project by definition deals with partners from different jurisdictions, and needs a solid contractual framework, especially since such projects are often intended for longer periods of time. A comparison of the legal systems in India, the U.K. (specifically with reference to English law) and Germany with respect to IT outsourcing, as well as the contractual frameworks available in each jurisdiction, would thus be helpful at this juncture.

A. Overview of the Different Legal Systems with Respect to IT Outsourcing

1. India

India has a detailed and well-defined legal system in place. The Indian legal system is based on English common law, and is thus governed by statutes, rules and case law. The Indian judicial system has a unified structure, with the Supreme Court, the High Courts and the lower Courts constituting a single

judiciary, the independence of which is guaranteed by the Indian Constitution. Generally, the contract is considered supreme among its parties.

2. The United Kingdom

Under English law there are no laws specific to outsourcing and, save for any contractual restrictions, in general, businesses have complete freedom to outsource on whatever terms they wish. Every outsourcing arrangement will involve a wide spectrum of contractual issues, some of which are discussed in more detail below. In addition to these, the parties to an outsourcing agreement governed by English law must consider the implication of legislations such as the Data Protection Act, 1998 (DPA) and the Transfer of Undertaking (Protection of Employment) Regulations, 2006 (TUPE). The DPA protects the rights of individuals in relation to the use of their personal data. A customer that outsources the processing of personal data remains responsible for any breaches of the DPA by the provider.[10] TUPE protects the rights of the employees of a business being transferred. Where TUPE applies in an outsourcing situation, any of the customer's employees who are engaged in the function being outsourced may, in certain circumstances, automatically transfer to the supplier (along with all related rights, liabilities, and obligations). There are a range of associated rights and obligations. For example, there must be consultation with representatives of the affected employees and such employees are protected from dismissal in connection with a transfer.[11] The customer must take all proper measures to avoid breaches of TUPE and minimise cost and disruption to its business. If the customer is regulated by the Financial Services Authority by virtue of being a financial services firm, bank, insurance company or any other regulated financial service provider regulated by the Financial Services and Markets Act 2000, then it must comply with FSA outsourcing regulations, which include taking "reasonable steps to avoid undue operational risk."[12] There

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[10] The DPA fixes responsibility on the 'data controller', who is defined in section 1 as "a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be, processed". Data Protection Act, 1998, § 1.

[11] *See* Transfer of Undertaking (Protection of Employment) Regulations, 2006, § 4-7.

[12] Council Directive 2004/39/EC, art. 13(5), http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2004/L/02004L0039-20060428-en.pdf (the Markets in Financial Instruments Directive, which came into force on November 1, 2007, replacing the existing Investment Services Directive); Financial Services

are also widely accepted best practices within the industry, such as exit strategy provisions, which will usually be followed by any party choosing to enter into outsourcing transactions in the U.K.

3. Germany

Pursuant to German law and IT outsourcing, the first and most important distinction that one has to make is between sales contracts (*Kaufvertrag*, governed by § 433–453 of the German Civil Code, known as the *Bürgerliches Gesetzbuch* or BGB), contracts to assist (*Dienstvertrag*, governed by § 611–630) and contracts to perform (*Werkvertrag*, governed by § 631–651). The German courts apply a 'centre of interest' analysis to establish which type of contract (and therefore which set of statutory provisions) governs a certain transaction.

If the main duty of the service provider is to grant a licence for a standard software of the service provider, and the customer customizes and installs the standard software himself, then this will be construed as a sales contract, and the German courts will apply the rules for sales contracts laid down in §§ 433–453 of the BGB. If the service provider writes a code for the customer, provides additional services, and is relatively free to decide how he will create and deliver his products/services, then the courts in Germany will most likely decide that it is a contract to perform, and they will apply § 631. In this case, the German Supreme Court, or *Bundesgerichtshof* (BGH), has held that the service provider is responsible for the end result.[13] This leads to a higher degree of responsibility for the service provider.[14]

In most, if not all cases, a complex IT outsourcing relationship will include various duties to be performed by the service provider, and will be construed as a contract to perform services. Ultimately, the service provider must deliver his

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Authority, *SYSC Senior Management Arrangements, Systems and Controls* 13.9, http://www.ukregulation.co.uk/topics/FSAH_SYSC_13_9_Outsourcing/48714.

[13] BGH NJW 83, 1489; BGH NJW 02, 749.

[14] The service provider is, for example, responsible for warranty claims of the customer in such a scenario. The customer also has to formally accept the deliverables to trigger the right of the service provider for his remuneration. This is not the case in a 'services to assist' scenario, where the only remedy of the customer in such a case is to terminate the contract and where the customer does not have to formally accept the deliverable.

products and services according to the specifications of his client, but he will decide how to best create and deliver these services.

The next legal test under German law is whether the contract is individually negotiated between the parties (*Individualvertrag*), or whether this is a 'terms and conditions' scenario (*Allgemeine Geschäftsbedingungen*[15]). Pursuant to § 305(1) of the BGB, a 'terms and conditions' scenario exists where the rules were drafted in advance for a (theoretically) repeated use, and where the party proposing the terms was not willing to negotiate such terms (where the terms were accepted by the other party without negotiations).[16] This distinction is very important under German law, and triggers a different legal review of the contractual clauses by the German courts. If the clauses are terms and conditions in the sense of § 305 of the BGB, then these clauses must withstand a more rigid test by the German courts. §§ 305-310 of the BGB were written to safeguard consumers against unfair contract clauses by large businesses, which are perceived to be in a stronger position to negotiate a contract vis-à-vis consumers. However, the German courts apply some of the same restrictions in a B2B context, and therefore IT outsourcing contracts in a 'terms and conditions' scenario are subject to much more rigid review by German courts.[17] It is therefore imperative for the service provider to discuss its own draft of the outsourcing contract with the German customer, and to keep a record of such discussions. The most common legal structure for complex IT outsourcing agreements is the contract to perform (*Werkvertrag*), on an individually negotiated basis (rather than a 'terms and conditions' basis).

B. Liability

1. India

In India, the issue of damages is covered under §§ 73 and 74 of the Indian Contract Act, 1872. The concept of extra-contractual damages (including

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[15] § 305–310 BGB.

[16] BGH NJW 77, 624.

[17] Some of the restrictions are enumerated in § 308-309 BGB. However, any breach of a material provision of the German Civil Code can be annulled by a German court pursuant to § 307(1)-(2) BGB as well. This has far-reaching implications for the parties. Once a part of a liability clause, e.g. the limitation of liability for consequential damages, is found to be in breach of German law, the German

punitive and exemplary damages) is not well established in Indian jurisprudence. Compensation is payable for loss which (a) naturally arose as a result of the breach, or (b) the party knew would arise as a result of the breach.[18] Here, the principle of restitution is applied and the party suffering the loss is compensated so as to put it in the same position as if the contract had been completed. In other words, the measure of compensation is directly related to the measure of loss actually suffered. § 73 itself provides that no compensation will be given for any remote and indirect loss resulting from the breach. This is, however, set to change if a recent ruling by the Delhi High Court is anything to go by. In *Microsoft Corporation* v. *Deepak Raval*,[19] Justice Sikri not only awarded compensatory and punitive damages, he went on to state:[20]

> *In the present case, the claim of punitive damages is of INR 500,000, which can be safely awarded. Had it been higher even, this Court would not have hesitated in awarding the same. This Court is of the view that punitive damages should be really punitive and not flea bite and quantum thereof should depend upon the flagrancy of infringement.*

Parties may agree beforehand to a fixed sum payable by the party committing the breach to the other party ('liquidated damages'). In such a case, § 74 of the Indian Contract Act would apply. If the sum agreed to is a reasonable pre-estimation of the expected loss, the court may award the entire sum without insisting that the innocent party prove that the loss actually suffered by it was commensurate. If the predetermined amount has the nature of a penalty, and if the party committing the breach is able to prove that the other party has not suffered any loss despite the breach, the innocent party may not be entitled to be the said predetermined sum.[21] Even if the party in default is not able to prove this, the innocent party is entitled only to reasonable compensation not exceeding the amount mentioned in the Contract Act. Finally, India also follows

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court will set aside the entire clause and apply the statutory German law. For the above example (limitation of liability for consequential damages is invalid), this means that the court will apply the statutory German law, i.e. unlimited liability for the service provider for intent and negligence and for direct and indirect damages. There are many such restrictions under German statutory law.

[18] Indian Contract Act, 1872, § 73.

[19] 2006 (33) PTC 122 (Del).

[20] *Id.* at 3174.

[21] *See* Indian Contract Act, 1872, § 74.

the principle of mitigation of loss/damages. Therefore, the innocent party is obligated to try and mitigate its losses in the face of the said breach.[22]

2. The United Kingdom

The principles governing damages for breach of contract are fundamentally the same in the U.K. as they are in India. The claimant is entitled to be put into the position he would have been in if the contract had been performed.[23] However, the claimant may only recover direct losses, which are those (a) arising naturally from the breach, or (b) as may reasonably be supposed to have been in the contemplation of the parties at the time they made the contract, as a probable result of the breach.[24] Furthermore, there is a principle which has developed through English case law over time that the claimant has a duty to mitigate his losses, so he cannot recover damages for any part of his loss which he could have avoided by taking reasonable steps.[25]

Both user and supplier are usually keen to avoid the uncertainty of legal technicalities, and so limitation and exclusion of liability clauses are the norm. Parties are generally free to do this, except that liability for fraud, death, or personal injury caused by negligence can never be excluded. In most circumstances any restriction on liability for misrepresentation must be reasonable, pursuant to the Unfair Contract Terms Act, 1977 (UCTA), and implied terms as to title to assets cannot be excluded or restricted.[26] Certain provisions of the UCTA are excluded in relation to international supply contracts.[27] It is common for parties to impose a financial cap on liability. The cap is, of course, a matter for negotiation, and a variety of commercial factors will apply in reaching the applicable cap (not least the bargaining strength of

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[22] *See* Indian Contract Act, 1872, § 73, Explanation; Murlidhar Chiranjilal v. Harishchandra Dwarkadas, A.I.R. 1962 S.C. 366.

[23] *See, e.g.*, Surrey County Council v. Bredero Homes Ltd., [1992] 1 W.L.R. 1361, *applying* Robinson v. Harman, [1843-60] All E.R. Rep. 383.

[24] Hadley v. Baxendale (1854) 9 Ex. 341, 355.

[25] British Westinghouse Electric Co. Ltd. v. Underground Electric Railways Co. of London Ltd., [1912] A.C. 673, 689.

[26] Unfair Contract Terms Act, 1977, § 2(1), 6(1).

[27] Unfair Contract Terms Act, 1977, § 26.

the parties). It is also common to exclude liability for certain types of loss, in particular economic loss (e.g., loss of profits, contracts, business, anticipated savings, goodwill and revenues). In the landmark *British Sugar* case,[28] it was held that the term 'consequential loss' only refers to foreseeable loss (such loss as may reasonably be supposed to have been in the contemplation of the parties at the time they made the contract, as a probable result of the breach) and does not include direct loss (losses arising naturally, according to the normal course of things, from the breach of contract itself). Therefore, a clause excluding only consequential or special loss would not preclude the recovery of pure economic losses that flow directly from the breach. However, where a service is business-critical, and particularly where it is intrinsic to the customer's ability to generate money, it may be perfectly appropriate to seek to recover lost profit where a service failure impedes that money generation. In addition, under the UCTA a party seeking to rely on a provision purporting to exclude or restrict liability for any other damage or for misrepresentation, where the agreement is made on that party's standard written terms of business, must show that the provision passes a test of 'reasonableness', a factor in which is the relative bargaining strength of the parties. However, the vast majority of outsourcing contracts are individually negotiated, and, where this is the case, any exemption clauses contained therein will not be subject to this test.

In practice, of course, it is unlikely that a customer would wish to sue an incumbent supplier for breach of contract, and therefore the recovery of damages by way of court action is generally unpalatable as an option unless the contract is terminated. It is therefore necessary to have other remedies within the contract, as otherwise the customer risks having no effective control over the performance of the supplier, making his position vulnerable (the supplier, of course, being aware that termination would be a risky and extreme option). Such contractually agreed remedies invariably include an escalation procedure and service credits in the form of liquidated damages. However, there is a wide range of other options, such as re-performance of failed services, services in kind (e.g. free consultancy), specific costs or losses (e.g. costs of wasted advertising or third party substitute services) and partial termination.

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[28] British Sugar plc v. NEI Power Projects Ltd., [1997] C.L.C. 622 (Q.B.D.).

3. Germany

Pursuant to the statutory provisions in §§ 631, 633 and 634 of the BGB regarding contracts to perform (*Werkvertrag*), the service provider of customised, or individual, software is obliged to deliver software/services that are "free of defects". In case he does not rectify the defects within a reasonable period of time (set by the ordering party), the vendor may be held liable for damages pursuant to §§ 280 and 281 of the BGB. Furthermore, in regard to the delivery of software, German courts have imposed additional pre-contractual and contractual duties upon the developer of individual software. In the event that the service provider's knowledge in regard to the requirements, complexity and expenses of the software is superior to that of the ordering party and the service provider is able to identify any shortcomings in the ordering party's ideas, the service provider has a duty to provide expert advice to the ordering party.[29] This is often referred to as 'expert liability'. The service provider thus has to ask all relevant questions in order to determine the actual requirements of the ordering party. He then has to advise the ordering party regarding the identified specifications of the software. The Cologne Federal State Court (*Oberlandesgericht*, or OLG) has held that this duty also applies in case of ambiguity in the specifications.[30] Moreover, the service provider should try to establish a high degree of IT knowledge on the part of the customer in the framework agreement.

The industry standard in Germany is that the service provider is liable without limitation for intentional acts,[31] or for gross negligence, but also that he can limit his liability for simple negligence. The actual limitation of liability for simple negligence is subject to the bargaining powers of the parties and, at the end of the day, is also subject to a fairness test applied by a German court on a case-by-case basis. That said, the most important issue concerning liability under German law is to establish the difference between simple (limited liability) and gross (unlimited liability) negligence (assuming, of course, that no service provider would intentionally harm a customer).

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[29] BGH NJW 1985, 1769, 1771; BGH NJW 1984, 2289, 2290; BGH NJW 1983, 2493, 2494.

[30] OLG Koeln NJW-RR 1993, 1528.

[31] *See* § 309 BGB.

While there are no statutory provisions defining gross negligence, the German courts, in a string of decisions, have developed a detailed concept of gross negligence.[32] Gross negligence means "a failure to act or a conduct that is so reckless that it demonstrates a substantial lack of concern for whether damage will result or not."[33] Gross negligence has to be distinguished from simple negligence. Simple negligence is generally considered as "a failure to exercise the degree of care considered reasonable under the circumstances, resulting in an unintended damage to another party."[34] In short, the distinction between simple and gross negligence is that while simple negligence is a standard of "may happen", gross negligence is a standard of "must not happen". German courts have defined the meaning of gross negligence as meaning, *inter alia*, a violation of a duty of care that exceeds simple negligence significantly and is individually inexcusable, a severe disregard for obvious and easily applicable security measures and for the necessary duties of care, the absence of the slightest precaution or alertness, and the disregard of obvious deliberations and of what would have been clear to everyone in the relevant situation.[35]

There is no precedent of gross negligence in the area of IT or outsourcing projects in Germany. The reason for this is probably that the majority of software contracts and outsourcing projects that were the subject of a legal dispute are high-profile transactions with established market players. Therefore they are mostly resolved through an out-of-court settlement between the contracting parties. Additionally, service providers in Germany usually do not want to be publicly exposed in the courts as having acted in a grossly negligent manner.[36] Importantly, the burden of proof to establish gross negligence is on the customer. It is therefore up to the customer to try to establish gross negligence on the part of the service provider by showing that the service provider mismanaged the project or that it used inexperienced developers.

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[32] OLG Frankfurt VersR 1981, 27, 30; BGH VersR 1970, 568, 569; BAG NJW 1982, 1013.

[33] BGHZ 10, 16; BGH NJW 92, 3236.

[34] BGHZ 39, 283.

[35] BGH NJW 1984, 789, 790.

[36] *See* § 169 GVG (*Gerichtsverfassungsgesetz*, or the German Court Organisational Act).

C. Warranties

1. India

Indian law implies a number of terms into any contract for goods or services. The Sale of Goods Act, 1930, implies a term that goods shall be of satisfactory quality and fit for their purpose.[37] A warranty is a stipulation collateral to the main purpose of the contract, the breach of which gives rise to a claim for damages, but not a right to reject the goods and treat the contract as repudiated. Where a contract of sale is subject to any condition to be fulfilled by the seller, the buyer may waive the condition or elect to treat the breach of the condition as a breach of warranty and not as a ground for treating the contract as repudiated. Thus, in a contract of sale, unless the circumstances of the contract are such as to show a different intention, there is:

(a) an implied condition on the part of the seller that, in the case of a sale, he has a right to sell the goods and that, in the case of an agreement to sell, he will have a right to sell the goods at the time when the property is to pass;

(b) an implied warranty that the buyer shall have and enjoy quiet possession of the goods; and

(c) an implied warranty that the goods shall be free from any charge or encumbrance in favour of any third party not declared or known to the buyer before or at the time when the contract is made. Where there is a contract for the sale of goods by description, there is an implied condition that the goods shall correspond with the description; and, if the sale is by sample as well as by description, it is not sufficient that the bulk of the goods corresponds with the sample if the goods do not also correspond with the description.

2. The United Kingdom

There are no standard warranties in an outsourcing contract, but English law does imply a number of terms into any contract for goods or services. The

[37] Sale of Goods Act, 1930, § 16.

Sale of Goods Act, 1979, implies a term that goods shall be of satisfactory quality and fit for their purpose[38] and the Supply of Goods and Services Act implies a term that services shall be performed with reasonable care and skill.[39] These terms are implied as conditions, which give the innocent party the right to terminate and claim damages, as opposed to warranties, which only give a right to sue for damages. However it is common for all implied terms to be excluded. Where the agreement is on the supplier's standard terms, such an exclusion clause is likely to be held unreasonable and therefore unenforceable under the UCTA, but as mentioned above, this will not be relevant where the contract has been individually negotiated.

There are some areas in relation to which express warranties will often be agreed, such as the standard to which the supplier will perform the services, confirmation of entitlement to enter into the agreement and perform the obligations, confirmation as to the accuracy of information exchanged prior to contract, compliance with the DPA and FSA regulations and the Euro currency compliance of the services or products being supplied. Clearly, however, the parties will seek to tailor warranties to the circumstances of each particular deal.

3. Germany

In the absence of a contractual provision in the framework agreement or statement of work, the warranty issue under German law is governed by §§ 633-639 of the BGB. The service provider is thus required to deliver the product/service free of errors and legal claims of third parties, with a statutory warranty period of twenty-four months. However, the parties are free to contractually agree to a lesser duration of warranty. In a 'terms and conditions' scenario, they can limit the warranty period to twelve months, and in an individually negotiated contract, they can limit the warranty period even further. A typical warranty clause should also address the following issues:

1. What happens if an error occurs: does the warranty period extend automatically, or does it start anew after the error was fixed?

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[38] Sale of Goods Act, 1979, § 14.

[39] Supply of Goods and Services Act, 1982, § 13.

2. What constitutes an error? What are the error classes and how do the parties categorise the errors?

3. When does the warranty period begin?

4. What are the rights of the customer? Can he demand the delivery of a new deliverable? Who can choose the right?

5. What are the limitations? Is the service provider still liable if the customer amends the services or uses the service against the recommendations of the service provider?

6. What are the overall liabilities under warranty?

Generally speaking, the service provider needs to accept responsibility for his deliverables, and the customer needs to understand that there must be a balance between the risk of the service provider and the potential profits. The definition of the obligations and the status of the service provider is an important aspect of a warranty. The service provider therefore has to make sure that the duties are well defined (and that the scope also expressly states what is beyond the scope!) In this respect, it is important to note that the German Supreme Court for Civil Matters has repeatedly held that the service provider has a special obligation as an expert and therefore has to point out if there are insufficiencies in the requirement specifications of the customer.[40] The parties therefore need to work diligently on defining the scope of the services.

Since missing or insufficient documentation and program descriptions are tantamount to an error in developing the software, the clearer the definition of the scope and the mutual responsibilities, the easier it is for the parties to define an error and to deal with a warranty situation. The service provider has to provide warranty free of charge. This includes all packaging and travel costs and all other costs associated with bug-fixing. Needless to say, there can be a conflict between maintenance and warranty, and the parties also have to describe an error clearly in order to agree if this is an error (e.g., under warranty and therefore free of charge for the customer) or an issue for maintenance.

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[40] BGHZ 102, 135 (the service provider has to assist the customer in defining the requirements and describing the solutions).

D. Intellectual Property Rights

1. India

There are several intellectual property rights principles and statutes that may be relevant in an outsourcing arrangement. Copyright can be transferred from the author to third parties, provided such transfer is recorded in writing.[41] As a general rule, computer programs and methods for doing business are not patentable in India, although computer-related inventions can be patented in some cases.[42]

2. The United Kingdom

There are several intellectual property rights principles that may be relevant in an outsourcing arrangement. For instance, IPR created by an employee acting in the course of his employment automatically vests in the employer unless otherwise agreed – there is no principle of work-for-hire under U.K. law (as there might be in the U.S.).

As in Indian law, copyright can be transferred from the author to third parties, provided such transfer is recorded in writing.[43] However there is also a distinct concept of an author's moral rights, which cannot be transferred. Moral rights include the right to be identified as the author of the work, but it should be noted that these do not apply to computer programs.[44] As a general rule, computer programs and methods for doing business are not patentable in the U.K., although computer-related inventions can be patented in certain narrowly-defined circumstances.[45]

3. Germany

Unlike most of the common law statutes, German civil law does not allow for a transfer of the copyright itself as stipulated in § 29 of the German Copyright

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[41] Copyright Act, 1957, §§ 18-19.

[42] Patents Act, 1970, § 3(k)-(ka).

[43] Copyright, Designs and Patents Act, 1988, § 90(3).

[44] *See* Copyright, Designs and Patents Act, 1988, §§ 77-89.

[45] *See* Aerotel Ltd. v. Telco Holdings Ltd., [2006] EWCA Civ 1371.

Act (*Urheberrechtsgesetz*), which permits transfer only by inheritance. The reason for this is the civil law concept of *droit moral* (*Urheberpersönlichkeitsrecht*), which is not as common in some of the common law countries.[46] This principle stipulates that the creator of a copyrighted work has some personal, 'moral' rights, and that these cannot be taken away from him. A clause in an outsourcing contract whereby the service provider transfers the copyright in a certain deliverable is, therefore, void under German law.[47] Thus, the correct legal mechanism under German law is a licence. The customer will demand a simple or exclusive license to use and exploit the deliverable for a certain period, and in a certain geographical area. Normally, the licence clause will include the following parameters:

a) Simple or exclusive licence (depending on the software itself; standard versus customised software);

b) Irrevocable or revocable licence;

c) Unlimited or limited licence (by time);

d) Unlimited or limited licence (by geographical reach);

e) Right to sublicense (or the absence thereof); and

f) Limited or unlimited rights of the licensee.

One additional question that needs to be addressed in the intellectual property and license clause is the point in time until which the license right is valid. This could be upon the conclusion of the contract, upon the formal acceptance of the deliverable, or upon the payment of remuneration in full. Another issue in this respect is the ownership of the documentation and program descriptions. These rights should also be addressed in an IT outsourcing

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[46] The U.S., for example, expressly stipulates the concept of *droit moral* only in the Visual Artists Rights Act, 1990, and recognises the general principle of *droit moral* to a far lesser extent; in the U.K., such rights are recognised in § 77 of the Copyright, Designs and Patents Act, 1988.

[47] As in many other countries, software is generally protected by copyright law under § 69 of the German Copyright Act. There are, of course, patents available for some deliverables but the requirement for a 'software patent" is generally speaking much higher than, say, in the U.S.. Databases are also protected under the German Copyright Act in § 87.

agreement, and they should correspond with the IPR clause, in which the service provider should include a provision that he is allowed to use and exploit the deliverable, and that he is free to use all 'pre-existing rights' for other customers and projects. Generally speaking, the customer will try to limit the ability of the service provider to execute similar projects for his competitors, and the service provider has an interest to advance his industry expertise by providing similar projects for numerous market players. This conflict of interest needs to be addressed up front, preferably in the master services agreement itself.

E. Indemnifications

1. India

Indemnity under the Indian Contract Act is a contract by which one party promises to save the other from loss caused to him by the conduct of the promisor himself, or by the conduct of any other person.[48] Damages under Indian law can generally only be recovered for breach of contract if the claimant can prove that the breach caused loss, and to the extent that those losses are direct and have been mitigated. However, these rules do not apply where the claimant relies on an indemnity. In most IT outsourcing contracts, the service provider is expected to indemnify the buyer of services for non-compliance with the specifications given by the buyer to create the software, for any intellectual property infringement of any third party, for any employee-related claims, for any personal injury or property damages, etc.

2. The United Kingdom

As in India, the rule that a claimant can only recover damages for breach of contract if he can prove that the breach caused loss (and to the extent that those losses are direct and have been mitigated) does not apply where the claimant relies on an indemnity, because the claim is for a debt rather than for a breach of contract. As such, indemnities are often heavily negotiated, and often avoided at all costs, in any outsourcing deal where there are likely to be significant potential losses which are too remote to fall within a claim for contractual damages.

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[48] Indian Contract Act, § 124.

In many outsourcing deals, intellectual property rights are either licensed or transferred, and it is standard for the recipient of the rights to be indemnified against any claims or losses resulting from the infringement of any third-party rights by the rights licensed or transferred. Indemnities are commonly tied to the agreed warranties, and so will often cover losses resulting from non-compliance with the DPA, security breaches, and for infringement of third party IPR. Where employees are transferred under TUPE as part of the outsourcing, the customer will generally agree to indemnify the supplier against historic liability in respect of those employees, and, likewise, the supplier will indemnify the customer against any future liability.

3. Germany

In most IT outsourcing projects, the service provider will create individual software for the customer. He will therefore be responsible for the result (error-free software). Since 2002, German law does not differentiate between errors in the deliverable because of factual deficiencies (*Sachmangel*) or legal deficiencies (*Rechtsmangel*). Both have the same consequences: the German customer can first demand rectification, reduce the price, or not pay the price at all. The customer can also correct the error (either himself or through a third party), and also claim damages.[49]

The industry standard in Germany is that the service provider only has to indemnify the customer if the customer (i) informs the service provider about a third-party claim, (ii) assists the service provider against such a claim and (iii) lets the service provider have the final word on how he wants to settle the dispute. Also, the amount of damages payable under the indemnity is usually limited to the same extent as the general limitation of liability.

F. Delay and Penalties

This is always a key area of negotiation. The customer will usually seek multiple penalties for delay, and the service provider will try and limit this. In both India and the U.K., the service provider may want to rely on statutory law requiring the customer to prove actual loss. Since it will often be difficult to

[49] §§ 434, 435, 437, 633 BGB.

predict the amount recoverable as contractual damages in an outsourcing deal, the parties may try to introduce some certainty by providing for liquidated damages, but, as mentioned earlier, unless the sum specified in such a clause represents a genuine pre-estimate of loss, it will be deemed to be an invalid penalty clause.[50]

The position in German law, however, is rather different. Generally speaking, the parties must agree on the delivery schedule in the contract in order to create a binding obligation for the service provider to keep a certain deadline. Unless stipulated in the contract, dates are generally not binding. However, most German customers will demand a fixed timetable, and these times are then binding for the service provider. Under German law, there is no delay unless (i) the time is fixed (contractually or by law), (ii) the service provider has received a final warning (unless an exception applies, e.g., if the service provider expressly or impliedly states that he will not perform his services), (iii) the service provider is late with the performance of his services, and (iv) he is at fault.[51]

The last point is especially important for the service provider. If, for example, the customer committed contributory negligence by not fulfilling one of his own duties under the contract, the service provider can argue that the delay is not attributable to his own fault. The industry standard in Germany on penalties for delay is that the service provider has to accept penalties to a defined amount. German customers are likely to expect that the service provider will accept responsibility for the timeliness of the execution and therefore would focus on the penalty amount rather than on the question of whether penalties will create an incentive for more timely deliveries. As a rule of thumb, a cap for all penalties is negotiable. Additionally, the service provider can try to direct the attention of the German customer to different performance-measuring tools, such as bonuses or other incentives that should safeguard the timely performance of services.

G. Acceptance

Outsourcing agreements generally provide for detailed acceptance provisions to set out the various duties that each party has to fulfil prior to, during, and

[50] Dunlop Pneumatic Tyre Co. v. New Garage & Motor Co., [1915] A.C. 79.

[51] § 286 BGB.

after acceptance. This is mostly also dealt with in the service-level agreement. Detailed provisions relating to how the services are to be implemented, rolled-out and/or deployed should be included for the sake of prudence. Any outsourcing arrangement should include agreed-upon acceptance criteria and a related acceptance process in order to gauge a successful service roll-out, as there are no particular laws in the U.K. or India relation to such procedures. The user may also want to build in other checks and mechanisms to monitor and influence service quality. These may include rights to survey and investigate service provision on regular occasions, to test service delivery, and to anticipate general satisfaction amongst the user base that relies on or uses the services.

In relation to delay, missing a contractual deadline entitles the innocent party to claim damages for loss, but does not confer a right to terminate, unless non-performance by a certain date is held to be a fundamental breach of the contract. If a party deems the performance of certain obligations to be time-critical, then it should seek an express provision that time is of the essence in relation to those obligations. This would enable the innocent party to terminate (as well as claim damages) for failure by the defaulting party to meet the deadline specified.

As mentioned earlier, German law differentiates between 'services to assist' and 'services to perform'. Acceptance is relevant only in 'service to perform' contracts, where the service provider is responsible for the end result. In such contracts, the customer must formally accept the deliverable. Acceptance is defined as the physical handing over of the deliverable together with a declaration by the customer that the deliverable essentially corresponds with the agreed scope. The service provider should direct all his attention to this point, and should try to make the customer accept the deliverable at the earliest time, as the legal consequences of the formal acceptance are very important for the service provider. The warranty period only begins after formal acceptance, and if there is no such acceptance, the customer does not have to pay for the services.[52] That said, it is of no advantage to the customer to sign the formal acceptance protocol. A possible solution is to include a deemed acceptance provision, stating that the deliverable is deemed to have been accepted if the

[52] § 641 BGB.

customer uses the deliverable for a certain time or does not sign the formal acceptance protocol although there are no major errors in the deliverable. However, it is still imperative for the service provider to define various error classes and to make sure that this mechanism can be used to ensure an early acceptance.

H. Duration

Generally speaking, all outsourcing contracts stipulate a certain duration, and are then either renewable or expire upon that date. There are no rules in respect of the term of outsourcing contracts in India or the U.K. The term is simply a matter for negotiation and depends on the nature of the work outsourced, although longer terms (five to ten years) can be common, given the amount of business disruption involved, the protracted supplier involvement, and management requirements as the deal is implemented. Although a contract can usually be terminated immediately in India and the U.K. in certain statutorily specified cases, it is usual for the parties to set out specific events that give rise to a termination right. These will generally include material breach (with a period during which the breaching party is first given the opportunity to cure the breach), minor but persistent breaches, change of control (i.e., effective ownership) of the supplier and insolvency (where a definition of insolvency is agreed upon). It is also common for the customer to negotiate a right to terminate for convenience, or 'without cause'. This will inevitably involve the customer having to pay a termination payment to compensate the supplier for wasted costs and loss of expected profits. It is important to remember that, unlike in India, contractual claims can be brought up to six years after breach in the U.K.[53]

In Germany, while, the parties are generally free to agree upon any term they wish, the customer will usually ask for an initial period and a right to extend this period perpetually, thus (hopefully) influencing the quality of the service provider. This also makes sense for the service provider, as he will not be in a position to legally force the customer to stay with him forever. In most instances, the parties will agree that the master services agreement will be for

[53] Limitation Act, 1980, § 5.

an indefinite period of time, or that it will be for a definite period extendable at the option of the customer. (The parties should also include provisions in the contract that deal with the question of what happens to an existing statement of work in case the master services agreement is validly terminated and vice versa.) German law differentiates between a normal termination right (*Einfache Kuendigung*, which always requires a notification period for the termination to be effective) and a termination for important reasons.[54] In most cases, the parties agree to a reasonable notification period for the normal termination (e.g., three months from the termination notice). German law also stipulates that the customer can terminate the agreement at any time prior to the completion of the deliverable, but in these cases the customer still has to pay the full contractual remuneration to the service provider, minus any saved costs.[55]

Naturally, the parties will disagree on the saved costs to the service provider, and this will often lead to a long negotiation about the right amount of payment for the customer's premature exit. To be able to terminate the contract without waiting for the end of such a notification period, the customer needs to show an 'important reason'. An 'important reason' is defined by the German courts as a reason so imperative that the party affected cannot be expected to wait until the end of the normal notification period.[56] However, this depends entirely on the individual facts of the case at hand,[57] and therefore it is almost always impossible to predict whether or not the breach of the other party can justify a termination for an important reason.

I. Retransition

Outsourcing relationships are very complex and personal arrangements, in the sense that the customer is looking very hard to find the right partner, and is trying to make sure that it will be a long-lasting relationship. The investments on both sides are thus quite significant (negotiating the framework agreement, transition of the system, transfer of know-how and employees). Therefore, most

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[54] § 626 BGB.

[55] § 649 BGB.

[56] BGH NJW 1993, 463; BAG NZA 94, 74 (German Supreme Court for Employment Matters).

[57] BAG NJW 85, 1853; BAG NZA 06, 491 (German Supreme Court for Employment Matters).

good outsourcing agreements also deal with the issue of retransition, and stipulate rules regarding how the parties will deal with each other once the contractual relationship ends and the system is transferred back to the customer or a third service provider, especially since parties usually do not want to involve the court in retransitioning the service and/or dissolving the contractual relationship.

Closing an outsourcing relationship is complex and time-consuming. Staff, contracts and assets may have to be reallocated, and in the U.K. staff may transfer under TUPE, regardless of any agreement between the parties. As well as being time-consuming, the exit procedure can be expensive, and it is prudent to set out how these costs are to be shared while the parties remain on good terms. It is common to see the agreement contain an exit plan, or a contractual obligation to agree and update an exit strategy throughout the life of the agreement. The retransition clause will expressly state what the mutual rights and obligations shall be upon the termination of the contract, and how long the service provider will be available for the customer or the new service provider to effect the transition. Generally, the retransition clause stipulates that the service provider will be available for one or two more releases of the software, and that during that period the responsibility for the system gradually shifts back to the customer or the new service provider. It also addresses issues such as availability of the project team during transition and the costs for such a transition. The user will usually argue that cost should follow fault, and that the supplier should be liable for exit costs when it is in breach of contract. Where there is no fault, costs are usually shared.

J. Summary

From the above legal analysis it is obvious that the three legal systems examined have substantial similarities as well as differences. Unsurprisingly, the Indian and English legal systems are very similar. On the other hand, the German civil law system deals with these issues differently, and has a different starting point; the German statutes and the concepts of *Werkvertrag* and *Dienstvertrag*. Above all the national legal systems, there are also international agreements and legal theories that can also play a role in finding the right answer to a specific legal issue.[58]

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[58] *See, e.g.*, United Convention on Contracts for the International Sale of Goods, *opened for signature* Apr. 11, 1980, 19 I.L.M. 671 (entered into force Jan. 1, 1988).

IV. CONCLUSION

Although very mature in some markets (especially the U.S. and, to a lesser degree, the U.K.), outsourcing and global sourcing are still in their infancy. There are quite a few central European and other markets that are virtually untapped by the outsourcing phenomenon. Outsourcing transactions and global sourcing initiatives are also becoming larger and more complex, as evidenced by the rise of the BPO market. Transactions are more global in nature, and more aspects of businesses are being outsourced. Multinational companies are not just outsourcing an aspect of their business in one jurisdiction, but are more likely to look at this from a global perspective. In terms of the outsourcing transaction, this means bigger rewards – and ultimately, bigger risks. Therefore, contracts have to be precise enough to deal with the various legal, technical, and operational issues, and at the same time flexible enough to leave room for development. Outsourcing relationships are by nature long-term relationships where trust and co-operation between the partners are required attributes and also necessities for success. Furthermore, various legal systems are involved in transactions such as offshoring and thus must be taken into consideration. The differences between the various legal systems need to be taken seriously, and the parties should make sure that the contractual relationships will withstand the test of all jurisdictions involved and comply with all legal requirements from the various supervisory institutions in those jurisdictions.

However, this does not mean that parties cannot structure their transactions in a way that safeguards them against risks associated with multi-party and multi-jurisdictional transactions and satisfies the compliance officers in both organisations. The parties are ultimately working on a common project, and a security or compliance problem will always affect both parties. This should motivate them to start the transaction on a solid legal basis and manage it closely. If the industry is not hit by any more security or compliance scandals, the market for outsourcing and global sourcing will continue to grow substantially over the next few years, benefiting both customers and service providers.

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A COLLECTIVE RIGHTS SOCIETY FOR THE DIGITAL AGE

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ABSTRACT

Variations in digital copyright law in the international sphere have created unnecessary transaction costs to both consumers and producers who wish to transfer digital media efficiently. This article argues that the international community should create a collective rights organisation to bring uniformity, fairness, and efficiency to the process of transferring digital media and endeavours to construct the ideal model for such a collective rights organisation by describing a hypothetical collective rights organisation named PICRO (Possible International Collective Rights Organisation) and examining its operation using the example of digital music distribution. By illustrating the PICRO model in the light of current trends in international digital copyright law, the article aims to highlight the advantages of the proposed new system while underscoring the inherent weaknesses of having different digital copyright laws for different territories.

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I. INTRODUCTION

Geography is no longer a barrier to expression. Hence decisions regarding the structure of digital entertainment law must be made with international implications in mind. It is of little importance that the United States Copyright Arbitration Panel has come to an agreement that weighs the interests of access and compensation for a particular service if another country comes to a different conclusion with a different royalty rate. The smart investor can simply choose to form his or her business in the kinder jurisdiction. Such digital copyright havens could cause global market distortions by charging their businesses a lower royalty rate.

Territorially limited rights and differing local laws impose unnecessary transaction costs for the worldwide transfer of digital entertainment. In order to reduce transaction costs for the distribution of digital music, a uniform method of regulating and licensing digital music is necessary for the internet market, which transcends traditional boundaries. Therefore, getting the nations of the world to agree upon a uniform compulsory licensing structure to regulate the distribution of music on the internet is in the interests of rights-holders, as well as the nations that benefit from their Gross Domestic Product (GDP).

However, getting the developing nations of the world to agree on the somewhat arbitrary royalty rates set by the United States and the United Kingdom will not be easy. An ideal package, to induce these nations to enter a uniform regime, should offer them the ability to participate in the global intellectual property market. The model solution would be one that allows production companies to set their own price flexibly, allows retailers worldwide to license the products efficiently, and allows consumers to purchase the product at a price that is reasonable considering their economic circumstances. Any solution should also, in order to ensure widespread acceptance among different legal traditions, consider the differences between the economic incentive

framework of copyright law found in common law countries and the respect for the rights of authors found in civil law nations.[1]

This article illustrates the need for an international rights organisation that is capable of granting publishing and recording rights to musical works throughout the world, and describes how that system could work. I will first illustrate the advantages of an international collective rights organisation over the traditional domestic rights organisations in the context of Internet distribution. After establishing the reasons why such an organisation would be superior, I will explore the Internet distribution models currently employed by the music industry and assess their feasibility in an international collective rights organisation. Further, I will describe how such an organisation could adopt distribution models and maintain price discrimination so that people throughout the world can afford access to musical works while balancing the interests of rights holders in an efficient manner.

II. THE ADVANTAGES OF AN INTERNATIONAL COLLECTIVE RIGHTS ORGANISATION

Blanket licensing of music is currently administered by a handful of collective rights organisations: in the U.S., for example, this is done by organisations such as the Harry Fox Agency, ASCAP and BMI. These bodies have proven capable of reducing transaction costs for multiple subscribers who would otherwise have had to negotiate directly with the recording and publishing companies.[2] They have done well for composers in the traditional radio and record markets that are easily confined to national boundaries, but are poorly suited for the challenges of the digital age because they do not have the power to license music throughout the world. The collective rights organisation of the digital age must be international in nature and must represent both the publishing and recording industries, because both publishing and recording rights are implicated in digital distribution models and dealing with

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1 *See generally* STEPHEN M. STEWART, INTERNATIONAL COPYRIGHT AND NEIGHBOURING RIGHTS (2d ed. 1989) (discussing copyright frameworks in both common law and civil law jurisdictions).

2 DONALD S. PASSMAN, ALL YOU NEED TO KNOW ABOUT THE MUSIC BUSINESS 220-21 (2003). *See also* AL KOHN & BOB KOHN, KOHN ON MUSIC LICENSING 2001 Supplement 135-37 (2d ed. 2001) (listing examples of overseas performance rights societies).

both would result in economies of scale.[3] It should also be focused solely on internet markets in order to increase their efficiency, provide a one-stop shop for webmasters, and respond to this fundamentally different market.

This collective rights organisation, the Possible International Collective Rights Organisation (hereinafter "PICRO"), should attempt to fill the demand for licensed content of currently employed methods of digital entertainment distribution to reach businesses and end users throughout the world. A central licensing grantor, capable of worldwide licensing after processing a simple application, will be useful in several ways.

Firstly, by creating a blanket rights organisation capable of granting licences to cover all territories, the PICRO would provide access to music for users throughout the world, especially users within the under-served nations outside of the major market. For example, a Tongan citizen's current ability to meet with music industry executives and strike licensing deals is slim and inefficient both to the Tongan, who may not be able to recover his negotiating expenses, and to the record company executives, who would probably prefer to focus their energies on more profitable projects.

Even though these markets are under-served, the countries they represent are charged with protecting these works from infringement through the TRIPS agreement,[4] the WIPO Copyright Treaty[5] and a range of other treaties. Whether a lack of digital music delivery services is a result of disinterest in the local market or a business decision to focus distribution efforts on the major markets is debatable. What is less debatable, however, is the unfairness of requiring developing nations to incur expenditure to enforce copyright interests in music that is not licensed to them. The PICRO could alleviate this problem with little transactional expense to the record company or the Tongan entrepreneur

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[3] *See generally* KOHN & KOHN, *supra* note 2, at 410-14 (discussing the distinction between the copyright in a recording and the copyright in a particular song). This collective rights organisation should not represent both industries in a lobbying role because of the conflicts between competing publishers and sound recording interests.

[4] Agreement on Trade-Related Aspects of International Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[5] World Intellectual Property Organization Copyright Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17 (1997), 828 U.N.T.S. 3 [hereinafter "WIPO Copyright Treaty"].

while opening the entertainment market to millions of distributors and consumers.[6]

Secondly, an international compulsory-licensing scheme that allows non-major-market users to distribute digital music can also prevent piracy in the major markets. As Internet use spreads among the non-major-market countries, the demand for digital entertainment will grow as well.[7] If music files are not available to people living in these countries at a reasonable price — which is determined by considering what the local market can bear — users will probably turn to piracy networks to gain access to music files.

An inefficient market for digital music is a problem for both the recording and publishing industries in terms of lost sales due to piracy in both major and non-major markets.[8] Because of the nature of file-sharing networks, piracy in foreign markets — even those markets that have never been a substantial source of revenue — will affect the total revenue the music industry can generate.[9]

Thirdly, peer-to-peer networks work through a series of connections that allow users to make copies of files on other users' system.[10] Current versions of such software allow the user to connect directly to a large number of users simultaneously, thereby increasing connection speed and reducing downloading time.[11] As users from other countries, especially those who are not offered viable entertainment solutions, turn to these networks, the variety in the networks' catalogues will increase, and download times will shorten further.[12] This may

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6 *See generally* KOHN & KOHN, *supra* note 2, at 234-35 (discussing the potential of the internet to expand the music industry).

7 While I appreciate that many people in the developing countries do not have Internet access, the market is growing. *See* Internet Usage World Stats – Internet and Population Statistics, *at* http://www.internetworldstats.com/. The problem should be confronted now before it becomes intractable. Additionally, kiosks can be used as a means of reaching users who cannot afford their own computer, but who can afford a digital audio player.

8 *See, e.g.*, Brad King, *Music Biz Laments: Stealing Hurts*, WIRED, Sep. 26, 2002, http://wired.com/news/mp3/0,1285,55393,00.html.

9 *See id.*

10 Kristina Groennings, *Costs and Benefits of the Recording Industry's Litigation Against Individuals*, 20 BERKELEY TECH. L.J. 571, n.1 (2005).

11 *See id.*

12 *See id.* at 586.

lead to increased piracy in the major markets, as peer-to-peer network providers close the "convenience gap" between themselves and legitimate suppliers.[13]

However, creating a uniform legal and licensing structure alone will not be sufficient to stem the tide of piracy and provide developing countries with manageable enforcement duties. The nations in the WTO and the entertainment industry must provide for a framework that allows people in developing countries to purchase entertainment at affordable prices. Otherwise, piracy will continue to grow in these countries, as will the associated cost of combating it.

The need to meet local pricing demands should be evident. After the Napster network demonstrated the high demand for digital music and the ability of pirate networks to undermine sales, the recording industry scrambled to provide consumers with a viable alternative to the pirate networks.[14] Along with creating user-friendly stores that add value to the customer's shopping experience, the recording industry roughly decided that a price of around one dollar per song is what the major markets could bear.[15] However, while one-dollar songs may sell well to the average American buyer, US$1 is a relatively high price to the average Indian buyer because of the considerably weaker purchasing power of the Indian rupee. Any international licensing policy should take into account the particular licence granted and the particular user paying for the licence when determining a reasonable sales rate to the end user, while balancing the interests of the creator or holder of the work.

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[13] *See* Ed Oswald, *Study: iTunes More Popular than P2P*, June 7, 2005, *at* http://www.betanews.com/article/print/Study_iTunes_More_Popular_than_P2P/1118158804. *See generally* Urs Gasser et al., *iTunes: How Copyright, Contract, and Technology Shape the Business of Digital Media – A Case Study*, June 15, 2004, http://cyber.law.harvard.edu/media/uploads/81/iTunesWhitePaper0604.pdf (explaining the value of the shopping experience on the iTunes music store, as compared to the experience on P2P networks).

[14] PASSMAN, *supra* note 2, at 373-77.

[15] *See* Alex Veiga, *Recording Labels, Apple Divided Over Pricing*, Apr. 2, 2006, http://www.msnbc.msn.com/id/12122837/. The files are reportedly licensed for roughly seventy cents apiece, with the remainder constituting the service providers' transaction costs and profit margin. *Id.*

III. DISTRIBUTION MODELS

In order to address the more important issues in international digital music licensing, and describe how they may be handled by the PICRO, it is useful to examine some existing business models:

A. Tethered-Download Subscription Services

'Tethered downloads'[16] is an industry term that refers to music files that have certain restrictions placed on them as to use and transferability to different mediums.[17] Tethered downloads have made an impact in the 'subscription service' model.[18] Users pay a monthly fee for access to a website's entire repertoire of music files, and are generally allowed to play an unlimited amount of music, but are restricted from transferring the files to portable music devices or storage media such as CDs.[19] Users are only allowed to use the files for a specified amount of time, and they lose access to the files if they do not renew their leases.[20]

The right the consumer has can be adequately characterised as a rental right, but is different from the current rental model popularly employed by movie rental stores.[21] The main reason behind this difference in distribution is that when a consumer 'rents' a particular music file, he does not *borrow* the web

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[16] *See generally*, KOHN & KOHN, *supra* note 2, at 152-54 (discussing interactive electronic transmissions and distinguishing them from non-interactive, or traditional broadcast, transmissions).

[17] Harry Fox Agency, Definitions, http://www.harryfox.com/public/InfoFAQDefinitions.jsp.

[18] *Id.*

[19] *See* Michael A. Einhorn and Bill Rosenblatt, *Peer-to-Peer Networking and Digital Rights Management: How Market Tools can Solve Copyright Problems*, Cato Institute Policy Analysis no. 534, 3-7 (2005), *available at* http://www.cato.org/pub_display.php?pub_id=3670.

[20] If the user does not pay his or her bill, the service may be cancelled by the provider. *See, e.g.*, Napster – Terms and Conditions, http://www.napster.com/terms.html (for example, "You agree to pay for all Tracks and Materials that you purchase through the Service and Napster may charge your billing payment method for any such payment(s) . . . [i]f Napster receives a notice alleging that you have engaged in behavior that infringes Napster's or other's intellectual property rights or reasonably suspects the same, Napster may suspend or terminate your account without notice to you").

[21] There is currently no first sale exhaustion of the copyright protection of a music file like there is for a DVD; this is because the second sale is likely to be a copy of the first and the product is leased. *See* David R. Johnstone, *The Pirates are Always With Us: What Can and Cannot be Done About Unauthorized Use of MP3 Files on the Internet*, 1 BUFF. INTELL. PROP. L.J. 122, 123-24 (2001).

distributor's file, like at the movie rental store, but makes a *copy* of the website's 'ephemeral' copy,[22] clearly implicating the author's copyright interests. Because of this copying, a licence must be obtained for both the publishing and the sound recording rights to provide these services.[23]

Currently, the rights to the sound recording are licensed to the service provider based on negotiations that take into account the size of the site's membership (or forecasted membership), the site's catalogue, the digital rights software employed, and the site's ability to act as a substitute to traditional consumer music ownership.[24]

If these rights were subject to a compulsory-licensing scheme, such a regime could possibly mimic one of the following models, neither of which is satisfactory from a business or a licensing standpoint:

1. Price per Song in Catalogue

In this model, the collective rights society would charge website owners a set amount each term to include a song in their catalogues. The price of inclusion would have to take into account the size of the site's membership, to address concerns regarding the amount of people who will forgo purchasing the album or the song because of their access to the subscription service. The size of the website's catalogue will also have to be considered. A smaller catalogue will probably be cheaper to offer, and if it had all the music the user wanted, it may be more attractive to the consumer as a substitute for purchasing music.

This 'price-per-song' method is clearly not amenable to a compulsory-licensing scheme. Songs that are accessed repeatedly are not rewarded as such

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[22] An ephemeral copy of a musical work is one that is usually copied from a CD and then placed on a computer server that will later be transmitted to the consumer. It implicates both the rights of the sound recording artist and the composer of the underlying work. *See* KOHN & KOHN, *supra* note 2, at 450.

[23] The Harry Fox Agency currently administers tethered download licensing, but there is no counterpart licence for the sound recording. *See* Harry Fox Agency, *Songfile*, http://www.harryfox.com/public/songfile.jsp (last visited Nov. 19, 2006); *see also* SoundExchange, *Licensing 101*, http://www.soundexchange.com/licensing101.html#a3 (last visited Nov. 19, 2006) (explaining how to obtain a statutory licence to produce ephemeral copies).

[24] *See generally* C. Krishan Bhatia, Richard C. Gay & W. Ross Honey, *Windows Into the Future - How Lessons From Hollywood Will Shape the Music Industry*, 17 J. INTERACTIVE MARKETING 70 (2003), *available at* http://www.boozallen.com/media/file/76799.pdf.

because their inclusion is based on a set price. On the other hand, if the webmaster had to pay an amount each time a user accessed a song, the model would be difficult to employ. It would have to take into account forecasted traffic in a market that is quickly evolving each day. Negotiation with the copyright-holder over licensing rights, specifically tailored to the provider's and the customer's needs, is preferable in this approach.

2. Percentage of Revenue

This method of determining a reasonable royalty rate is another possible means of structuring internet radio licences.[25] By this approach, a percentage of revenue collected by the service provider is put aside for royalty payments. The amount collected is disbursed to the copyright-holders based on the number of times a particular work was accessed by a user. This method has the benefit of taking into account the size of the user's membership. The more users a site has, the more revenue is increased. This method also takes into account each song that is potentially used as a substitute for purchase. Songs in the catalogue that are accessed frequently are rewarded as such. If applied to a tethered download subscription service, the model could look like this:

(a) A website owner operating under this compulsory licence must pay X% of all subscription revenue earned.

(b) A website owner operating under this licence must provide reports of the songs accessed by users, and the total amount of 'spins' their service provided for each song, and the totals for the amount of all songs accessed for that month (or different term).

The problem is evident – if the subscription cost is only a dollar per year, but the website collects advertising revenue for its profit, the copyright-holder is short-changed. On the other hand, requiring the website owner to pay a percentage of revenue from all sources would stifle innovative businesses that incorporate multiple business models and revenue streams. The only viable

[25] *See* U.S. Copyright Office, *Summary of the Determination of the Librarian of Congress on Rates and Terms for Webcasting and Ephemeral Recordings*, http://www.copyright.gov/carp/webcasting_rates_final.html (discussing how the Librarian of Congress rejected the proposal of using a percentage of revenue model within the internet radio context).

alternative would be to require a minimum subscription price for a catalogue of a certain size. This would entail complex business decisions, which should be specialised rather than open to a compulsory-licensing scheme.

Furthermore, policing costs for this model are particularly high. If many webmasters were allowed to employ this model, there would be far too many providers who would have to be trusted to report their revenue honestly. If the PICRO were charged with policing their revenue, it would have to take on an additional service – auditing revenue. This would be inefficient with the model proposed for the other forms of digital licensing, because it is so different from monitoring use.

Despite the popularity of tethered downloads, this is the method of distribution that is least favourable to a compulsory-licensing scheme, mainly because of the complex business decisions that must go into catalogue pricing in this particular model. The widespread international agreement needed for this scheme is also problematic because of the complex negotiations involved, which could extend the process indefinitely.

Because of these difficulties, a tethered-download model should not be included as one of the PICRO's licensing schemes.

B. Internet Radio

Radio is the most popular means of transmitting audible sound throughout the world. This is partly because the user receives radio transmissions for free, and partly because the technology is mature and can be employed with little infrastructure.[26] Traditionally, radio is broadcast through radio waves to consumers within a certain radius of the radio transmitter.

Internet radio is fundamentally different. The consumer of Internet radio, unlike traditional radio, can be located anywhere in the world when they access the Internet radio channel no matter where the broadcaster is located. Because the broadcaster can reach a worldwide audience, there is a real incentive to

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[26] *See generally* Internews.org, *Activity – Media Infrastructure – Building Radio Stations*, http://www.internews.org/activity/infrastructure/radio.shtm (discussing the ease of setting up radio stations in countries with little infrastructure).

conduct forum-shopping to find the nation that offers the most attractive licensing system with regard to the technical requirements and royalty rates for a compulsory licence to broadcast music over the internet. For example, both the United States and the United Kingdom require the webmaster's Internet radio station to meet a number of technical requirements to qualify for a compulsory licence.

The most important of these is the sound recording performance requirement.[27] This requirement is placed on webmasters to allay the music industry's fears that the combination of the use of Internet radio capture technology and the predictability of radio station programmes will lead to piracy.[28] The requirement is as follows:

(a) The station cannot play more than three songs from any particular album, or more than two songs from the same album consecutively, during any three-hour period. [29]

(b) The station cannot play more than four songs by a particular artist, or more than three songs from a particular artist consecutively, during any three-hour period.[30]

While this approach is rationally tailored to the goal of minimising piracy, it is questionable whether or not each country in the world will agree on the particular numbers employed by the Copyright Arbitration Panel, especially since the threat seems to be somewhat a product of the record companies' nightmares.

Radio stations had, for a long time, broadcasted hour-long blocks featuring an artist or an album.[31] During this period, songs could easily be duplicated on

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[27] Other provisions require a webmaster to use and transmit songs that are protected by digital security software, to take steps to prevent copying, and to give the author of a work proper attribution. These protections are established by article 16 of the WIPO Copyright Treaty and should not be difficult to implement. WIPO Copyright Treaty, *supra* note 7, at art. 16.

[28] *See* KOHN & KOHN, *supra* note 2, at 432-33.

[29] 17 U.S.C. § 114(j)(13)(A) (2006).

[30] *Id.* at § 114(j)(13)(B).

[31] For example, Gater 98.7 FM aired a programme in South Florida called "Get the Led Out," which was an hour-long block of Led Zeppelin songs.

to cassettes, yet there was no corresponding decline in cassette sales.[32] The assertion that captured radio will serve as a commercially significant market substitute to music purchases is therefore questionable. The argument that users will use this combination to commit piracy is further weakened when one considers the many options the user has to select an illegal file-sharing network that can deliver all the pirated music needed within minutes.

The above restrictions can limit the music programmes that an internet radio station can broadcast. Many countries may resist placing these restrictions on their webmasters to give them an advantage over their foreign counterparts, or to protect freedom of speech. Of course, to some extent, these minimums are necessary – otherwise, webmasters could set up entire stations devoted to specific artists, specific albums, or even specific songs, in which case they might possibly serve as free substitutes for the tethered-download system. Therefore, the United States and the United Kingdom have an interest in persuading other nations to acquiesce to this particular scheme or a variation thereof because of these possible distortions in the market. This can perhaps be accomplished through favourable discounts in other compulsory licensing mechanisms, or through trade concessions.

Related to the restrictions placed on Internet broadcasters' programme formats is a requirement that broadcasters refrain from letting their users know their playlist in advance.[33] This restriction was also put in place out of fear of the effect of capture technology.[34] This point should be easier to implement internationally. While Internet radio stations' publication of song lists may be a feature consumers enjoy, the requirement is reasonable, and rational, if not well suited to its goal.[35] Furthermore, the lack of arbitrary numbers regarding its implementation also makes it easier for this particular requirement to get uniform acceptance. It is a simple concept to understand, and therefore, is not open to

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[32] RECORDING INDUSTRY ASSOCIATION OF AMERICA, 2005 YEAR-END STATISTICS (2005), http://www.riaa.com/News/newsletter/pdf/2005yrEndStats.pdf.

[33] 17 U.S.C. § 114(d)(2)(C)(ii) (2006).

[34] The perceived threat is that an Internet surfer could know when to begin recording songs from a station, and could find playlists through search engines. Teasers or hints as to what the playlist will be are allowed. *Id.*

[35] Such a requirement would be in accordance with the anti-circumvention norms embodied in the WIPO Treaty. WIPO Copyright Treaty, *supra* note 5, at art. 12.

many interpretations. Achieving consensus on this point should thus not be particularly difficult.

The final, and perhaps the most crucial, part of a worldwide blanket licence is setting the rate. The rate chosen should be a reasonable royalty rate resembling that to which a willing buyer and seller would agree. For this, the first step is determining the value of the right to the business In order for the business applying for the blanket licensing to determine the value of the copyrighted material, it is important to look at the end user of the product. In the case of Internet radio licensing, as opposed to other forms of licensing discussed in this essay, the end user is largely unknown at the time of broadcast. Because the broadcast is free to users and can be accessed by users worldwide, the end user can adequately be described as anyone in the world with an internet connection. The rate set by the PICRO should be uniformly charged to every Internet radio owner in the world, regardless of their locale, so that businesses have equal footing in light of the fact that an Internet radio station can compete with other stations around the world for the same user.

Of course, this will be no easy task. In order for the PICRO rate to be effective, it must be lower than, or equal to, the statutory rate set by each country. Getting the nations of the world to agree on a set rate will certainly be difficult; getting them to agree on the changes that need to be made every couple of years only compounds the problem. There are two solutions for setting the rate today and in the future. One way would be to set a price-increase formula at the outset. The other way would be to establish an arbitration panel that will hear arguments from the recording, publishing, and broadcasting industries. Based upon their findings, the arbitration panel would set a rate structure. The rate structure could then be adopted by the nations as part of their total adoption of the PICRO system. This arbitration panel could be an ad hoc panel at the WIPO or other international body, or a panel in a completely new international organisation. The arbitration panel should be separate from the PICRO because it cannot represent both the interests of the recording and publishing industries. (The PICRO should not have any role to play in the determination of rates; it should simply implement the decisions that are made.) Rate changes in the future would be deemed approved, unless there is a consensus of disapproval (similar to the WTO method).

C. Digital Permanent Downloads

Digital permanent downloads (DPDs) are quickly becoming the most popular means of distributing digital music.[36] When a user receives a DPD, he or she has the full ability to transfer the file to portable media devices and storage media such as CDs, MP3 players, and computers without having to pay a subscription fee.[37]

Currently DPDs are distributed to the major markets through services like Napster, iTunes, and Walmart.com. The demand for this product should continue to grow throughout the world because of the flexibility of DPD use.[38]

While these licences are popular throughout the world, they are not offered to consumers worldwide. Where the market has failed to offer a legal option to acquire digital music, the pirate networks have delivered and will continue to do so. As these networks gain popularity in areas where legal supply is non-existent and demand remains high, the cost of copyright policing will increase. In order to combat this threat, or at least allow users to have an option to obtain digital music files, nations should enact compulsory licensing laws for the delivery of DPDs. This would allow for the proliferation of businesses that offer digital music online.

Without requiring the negotiation of specific licences with each prospective distributor, the transaction costs and upfront costs of operating a digital music store will be greatly reduced. This reduction in costs will open up the market to increased competition among the various distributors, of whom there is now only a handful. Instead of generic stores, owned by corporations engaging in lengthy negotiations with industry executives in order to appeal to a wide and sterilised market, the small 'mom and pop' webmaster can apply for compulsory

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[36] *See generally* Johnstone, *supra* note 21; Harry Fox Agency, *supra* note 17 (defining digital permanent downloads).

[37] *See* Harry Fox Agency, *supra* note 17 (defining digital permanent downloads). *See generally* MusicMatch, Terms of Service for Yahoo Music MusicMatch for Yahoo! Music MusicMatch Jukebox 10.1, Term #16, http://www.musicmatch.com/info/terms/10-1.htm (last visited Nov. 26, 2006) (Term #16, Permanent Download of Content, provides the terms that govern what a purchaser can do with a DPD music file).

[38] *See* IFPI, *Global Digital Music Sales Triple to US$ 1.1 Billion in 2005 As New Market Takes Shape*, http://www.ifpi.org/content/section_news/dmr-2006.html

licences and establish independent digital music stores. The local operator, run out of business by multinational corporations, can compete in a world where travel to the next store is instantaneous and sales are made based on the value a service adds to the product.

The record companies should not, however, be forced to give up their right to receive an economic benefit for their work. Therefore, it is essential that the PICRO offer the recording and publishing industries a flexible royalty structure. The simple solution would be to allow the recording industry to set their own price for each item that is licensed, and have them work out their own separate agreements with the publishing companies, as they do with CDs.[39] The recording company will set the lowest price for which they license the product, with exceptions available for promotional discounts. The wording of these exception provisions should be carefully written so as to avoid monopolistic behaviour. The rate will be based on a type of most-favoured-nation clause that allows all webmasters to compete on the same footing, regardless of their power in other areas.

It is also necessary to offer digital music to the citizens of the developing nations at an affordable price. If citizens in developing nations are required to pay a higher price for digital music, these users may turn to pirate networks. If users in developing nations begin to turn to pirated digital music, then the leaders of these nations will not be able to receive the benefits needed to compensate for the concessions they make on internet radio broadcasting rates. If the recording industry were able to set its own prices for each country, it is foreseeable that it might not make the kind of reductions necessary to make music affordable to non-major-market users. This fact will dilute the benefit of the PICRO system, and may weigh against the total adoption of this licensing scheme.

In order for the non-major-market countries to be sure that the PICRO will open access to the arts for their people, the discount formula for licensing

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[39] Publishers should also be forced to accept the pro-rata discounts that will be applied by the PICRO so mechanical royalties do not become uncontrollable. *See* David Kostiner, *Will Mechanicals Break the Digital Machine?: Determining a Fair Mechanical Royalty Rate for Permanent Digital Phonographic Downloads*, 21 SANTA CLARA COMPUTER & HIGH TECH L.J. 235 (2004) (offering a detailed discussion of the importance of controlling the cost of mechanical royalties in this digital distribution model).

rates must be part of the overall structure. This discount formula should be one that aims to make music affordable to the majority of a country's citizens, following the pricing plan that the music industry employs in the major markets.[40]

One possible way the discount formula could work is that a single country will be chosen as the base market. For the sake of simplicity, the base market country should be the country that had the highest amount of music sales for the previous year. This market will also be the market that the majority of the entertainment industry will base its price on, because it is the most important source of revenue for them. In years where the base market changes, the formula used the next year must take into account those changes so that the price per point does not change; otherwise users with previously purchased points will have their point values changed.

The copyright-holder will then set a price for the base market, as previously discussed. All the other nations of the world will be compared to that base market in terms of the money their average citizen has. Perhaps the comparison should be done by the use of a formula based on the GDP of a nation, or its purchasing power parity, or both.[41] This system will almost certainly be a point of much debate and negotiation, and this author will not attempt to choose which system will be best for this purpose. For the purpose of illustration, let us say that the base market price is tied to GDP per capita, so that if a non-base country has a GDP per capita of US$20,500, and the base country has a GDP of US$41,000, the non-base-market users will only pay half as much for the file as the users in the base market. On the other hand, if the non-base country had a higher GDP per capita than the base country, the non-base-market users would pay more.

This scenario illustrates a potential problem. How do webmasters sell regularly priced music to one user and discount-price music to another user on the same site? One answer to the solution would be to display all the songs as a

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[40] I realise that not every citizen in the major markets can afford the luxury of purchasing digital music, but it is fair to say that the market is not tailored only for wealthy people in these nations. Therefore, the discount rate that applies to a country like India, a non-major-market nation, should not only make it affordable to wealthy Indians, but also to the average Indian.

[41] It is probably more realistic to set the discount rate to only a certain portion of the price so that there is a base, or to use a less steep formula, but this is merely for the purpose of illustration.

price in "credits" or "points". Each point will represent a unit of currency in the base market, or could be otherwise tied to the base currency. The currency conversions and discounting will be done when the user purchases the credits. After the credits are stored in the purchaser's account, the purchaser may spend them in online music stores without realising that the pricing difference has been hidden from them. Of course, the website owner who wants to deal in currency can always opt to change the points back to currency by reversing the formula.

For example, website owner A who wants to sell his products to users worldwide will have a store that shows these prices in the universal 'points' price along with the likely addition of a few fractions of a point or a premium for access, to cover his time, costs and profits. When a United States user buys points in this model, she will be offered no discount, because she lives in the base market. However, when B, a resident of India, purchases a song, the software will recognise her location by her billing address, or IP address, as being a nation subject to a discount. It will then perform the proper formula to show the discount and convert the currency. The fact that the credits represent a different amount of money to different users is of no importance; the price can be displayed universally. Webmasters no longer need to negotiate the terms of the deal and establish a new site for every country because of the universal pricing structure. They have a universal price that can handle the rights implicated by users who access the site worldwide. The site just has to be translated to all of the major languages, a task that will be accomplished as long as there is interest in it.

IV. EFFICIENT POLICING OF LICENCES

Policing the compliance of norms set by the PICRO is another relevant issue. By pooling the costs of the employees who will have to surf the internet to ensure that internet radio and DPD stores are complying with the regulations set by PICRO, expenses that are currently being incurred by the Harry Fox Agency, ASCAP, BMI, SoundExchange, and their counterparts around the world can be saved. The DPD scheme would increase policing costs, but only because it creates a new service. To keep their duties manageable, webmasters must agree to be audited both in their accounting and traffic statements. Website owners must also be required to keep detailed reports of both these items.

However, checking the accounting of even randomly selected sites will be expensive, and will not help the PICRO make distributions for the sale of DPDs to the right artists on a regular basis. This is because there is always some degree of error in sampling. When sampling through more variables – in this case the number of songs available – sampling becomes even more problematic. Therefore, after webmasters select which DPD songs will be included in their catalog, the PICRO software will generate links that will identify the song and relevant licence by code. The vendor's code will be included in the link, similar to current affiliate-programme software. Whether the link will lead to a digital repository of songs managed by the PICRO, act as a buffer, or be a redirect link, will be a matter of debate.

If the generated link is used to access a digital repository, then users anywhere will be able to sell the products in their online stores without having to buy the CDs individually, or pay for an ephemeral licence for the music that is placed on their servers. This could reduce the cost of opening an online music store drastically, provide access to music worldwide that may not be available locally, and create uniformity in copyright management software among stores, thus reducing the need to police standards. Therefore, it should seriously be examined as a potential means of distribution, especially since centralising the servers will reduce server costs.[42] If this were the case, the PICRO would have to charge either the webmaster or the author for the transfer costs. If the link acts simply as a buffer link that hits a counter to let the PICRO know how much a particular account had earned, the DPD provider will have to deal with the issues of ephemeral licensing and software security as part of the package.

In either situation, the price charged will be set by the owner of the work in relation to the number of hits an item has. The number of hits will be multiplied by the price to create an amount that is owed to the owner of that work. When all such charges are added up and sorted by vendor ID, an accounting method can be employed. Either billing will be sent out to them for the products they sold or checked against reserve accounts from money paid in advance.

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[42] This is based on the widely accepted theory that economies of scale can reduce the costs of producing a unit – in this case a unit of bandwidth – by taking advantage of operational efficiencies. *See* BLACK'S LAW DICTIONARY 531 (7th ed. 1999) (defining economy of scale).

In order to calculate the correct amount to charge, the PICRO must know which uses came from which countries and so forth. That is why when a user is, in whatever way, directed through the ID link described above, their link will not only represent the information mentioned before, but will also include the country code or discount code that was applied to the sale. This full link will be what is recorded at the PICRO. Based on the country code, proper accounting and billing can be done with a minimal amount of human labour, thereby increasing returns to rights-holders and/or lowering prices to distributors and consumers.[43]

V. PROTECTION OF MORAL RIGHTS

Under the Berne Convention and the national laws of many moral-rights-based copyright regimes, artistic integrity is protected by operation of law.[44] The provisions establishing the PICRO should also recognise and address these rights.

Protection for the rights of authors is easier in the context of Internet radio. The provider must use legally obtained music, not bootlegs or unauthorised versions of a work.[45] Additionally, the webcaster has to give proper attribution to the artist. In addition to these moral rights protections, the webcaster must also take steps to ensure that it does not infringe on the artist's right to publicity by using a work in a way that suggests endorsement.[46]

The DPD music storeowners could do the same, but there are some additional concerns. For example, an artist might have reservations about having his or her music sold on certain sites, especially those that deal with pornography or hate speech. The decision to revoke the licence for these types of sites should be allowed to the artist, who should be able to place reasonable restrictions on the PICRO database, so that website owners in these and other similarly situated

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[43] *See generally* KOHN & KOHN, *supra* note 2, at 211-13.

[44] Berne Convention for the Protection of Literary and Artistic Works, art. 6, Sept. 9, 1886, *as last revised at* Paris on July 24, 1971, 1161 U.N.T.S. 30.

[45] 17 U.S.C. § 114(d)(2)(C)(vii) (2006).

[46] *Id.* at § 114(d)(2)(C)(iv).

categories of content providers could know not to carry the file.[47] Clear violations by the website owner should be punished by fines.

Artists interested in this system can manage their listings through their PICRO account, which will show them all their products and where they are licensed. While the price should be set by the copyright holder, the right to revoke a site's use of the song should be left to the author. It should also be an inalienable right in order to ensure that the record companies do not use this as a way to direct traffic to companies with which they have ties or which they own.[48]

In addition to the protection of authors from having their work associated with unsavoury sites, there is also a need to protect the quality of the work that is distributed. Therefore, along with the information already supplied to the PICRO with each song, the author should be allowed to set a minimum bitrate at which a music file of their work can be sold under the licence. If the PICRO acts as a central server, there will be no need for these provisions or their policing. Only those files that the artist submits will be offered by the PICRO. If the artist chooses not to submit singles and only submits full albums for sale, the PICRO should respect that decision and only allow webmasters to offer the entire album.

Other issues that will need to be addressed include the need of website owners to have images to correspond to their products, and the need of copyright owners to receive protection for the images they create.[49] The licensing scheme should then contain a provision that would allow website users the right to use an album cover or other cover art associated with a particular single or album. There would be no significant loss to the music industry from this, since these images are traditionally widely distributed as part of the promotion to sell the single or album and can be said to fairly represent the work. Furthermore, the cost of creating the image can be factored into the price set at the PICRO.

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[47] *See* Rajan Desai, *Music Licensing, Performance Rights Societies, and Moral Rights for Music: A Need in the Current U.S. Music Licensing Scheme and a Way to Provide Moral Rights*, 10 U. BALT. INTELL. PROP. L.J. 1, 22 (2001).

[48] *See, e.g., id.* at 12-14 (suggesting the adoption of protections for authors that exist under the French model).

[49] Images are covered in the scope of protected works under the Berne Convention. *See* Berne Convention, *supra* note 45, at art. 2(1).

VI. CONCLUSION

The PICRO could establish a new age of digital distribution by removing the barriers to negotiating licences and the cost of maintaining inventory. By allowing every entrepreneur in the world to open his or her own digital record store, the PICRO could take advantage of the decentralised nature of the internet and serve as a catalyst for niche market stores specialising in a particular genre, or for the development of innovative business models. Through the proliferation of unique distribution outlets, users will be exposed to and influenced by a variety of expressive creations and may come across music that they would not normally be exposed to because of the market distortions caused by advertising.

In addition, the PICRO will offer the nations of the world a viable means of obtaining reasonably priced artistic creations, without the need of independently establishing and maintaining their own collective rights societies. The potential affordability, access, efficiency, and uniformity features that the PICRO would have to offer indicate that such an organisation would be of considerable help in tackling tasks such as digital music distribution – in fact, an organisation such as the PICRO could be of immense help in other divergent areas as well. However, initiative needs to be taken to put this plan into action, and thus the merits of setting up a PICRO-styled organisation need to be made clear to the players involved so that the benefits can be felt by both developing and developed nations alike.

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DATA EXCLUSIVITY WITH REGARD TO CLINICAL DATA

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ABSTRACT

Intellectual property rights have evolved over the years with the intention of protecting novelty and innovation of ideas while creating a competitive market, at both a local and global level. The strongest tools to achieve this end have arguably been patents – protecting inventions that are novel, non-obvious and demonstrate utility. Most countries give a protection term of twenty years from the date of filing a valid submission. In the field of pharmaceuticals, foods and agrochemicals, marketing of products requires statutory clearances from the appropriate national regulatory bodies, in order to ensure that the products satisfy certain minimum criteria of quality and safety. Generating such data generally involves elaborate experimentation, trials in various phases, chemical analysis, and an estimation of the impact on the environment, all of which are time-consuming and expensive processes. Thus the intellectual property right of data exclusivity becomes important, as it involves the question of whether these processes, once completed, can be taken advantage of by other applicants. This paper analyses the concept of data exclusivity, studying article 39 of TRIPS, and addresses the question of whether data exclusivity laws should be introduced in India.

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I. INTRODUCTION

The pharmaceutical industry can be said to comprise of pioneer and generic companies: the former develop and market new drugs and the latter copy some or all aspects of those drugs and sell them.[1] Data exclusivity, also known as marketing exclusivity, refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of a pioneer company to be used to register a therapeutically equivalent generic version of that medicine.[2] It other words, during a set period of time, data exclusivity would prevent a pharmaceutical applicant from obtaining a marketing authorisation for its drug through a facilitated procedure entailing reliance on preclinical and clinical data generated by a previous applicant to support a successful application for its own drug, where the drugs manufactured by both applicants are effectively the same and thus can be approved or rejected by taking the same data into account.[3] Thus, data exclusivity guarantees additional market protection for originator pharmaceutical companies[4] by preventing health authorities from accepting applications for generic medicines during the period of exclusivity.

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1 Valerie Junod, *Drug Marketing Exclusivity under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, 479 (2004).

2 Praveen Dalal, *Data Exclusivity: An Indian Perspective*, *at* http://www.ipfrontline.com/depts/article.asp?id=12300.

3 *Id.*

4 An 'originator pharmaceutical', as opposed to a generic pharmaceutical company, is one which produces a new, original drug, rather than producing a generic equivalent of an already produced drug.

During the limited period of exclusivity, the second entrant can obtain marketing approval only if it generates its own data supporting the safety and efficacy of its drug. The practical consequence is that generic competition is delayed for the duration of marketing exclusivity.[5] Protection of registration data, through the data exclusivity that results from non-reliance on the data, is a governmental function. The registration data is provided to the authorities in confidence and is not meant to be referred to by third parties. Further, governments should be required to protect the data that they receive in a manner that will enable the originators to enforce their rights.[6] It is thus the government, through its regulatory agencies, and not the originator of the data, that is responsible for preventing copiers from taking advantage of proprietary data during the period of data exclusivity.

A. Data Exclusivity as a Separate Intellectual Property Right

Data exclusivity is often considered to be an extension of the rights under a patent. However, it is important to note the distinction between the two rights, as data exclusivity qualifies as an independent intellectual property right. Patents and data exclusivities are awarded independently. Unlike a patent, which gives the holder the right to exclude others from making, using, selling, offering for sale, or importing the patented product, the protection that governments must accord proprietary test data does not prevent any manufacturer from running its own tests and submitting the results to the regulatory authorities. Assuming the absence of any intervening patents, a generic alternative may still receive marketing approval, provided that the generic manufacturer conducts its own preclinical and clinical trials and independently seeks marketing authorisation by the regulatory bodies.[7] For instance, the drug's patent may expire or be ruled invalid before marketing approval and marketing exclusivity are granted. Similarly, if a valid patent covers the pioneer drug, it effectively prevents generic entry, whether or not a marketing exclusivity period is running.[8] Data exclusivity also differs from a patent in that

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5 Dalal, *supra* note 2.

6 Int'l Fed'n of Pharm. Mfrs. Ass'ns, Encouragement of New Clinical Drug Development: The Role of Data Exclusivity 15 (2000), http://www.ifpma.org/documents/NR83/DataExclusivity.pdf.

7 *Id*. at 3.

8 *Id.*

it is not a right that the pioneer firm can invoke directly against a generic firm.[9] In particular, the pioneer firm cannot directly challenge the second entrant to whom the agency would have mistakenly granted marketing approval, despite an ongoing marketing exclusivity, as data exclusivity merely protects the data given to the agency in order to approve the product, unlike a patent, which protects the product itself.[10] Thus, data exclusivity and patents are distinct forms of protection – the protection of one right is neither dependent nor linked to the other in any intrinsic way.[11]

B. The Advantages of Data Exclusivity

The purpose of data exclusivity is to ensure that the initial registrant of a new drug can recover the costs of testing the drug for efficacy and safety. Extensive testing directly translates into considerable costs for generating the data necessary to obtain approval of each new active ingredient. Drug developers contend that they cannot afford to bring drugs to market without data exclusivity because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free-ride on the initial registrant's approval and sell the same or similar drug at a lower price.[12]

One argument for data exclusivity laws is that pharmaceutical manufacturers will have a greater incentive to develop drugs for diseases that are considerably more prevalent in developing countries, as incentives based solely on sales in developed countries will not encourage the creation and testing of these products if the market for them in the developed countries is limited. This is premised on the assumption that a lack of data exclusivity in a certain country would make

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[9] *See* Junod, *supra* note 1, at 493.

[10] *Id.*

[11] *See, e.g.*, Organon v. Teva, 244 F. Supp. 2d 370, 373 (D.N.J. 2002); *see also id*, at 482 (noting that a drug's patent may expire or be ruled invalid before marketing approval and marketing exclusivity are granted, or, similarly, that a valid patent covering a pioneer drug effectively prevents generic entry, whether or not a marketing exclusivity period is running); INT'L FED'N OF PHARM. MFRS. ASS'NS, *supra* note 6, at 15 ("Data exclusivity is an independent intellectual property right and should not be confused with the protection provided by other rights, especially patents.").

[12] G. Lee Skillington, *The Protection of Test and Other Data Required by Article 39(3) of TRIPS*, 24 NW. J. INT'L L. & BUS. 1, 8 (2003) ("Estimates of costs vary widely, but studies by the Tufts Center for the Study of Drug Development indicate that the costs of developing a new drug [were] $54 million in 1976 (in 1976 U.S. dollars), $231 million in 1991 (in 1991 U.S. dollars), and $802 million in 2002 (in 2002 U.S. dollars)." (footnote omitted)).

it very difficult for the pioneer manufacturer to recover the expenses associated with research and testing in that country, as subsequent generic manufacturers would be able to undercut its prices by copying the pioneer's drug after the patent expires and reusing the pioneer's data in order to obtain approval, thus reducing costs significantly.[13]

II. DATA EXCLUSIVITY UNDER TRIPS

Proponents of data exclusivity argue that it is mandated in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[14] The controversy surrounding data exclusivity has in large measure been related to the different interpretations given to the relevant provisions of TRIPS.

Section 7 of TRIPS is entitled Protection of Undisclosed Information, and article 39 therein talks about data exclusivity.[15] TRIPS introduced the first international standard on the subject. Article 39(1) talks about protecting member states against unfair competition[16] and article 39(2) states that natural and legal persons have the possibility of preventing information lawfully within their control from being disclosed to others without their consent in a manner

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[13] *Id.* at 13-14.

[14] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 (1994); Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31 (1994), 33 I.L.M. 81 (1994) [hereinafter TRIPS].

[15] TRIPS, *supra* note 14, at art. 39.

[16] Article 39(1) reads: "In the course of ensuring effective protection against unfair competition as provided in article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 below and data submitted to governments or governmental agencies in accordance with paragraph 3 below". *Id.* at art. 39(1). Article 10bis of the Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 828 U.N.T.S. 107, as last revised at the Stockholm Revision Conference, July 14, 1967, 828 U.N.T.S. 303 [hereinafter Paris Convention], requires all countries of the Paris Union to provide all nationals of the Union with effective protection against unfair competition, and this protection must be provided on a 'national treatment' basis pursuant to article 2.

contrary to honest commercial practices.[17] Article 39(3) is the provision directly concerning data exclusivity and reads as follows:[18]

> *Members, when requiring, as a condition of approving the marketing of a pharmaceutical or of agricultural or chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except when necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*

On the face of it, it seems that this provision mandates data exclusivity. The structure of article 39 suggests that the negotiating parties conceived of the regime for test data as a particular case in the framework of the protection of undisclosed information.[19] However, the article must be carefully scrutinized keeping in mind its legislative history and intention. TRIPS is not a uniform law and it only establishes broad parameters for national rules for different members. The inclusion of test data in TRIPS as a category of intellectual property does not permit one to draw any conclusion about the nature of the protection conferred.[20] The question that then arises is how much freedom TRIPS allows WTO members to apply different approaches for test data protection, and to what extent a competitive model without exclusivity would

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[17] Article 39(2) states that "natural and legal persons" should be able to prevent "information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices" as long as the information in question is a "secret" under sub-clause (a), "has commercial value because it is secret", and "has been subject to reasonable steps under circumstances, by the person lawfully in control of the information, to keep it secret". TRIPS, *supra* note 14, at art. 39(2).

[18] *Id.* at art. 39(3). The proviso to the article states:

> *For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.*

[19] Carlos M. Correa, *Unfair Competition under TRIPS: Protection of Data Submitted for Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69, 72 (2002).

[20] *Id.* at 70.

be compatible with the minimum standards set out by article 39(3).[21] This calls for an analysis of article 39(3) and its possible interpretations.

A. An Analysis of Article 39(3)

1. Data Necessary for Marketing Approval

Article 39(3) makes it clear that the first condition for its application is that a member state stipulates data submission as a condition for obtaining marketing approval for pharmaceuticals or agrochemical products. Thus, the obligation to protect test data only arises in the member states where national regulations require the submission of such data. If a member state opts not to require this data, article 39(3) will naturally not apply.[22]

2. Undisclosed Data

To qualify for protection under article 39(3), the pertinent information must be undisclosed. This means that information that is already public (due to publication in a scientific journal or magazine, for example) does not fall within its scope. Any requirement for the submission of published or otherwise disclosed information to national regulators shall not generate any private right limiting the use of such information by the government or third parties, since the information is already available to the public.[23]

3. New Chemical Entities

Another important condition for the application of article 39(3) is that the data must refer to a 'new chemical entity'. TRIPS, however, does not define the term 'new'.[24] Proponents of data exclusivity argue that article 39(3) protects data and products involved in the marketing approval systems. The word "new" thus refers to the status of a chemical entity within the marketing approval system, not with respect to the state of the art or novelty in the patent sense.[25]

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[21] *Id.*

[22] *Id.* at 73.

[23] *Id.* at 73.

[24] *Id*. at 74.

[25] *See id.*

A chemical entity may be deemed new in the absence of any prior application for approval of the same drug, or if the same drug has not previously used in commerce.[26] However, one could also argue that article 39(3) refers to a chemical entity that was not found within the marketing system at the time of submission. Therefore, only data related to products with chemical entities that were not publicly known before the submission of the data would be eligible for protection.[27]

Since TRIPS avoids defining the term 'new chemical entity', there is no way of declaring one interpretation as superior to the others, and thus member countries have a certain degree of leeway in their implementation concerning this area. Thus, to argue that the definition of a 'new chemical entity' would include a new therapeutic use of an old drug, an argument that holds sway in developed countries like the USA, would amount to giving a strained meaning to a provision that allows for flexibility. In fact, article 39(3) would not apply in cases where approval is sought for new indications, dosage forms, combinations, new forms of administration, crystalline forms, isomers, etc. of existing drugs, since there would be no novel chemical entity involved.[28] This is because the new product will be intrinsically similar to the previous product and will not require data exclusivity protection.[29]

4. Considerable Effort

Article 39(3) mandates protection when the process of obtaining the data involved a "considerable effort". However, the article is vague about the type of effort (technical or economic) involved or the magnitude of it that would be deemed considerable. The term may be interpreted to mean the concentrated

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[26] *Id.*

[27] See *id.*

[28] *Id.* at 75.

[29] *See* Case C-368/96, The Queen v. Licensing Auth. established by the Medicines Act 1968, ex parte Generics (U.K.) Ltd, 1998 E.C.R. I-7967, [1999] 2 C.M.L.R. 181, 220 (1998). The Court held that a second product is essentially similar to an earlier approved product if the second product has the same qualitative and quantitative composition in terms of active principles, the same pharmaceutical form and is bio-equivalent to the first product, unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy. In these cases, the original applicant does not receive new periods of so-called "marketing exclusivity" for each new indication, dosage form, or dosage schedule.

or special activities, physical or mental, that are extensive in scope or duration.[30] Inclusion of this standard also suggests that national regulatory authorities may call for the applicant to prove that the information for which protection is sought is the outcome of considerable effort.

5. Unfair Commercial Use

The interpretation of this phrase has by far given rise to the maximum debate concerning data exclusivity. The non-disclosure obligation under article 39 requires that the test data not be disclosed unless steps are taken to ensure that the data is protected against "unfair commercial use". Here, the key questions are: what constitutes unfair commercial use, and how can that protection be guaranteed? If the government authority relies on the dossier of the pioneer manufacturer in order to grant permission to a generic manufacturer, does this amount to unfair commercial use?

Developed nations argue that a member state's reliance, at or without the request of a competitor of the originator of data, on data submitted by the originator in a manner that benefits the competitor, would constitute unfair commercial use of the data.[31] Their argument states that any reliance on the data by a competitor before the originator has had the opportunity to recoup the costs associated with the considerable efforts to develop the data would be unfair, as it would give the competitor a free ride on the investment made by the originator. However, since there is no absolute or universal rule to determine when certain practices should be deemed unfair, it is likely that different countries will judge the fairness of certain situations differently, depending on their values and competitive advantages.[32] If the drafters of TRIPS had intended the obligation to be fulfilled by the creation of such a private right, they would have expressly required the member states to give submitters a private right of action.[33] Article 39(3) could have certainly adopted a stance proscribing reliance

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[30] Skillington, *supra* note 12, at 28.

[31] *Id.* at 29.

[32] *Id.* ("Some countries may consider it an unfair practice for a follower company to commercially benefit from the data produced by the originator via a marketing approval system based on similarity … In others, it may be regarded as the legitimate exploitation of an externality created during legitimate competition in the market.").

[33] *Id*. at 22.

on clinical data and specifying a time period for protection. The U.S. had in fact made such a proposal in the TRIPS negotiations, but the proposal was not incorporated into the final text of TRIPS.[34] Article 39(3) can be clearly distinguished from the more explicit provision in the earlier NAFTA agreement, in which disclosure and reliance of clinical data is specifically proscribed, and a minimum exclusivity period of five years is stated.[35]

One of the most important rules of statutory interpretation is that what is not explicitly included is thereby excluded (*expressio unis est exclusio alterius)*.[36] Keeping this rule in mind, the drafters of TRIPS certainly had the opportunity to impose more specific requirements of data exclusivity, but chose not to do so. Thus, contrary to those who argue that article 39(3) mandates data exclusivity, it is entirely consistent with the language of the article to simply require that data submitted for drug approval be kept confidential by the government authority while allowing the authority to rely on this data to approve subsequent generic applications.

B. Summary

In sum, article 39(3) clearly requires some form of protection for test data, but does not require member states to grant exclusive rights. Its main purpose is not to prevent the use of such data by governments, but to prevent unfair use by competitors. The language, context, principles of statutory interpretation and purpose of the article do not support an interpretation that the required protection can be implemented only on the basis of exclusivity rights. This interpretation is confirmed by the history of the negotiation of TRIPS. The United Nations Conference on Trade and Development (UNCTAD) has also stated that "authorities are not prevented [under article 39(3)]… from using

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[34] Correa, *supra* note 19, at 77.

[35] North American Free Trade Agreement, Dec. 17, 1992, Can.-Mex.- U.S., art. 1711, 32 I.L.M. 605, 675 [hereinafter NAFTA].

[36] 82 C.J.S. § 323; ABC Laminart v. AP Agencies Salem, (1989) 2 S.C.C. 163 (applying the maxim in India); Gilmore (Valuation Officer) v. Baker-Carr, [1962] 1 W.L.R. 1165 (CA) (applying the maxin in the U.K.); West Virginia University Hospitals v. Casey, 499 U.S. 83 (1991) (applying the maxim in the U.S.).

knowledge and data, for instance, to assess subsequent applications by third parties for the registration of similar products.[37]

The correct interpretation that must be given to article 39 is quite clear and unambiguous at this point. TRIPS does not make granting of data exclusivity rights mandatory, but gives the member states the freedom to choose the nature and extent of protection they want to offer.

However, the question of whether India should grant data exclusivity is quite separate from what the interpretation of article 39 is. TRIPS gives a country the option to choose whether or not to grant data exclusivity rights. The question as to whether or not a country should actually grant this right to pharmaceutical companies is a totally separate one, and that answer must be arrived at on its own merits and is not linked to the interpretation of article 39 of TRIPS.[38]

III. DATA EXCLUSIVITY LAWS IN NORTH AMERICA AND THE EU

Although courts across jurisdictions have not dealt with data exclusivity rights extensively, two relevant cases throw some light on the nature and extent of data protection rights. In *Ruckelshaus* v. *Monsanto Co.*,[39] the U.S. Supreme Court described the extensive practice of relying on data submitted by the first applicant in the U.S. and recognised that the relevant authority could use the data submitted by the originator to assess second-entrant applications. According to the law applicable at the time of the complaint, the applicant was entitled to compensation, but not to exclusive use of the data. On the other

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[37] UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, TRIPS AGREEMENT AND DEVELOPING COUNTRIES (UNCTAD/ITE/1) 48 (1996).

[38] It is crucial to understand this distinction as it negates the claims that as signatory to TRIPS, India is obligated to grant data exclusivity rights.

[39] 467 U.S. 986 (1984). The *Ruckelshaus* case relates to the protection of data submitted for the registration of an agro-chemical product. Though a subsequent applicant was obliged to compensate for the use of Monsanto's original data, Monsanto argued that such use undermined its reasonable investment-backed expectations and was unconstitutional. The basic argument of the plaintiff was that the possibility given to a competitor by US law of using the data submitted for the registration of a product without compensation nullified the data originator's "reasonable investment-backed expectation", which the court upheld.

hand, in *Bayer, Inc.* v. *Canada (Attorney General)*,[40] the General Court of Appeal of Canada decided, despite the fact that NAFTA provides for a minimum term of exclusivity, that the approval of a subsequent application on the basis of a prior registration was legitimate.[41] The Court observed that the health authority neither requested undisclosed information a second time nor examined it; the authority just checked whether the original and subsequent products were indeed the same.[42] The issue was decided under Canadian law and NAFTA article 1711.[43] The Court held that if the authority does not actually examine and rely on that confidential or trade secret information on behalf of the generic manufacturer, there is no use of data, and hence the exclusivity provision is not applicable.[44]

The popular argument in the USA and the EU nations is that data exclusivity is a mandatory right that must be granted by member states under TRIPS, since the manufacturer that developed the test data has invested heavily and deserves a fair return on investment. Where patent law fails to provide

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[40] Bayer, Inc. v. Canada (Attorney Gen.), [1999] 243 N.R. 170 (Fed. Ct.) (Can.).

[41] Correa, *supra* note 19, at 80.

[42] *Id.*

[43] The relevant portion of article 1711 reads:

> *(5) If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such data involves considerable effort, the Party shall protect against disclosure of the data of persons making such submission, where the origination of such data involve considerable efforts, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.*
>
> *(6) Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for the product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.*
>
> *(7) Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.*
>
> NAFTA, *supra* note 35, art. 1711.

[44] Correa, *supra* note 19, at 80.

protection unless data exclusivity is granted, proponents of data exclusivity argue that competitors would face no barrier to producing and registering an exact copy of the product.[45] In the EU, Council Directive 65/65[46] provides a period of data protection of either six or ten years, depending on the member state concerned: the larger member states provide ten years, while the smaller provide only six years. However, for products that are approved through the centralised procedure, Regulation 2309/93[47] provides a ten-year period of data protection. During this period of time, the regulatory authorities cannot approve any applications that seek to rely on the originator's data.[48] The U.S. law has changed since *Ruckelshaus*, with the passing of the Drug Price Competition and Patent Term Restoration Act of 1984,[49] otherwise known as the Hatch-Waxman Act, and in such a scenario the authorities now would be unable to rely on the plaintiff's data. U.S. law now specifically provides that a subsequent applicant cannot use the initial applicant's safety and efficacy data that the Food and Drug Administration (FDA) relies upon for approval for five years after the initial date of approval.[50] Furthermore, there is no requirement that the pharmaceutical product be patented, have current patent protection, or even be patentable.[51] Thus, the law protects non-patentable products or products whose patent protection will terminate before the five-year exclusivity period

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[45] Carlos María Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 83 (2004).

[46] Council Directive 65/65/EEC, 1965 O.J. (No. 22) 368, *reprinted in* 1965-1966 O.J. SPEC. ED. 20 (1972).

[47] Council Regulation 2309/93 of 22 July 1993, 1993 O.J. (L 214) 1 (laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products).

[48] INT'L FED'N OF PHARM. MFRS. ASS'NS, *supra* note 6, at 3-4. The new system adopted by the European Parliament in December 2003 employs an "8+2+1" period of data protection for all member states, granting an initial eight years of data protection for the dossier of an innovative pharmaceutical product. Subsequent to this, a generic company may manufacture and register an analogous drug, but cannot commercialize it until the end of the tenth year. This may be extended by one year if any new indications are discovered for the innovative drug. David Childs, *The World Health Organization's Prequalification Program and its Potential Effect on Data Exclusivity Laws*, 60 FOOD & DRUG L.J. 79, 81 (2005).

[49] 35 U.S.C. § 156 (1988). The Act prohibits competitors from relying on the data submitted by the originator for a five-year period after approval of the product associated with the data, if the product contains an active ingredient that had not been previously approved by the U.S. Food and Drug Administration.

[50] 21 U.S.C. § 355(c)(3)(D)(ii).

[51] *See id.*

expires.[52] However, an initial applicant may set up financial arrangements with subsequent applicants to use the dossier in attempts to secure marketing approval.[53] Applicants can obtain a 'right of reference' from the initial applicant, as per which permission is given by the initial applicant to rely on its data, after which the beneficiary of this right can submit its application regardless of marketing exclusivity.[54] Further, as a balance of incentives to first entrants in the markets, the Hatch-Waxman Act provides an extension of patent term for first products. Where a drug is approved by the FDA and a patent exists covering the drug, its use, or manufacture, an extension of the patent term can be granted, proportional to the period needed for regulatory approval of the product.[55]

However, infectious diseases kill over ten million people each year, more than ninety per cent of whom are in the developing world.[56] The magnitude of this crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering.[57] The reasons for the lack of access to essential medicines are manifold, but in many cases the high prices of drugs are a barrier to needed treatments.[58] The Doha Declaration on TRIPS and Public Health, 2001, emphasised that TRIPS should be interpreted and implemented in a manner that supports WTO members' right to protect public health and, in particular, to promote access to medicines for all.[59] For these reasons, various developing

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[52] John A. Tessensohn, *Reversal of Fortune—Pharmaceutical Experimental Use and Patent Infringement in Japan*, 4 J. INT'L LEGAL STUD. 1, 60 (1998)

[53] Childs, *supra* note 48, at 80.

[54] Junod, *supra* note 1, at 492.

[55] Erica J. Pascal, *The Billion-Dollar Naming Game: How Ambiguities in Patent Term Extension Provisions Allow Companies to Add Billions of Dollars to the Bottom Line*, 24 BIOTECHNOLOGY L. REP. 547, 548 (2005).

[56] Ellen 't Hoen, *TRIPS, Pharmaceuticals Patents and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 27 (2002).

[57] *Id.*

[58] *Id.*

[59] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2 (Nov. 14, 2001), ¶ 4, *available at* http://www.wto.org/english/thewto_e/minist_e/mindecl_trips_e.pdf; *see also* The Separate Doha Declaration Explained, *at* http://www.wto.org/English/tratop_e/trips_e/healthdeclexpln_e.htm. The Doha Declaration was designed to respond to concerns that TRIPS would make access to medicines difficult for patients in developing nations, and was the result of considerable discussion among developing and developed nations on the correct interpretation and role of TRIPS in this context. *See generally* Daya Shanker, *Access to Medicines, Paragraph 6 of the Doha Declaration on Public Health, and Developing Countries in International Treaty Negotiations*, 2 INDIAN J. L. & TECH. 8 (2006).

nations as well as human rights groups and NGOs argue that TRIPS does not mandate granting of data exclusivity rights. These polarising viewpoints have given rise to extensive debate about data exclusivity in various jurisdictions, including India.

IV. DATA EXCLUSIVITY: AN INDIAN PERSPECTIVE

A. The Current Legal Regime

The Drugs and Cosmetics Act, 1940 (DCA) regulates the import, manufacture, distribution and sale of drugs in India. The right of a manufacturer to market a drug arises upon the grant of a licence under the DCA and the Drugs & Cosmetics Rules, 1945. In 1988, major changes were introduced in the DCA to regulate the granting of approval of new drugs for manufacture or import.[60] Part X-A was added for the regulation of import of manufacture of new drugs including biological and special products. Rule 122-E gave a new and much wider definition of the term 'new drug'.[61] Irrespective of the fact that the safety and efficacy of a drug is established in another country, fresh data as to its safety must be submitted in India, but the level of clinical trials depends on the status of the drug in other countries.[62] Further amendments were made in 2001 to deal with requirements of subsequent approval, and Appendix 1-A was added to Schedule Y[63] as per which the entry of generic drugs is made relatively easy and expeditious under DCA. Generic manufacturers are only

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[60] N.S. GOPALAKRISHNAN & BENOY KADAVAN, STUDY ON TEST DATA PROTECTION IN INDIA 28 (2005).

[61] The new definition includes three categories of drugs where it is obligatory to provide data for approval. The first category is a new substance of chemical which is not used in the country for a long period and which has not been recognized as effective and safe in the country. The second category is an approved drug with new indication, dosage or dosage form. The third category is a new combination of two or more already approved drugs or an existing combination with new indications, dosage or dosage form.

[62] *See* SATWANT REDDY & GURDIAL SINGH SANDHU, MINISTRY OF CHEMICALS & FERTILIZERS, REPORT ON STEPS TO BE TAKEN BY GOVERNMENT OF INDIA IN THE CONTEXT OF DATA PROTECTION PROVISIONS OF ARTICLE 39.3 OF TRIPS 11, 42 (2007), http://chemicals.nic.in/DPBooklet.pdf. If the drug is already approved in another country, Phase I and Phase II trials are not to be conducted again in India. Only Phase III or confirmatory trials are required to be conducted. *See id.* at 47.

[63] Schedule Y talks about the "requirement and guidelines on clinical trials for import and manufacture of new drugs". Drugs and Cosmetics Act, 1940, sch. Y.

required to prove that the generic version is bio-equivalent to the original drug.[64] They are not bound to provide any other data mentioned in Schedule Y. This in turn allows them to enter the market quickly with cheaper generic alternatives. Thus, data with considerable effort is only insisted in case of new drugs introduced in the market for the first time.[65] This position is evidently in contradiction with the objective of data exclusivity. Under the Insecticides Act, 1968, any subsequent applicant for registration of the same insecticide has to be granted registration on the same conditions as imposed for the original registration. In other words, the subsequent applicant need not give data proving the efficacy and safety of the insecticide. He has to submit only the chemical composition and leaflets that were approved for the original registrant.[66]

Under pressure from various interest groups, the government has recently been considering proposals to amend the DCA in favour of data exclusivity. It is proposed to add a new section 18A for prohibition and liability for disclosure of information and to amend the Rules.[67] For approval under subsection (1) of the new section, the licensing authorities may ask for submission of undisclosed information by the applicant. Under sub-clause (2), the licensing authority will have to keep undisclosed information submitted for new drugs, unless the government by notification seeks disclosure of such information in public interest.[68] In addition, the Organization of Pharmaceutical Producers of India has requested the Government to amend Schedule Y of the DCA to include a provision for data exclusivity for a period of six years from the date of marketing approval.[69]

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[64] Letter from Anand Grover, Lawyers Collective HIV /AIDS Unit, to Prabhunath Singh, Chairperson, Petition Committee, Parliament House (Jul. 7, 2006), http://www.lawyerscollective.org/%5Eamtc/data_exclusivity/LCHAU_submissions.doc.

[65] GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 34.

[66] *Id.* at 38.

[67] Alfred Adebare, *Data Exclusivity: The Implications for India*, *at* http://www.articlealley.com/article_16562_18.html n.3 (noting that the introduction of § 18A will ensure that no person is entitled to the licence under § 10(c) or under § 18(c) for a drug unless approved by the licensing authorities in accordance with the rules prescribed under the DCA).

[68] *Id.*

[69] *Id.*

B. Arguments in Favour of Data Exclusivity in India

As mentioned earlier, drug developers contend that they cannot introduce new drugs in the market without data exclusivity laws to protect their interests. Proponents of data exclusivity refer to the success of the Hatch-Waxman Act in the USA, which has so far resulted in dramatic benefits for consumers. Within three years of its enactment, fifty-four more new drugs were under development and testing – far more than the total number of orphan drugs in the market on the date of enactment.[70] As of January 2001, a total of 212 orphan drugs had been approved, with another 855 drugs as candidates for development.[71] Hence, introduction of data exclusivity would end up benefiting the consumers in a big way. Furthermore, one of the most significant problems for developing countries like India is the formulation of products directed at diseases or conditions that are not normally found in developed countries. Drugs catering to the needs in India will only be developed if data exclusivity laws exist in India. It is only when sufficient protection is accorded to drug manufacturers that they will come to India and spend their resources and time on developing drugs for diseases endemic to India. Another argument is that granting a reasonable data exclusivity period will make India an attractive destination for research and development work.[72] Given these reasons, and international pressure as well as demands from the pioneer pharmaceutical industries, should India make way for a data exclusivity regime? To answer this question, let us examine the demerits of introducing data exclusivity in India.

C. Why Say No to Data Exclusivity?

Most drug manufacturers in India work only on generic drugs.[73] If data exclusivity is approved, domestic enterprises would be prevented from obtaining marketing approvals on the basis of the data submitted by the first enterprise that had generated and submitted the data. There are various reasons why data exclusivity rights should not be granted in India.

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[70] Skillington, *supra* note 12, at 12-13.

[71] *Id.*

[72] GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 41.

[73] *Id.* at 40.

Firstly, there seems to be no clear economic justification as to why data exclusivity should be granted to firms that already avail a patent protection term of twenty years globally for their products. The Patents Act, 1970, was recently amended by the Patents (Amendment) Act, 2005, introducing many changes favourable to the pharmaceutical industry, including re-introduction of product patents for drugs, medicines, and foods, including products of chemical reactions.[74] The patent term has been made twenty years from the date of submission of the complete specification. New and wider definitions of terms relevant to the pharmaceutical industry have been given under the amended Act. Indian companies such as Dr. Reddy's, Sunpharma and Cipla are also of the view that data exclusivity will prolong the monopoly already given by product patents.[75]

If the generic industry in India is curbed further, a large amount of cheap supply of medicines at very competitive prices will be seriously affected. In practice, data exclusivity terms, since they are granted from the date of introduction of a particular product in a given market, may have the effect of extending the monopoly term of the patent holder beyond the term of the patent and delaying the entry of generics.[76] A hypothetical situation could help in explaining this argument. Assuming Indian law granted data exclusivity for five years, this would mean that a patent granted for a product in 1995 would be valid until 2015 under the amended Patents Act. However, if this product were introduced in the Indian market only in 2011, then data exclusivity in Indian law would protect the regulatory data submitted by the company until 2016 thus delaying the entry of generics, and extending the product monopoly for another year beyond the patent period.[77]

Secondly, India is a major supplier of the world's generic medicines and exports two-thirds of its generic drugs to developing countries. The excellent capability of Indian pharmaceutical industry to produce generic drugs at

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[74] *See generally* Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment Act), 2005*, 1 INDIAN J. L. & TECH. 15 (2005).

[75] GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 42.

[76] Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry*, *at* https://www.who.int/entity/intellectualproperty/studies/PadmashreeSampathFinal.pdf.

[77] *Id.*

affordable cost is a well-established fact.[78] These exports are critical for addressing and treating a great number of public health illnesses and in the global fight against AIDS.[79] India has been largely responsible for reducing the prices of antiretroviral drugs by as much as 98%.[80] Thus, Indian generic manufacturing clearly plays a vital role in the global fight against diseases.[81] If data exclusivity rights are granted, this respectable status that India enjoys in the eyes of the developing world would certainly be lost and new data exclusivity provisions may have a disastrous affect on health conditions worldwide.

Thirdly, the research-based pharmaceutical industry claims that data exclusivity provides incentives for companies to generate the necessary data, since without marketing exclusivity, brand-name companies would not want to conduct expensive preclinical tests and clinical trials.[82] This argument is flawed because pharmaceutical companies do not need incentives to produce preclinical and clinical test data because they have no choice in that matter: they must supply this information if they want to sell their drugs.[83] Preclinical testing and clinical trials are a requisite for any new drug marketing application.[84] In India, the tests have to be supplied to the Drug Controller General of India (DCGI), whether or not marketing exclusivity is granted.

Fourthly, one of the perceived gains of data exclusivity is an increase in foreign direct investment in the pharmaceutical sector and the arrival of newer medicines for Indian patients. The argument that data exclusivity laws will encourage the introduction of new medicines into the Indian market betrays a misunderstanding of their implications. In fact, there is a possibility that data exclusivity would actually provide incentives to delay the entry of new products

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78 GOPALAKRISHNAN & KADAVAN, *supra* note 60, at 40.

79 *See AIDS Drugs Threatened*, N.Y. TIMES, Mar. 5, 2005, at A12, http://www.nytimes.com/2005/03/05/opinion/05sat3.html.

80 Health Global Access Project, *India Could Cut-off Africa's Access to Affordable AIDS Drugs; Indian Parliament May Begin Considering the Issue*, *at* http://www.healthgap.org/press_releases/05/030104_HGAP_AA_INDIA_IPR.html.

81 Jeremy Clark Ogusky, *Data Exclusivity Regulations in India*, *at* http://www.bilaterals.org/article-print.php3?id_article=5425.

82 *See* INT'L FED'N OF PHARM. MFRS. ASS'NS, *supra* note 6, at 1.

83 Junod, *supra* note 1, at 485.

84 *Id.*

for MNCs would prefer to keep prices high in developed markets by delaying their entry into the developing world at lower prices.[85] This is because introducing the drugs in developing countries at lower prices will invariably lead to a fall in their price globally also. To preserve that high price, new drugs would only be introduced after a delay in developing countries.

Fifthly, data exclusivity would render redundant the use of a compulsory licence, a market exclusivity waiver on patents provided by TRIPS in the event of a health emergency. A compulsory licence is the instrument available in India to curb the abuse of monopoly by multinational companies. The government can issue such a licence after three years of the grant of the patent, if it is found that the patented drug is not available, or it is too expensive, or the development of domestic industry or an expert market is hampered. However, if data exclusivity laws are introduced, they may act at cross purposes with compulsory licences, because the DGCI may have to ask Indian companies to conduct fresh clinical trials before getting marketing approval.[86] There is a possibility that the domestic sector may not be able to duplicate even its own data for getting marketing approval even when the companies may be granted a compulsory licence for meeting the demands for some patented products.[87]

Sixthly, in order to enter even small and marginally profitable markets, generic competitors would be required to duplicate expensive and time-consuming clinical trials in order to establish safety, quality, and efficacy. Another concern is that animals and other research subjects are dangerously exploited if the second applicant has to replicate studies already performed by the pioneer company.[88] If the same agency has approved a drug based on clinical data provided by one company, there is no logical reason why the same drug should be refused marketing approval if another company produces it.

Finally, currently, the DCA defines 'new drug' requiring regulatory approval as something much wider in scope than 'new chemical entity', including drugs

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[85] Grover, *supra* note 64, at 4.

[86] Dalal, *supra* note 2.

[87] Adebare, *supra* note 67.

[88] Junod, *supra* note 1, at 486.

"proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form … route of administration."[89] If the data exclusivity law is enacted as mandatory for all 'new drugs' as presently defined under the DCA, drug companies will be able to enjoy *de facto* monopoly rights over trivial changes that may not even be patentable under patent laws for lack of inventiveness, but still qualify as new drug under the DCA. This can arguably constitute protection to an unreasonable extent for pioneer pharmaceutical companies. The extension of intellectual property beyond its boundaries, so as to protect investment and not intellectual contributions, disrupts the essence of a system conceived to reward the creators of original ideas and new inventions.

V. CONCLUSION

Considering the fact that various interest groups are seeking amendments in Indian law to introduce data exclusivity provisions, the issue is a crucial one. As noted above, there are several reasons why data exclusivity laws should not be brought into India at this stage. An analysis of article 39 of TRIPS and its legislative history indicates that TRIPS speaks of data protection in a flexible manner, and does not mandate data protection to be implemented by bringing in a data exclusivity regime. Thus, the argument that data exclusivity must be provided for in Indian law for India to be in compliance with TRIPS is fallacious. Protection against "unfair commercial use" under TRIPS must be interpreted to mean protection through non-disclosure and prohibiting others from accessing test data for unfair commercial use. TRIPS gives member states the freedom to choose the nature and extent of protection they want to offer. This interpretation of TRIPS finds support from most Indian pharmaceutical companies.[90]

Most Indian companies recognise the government's use of data as an exception and support allowing authorities enough discretion to use research data for comparison with a subsequent product's data.[91] Use of pioneer data by the authorities for granting approval to a subsequent product is not an unfair

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[89] Dalal, *supra* note 2.

[90] Gopalakrishnan & Kadavan, *supra* note 60, at 42-43.

[91] *Id.* at 43.

commercial use, but is a harmonious balance between public and private interests, and is also the exercise of a sovereign function of the licensing authority. The introduction of product patents in India has provided further protection to pioneer manufacturing companies, and the generic industry in India as well as the general health of ordinary citizens seems likely to suffer if data exclusivity were brought into effect in India. Thus, it does not seem advisable to enact data exclusivity laws in India or to amend the DCA or the Insecticides Act to accommodate data exclusivity.

This, however, does not mean that no change at all is required in data protection laws in India. While, a specific clause should be introduced that allows the DCGI to demand undisclosed information for drug approval for manufacture of generic drugs,[92] at the same time, provisions creating obligations on the part of the DCGI to keep the undisclosed information submitted to them secret should be introduced so that information is not leaked to other competing companies. While the Indian pharmaceutical sector is largely against data exclusivity, it does support a stronger system of data protection in India.[93] There is no express provision in the DCA or the Rules obligating the Drugs Controller General of India to keep the data submitted to him under these laws in confidence. Although Rule 53 creates an obligation on part of the Drugs Inspector to keep the information supplied to him secret, this has not been extended to the office of the DCGI.[94] In the absence of such a provision, the DCGI may not be covered by the Official Secrets Act, 1923 eiheeither. The common law protection of trade secrets submitted to the authorities has not extended to India through case law as of now.[95] Thus, there seems to be a lacuna in the law for ensuring protection of undisclosed information submitted to the DCGI for approval. Strong trade secret protection laws are thus required to fill this void and to satisfy the demands of the Indian pharmaceutical sector. Thus, the DCA should be amended not to focus on data exclusivity but to introduce mandatory provisions for ensuring the safety and quality of drugs.

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[92] *Id.* at 46.

[93] *Id.* at 44.

[94] *Id.* at 35.

[95] *Id.* at 36.

Until the Indian market reaches a stage at which data exclusivity laws will be useful or conducive to the Indian pharmaceutical sector, the move to amend the DCA and other laws to accommodate data exclusivity should therefore be opposed, subject to the introduction of the changes recommended in this article.