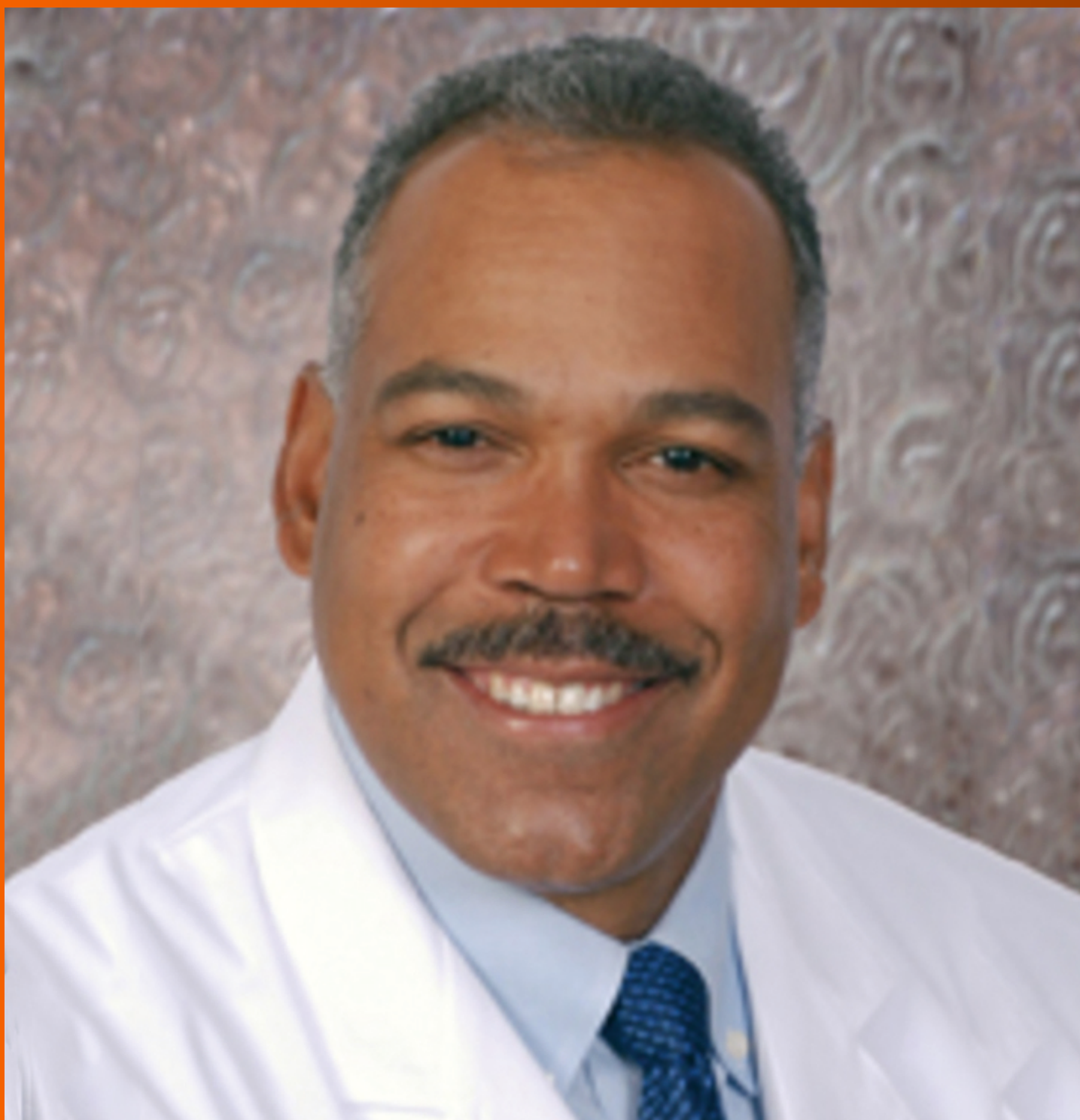


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Patents and intellectual property in orthopaedics and arthroplasty

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Abstract

The provision of musculoskeletal services comes at a cost. This is, in part, due to the expense of patent-protected orthopaedic implants. However, patents have a finite lifespan. Patents of the most successful implants are now beginning to expire. They will be exposed to competition from generic but equivalent implants. The net effect is potentially a dramatic diminution in cost. One company, Orthimo, has taken advantage of this and begun manufacturing generic implants with identical design specifications to the most bio-durable hip prostheses. This will ultimately have a radical impact upon musculoskeletal healthcare provision with regard to cost and accessibility. The expiration of drug patents, with the subsequent use of generic drugs saves £7.1 billion annually in the United Kingdom and \$254 billion in the USA. Estimates suggest the introduction of equivalent implants could result in an annual cost saving to the United Kingdom National Health Service of £120 million. Intellectual property remains an enigmatic area of law. It encompasses anodyne principles that seek to protect innovation but are open to manipulation and exploitation. The last decade has seen the emergence of undesirable practices in the medical industry such as "patent trolling". Here we explore patents and their repercussions for musculoskeletal care.

Key words: Patent; Arthroplasty; Patent trolling; Implant approval; Intellectual property; Health care costs

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Core tip: Patents for the most successful orthopaedic implants are due to expire. This provides a novel opportunity to transform healthcare and the accessibility of arthroplasty devices.

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INTRODUCTION

The demand for orthopaedic services represents a significant challenge for the future provision of healthcare worldwide. In the United Kingdom this was highlighted in the flagship "Getting it Right First Time" (GIRFT) Report^[1]. £10 billion of the £110 billion annual NHS budget is attributable to musculoskeletal services; third only to cardiac and mental health care^[1]. A significant component of the cost is due to the value of orthopaedic devices. The GIRFT report identified a reduction in the cost of orthopaedic implants as one of its key short-term goals. The National Joint Registry of England Wales and Northern Ireland reported 93234 primary hip arthroplasties were performed in England and Wales alone in 2016^[2]. By 2017 this had risen to 96717; a 3.7% rise in a single year and hurtling toward the 100000 threshold^[3]. The corresponding figures for primary knee and shoulders arthroplasty were 3.7%, and 9.1% respectively^[4-7]. Future projections are daunting. It is estimated that in the United Kingdom alone, the annual rates of combined total knee and hip arthroplasty procedures may be as high as 1.5 million by the year 2035^[8]. It is not clear if such increases are financially sustainable. The end-of-year net deficit for the United Kingdom National Health Service was reported as £2.45 billion^[9]. By 2020 the annual deficit may soar to £20 billion^[10]. Lord Carter of Cole, in his 2015 report, commissioned by the United Kingdom department of Health to address this polemic; identified specialty areas in the NHS where financial savings were necessary and possible^[11]. Annual savings of £283million were possible in orthopaedics^[10]. This represented the third highest figure; superseded only by the General Medicine and Obstetrics and Gynaecology. Lord Carter, like the GIRFT report, highlighted the cost of orthopaedic implants and devices as one of the cardinal areas in which costs savings should be made. However considerable and unexpected savings may come from an unlikely source.

The orthopaedic landscape is potentially on the verge of a radical change. Until very recently the most successful orthopaedic implants were protected by patents such that they could only be manufactured by those who invented the devices or those to whom patent rights were transferred. However patents have a finite lifespan. Once this expires other manufactures can create the exact same implant without infringement of intellectual property rights. These imitations are known as generic devices. The introduction of generic products in all other areas of healthcare provision has been accompanied by a precipitous fall in the product price; facilitating access to various aspects of health. The device is immediately available from other providers, with competition resulting in "price decay". It is estimated that the transition to generic drugs; following the expiration of patented drugs from 1976; saves the NHS annually over £7.1 billion^[12]. In the United States the annual saving from generic drugs is astronomically high at \$254 billion^[13]. Analogous savings in the field of orthopaedic implants could radically transform healthcare, not only in the United Kingdom, but globally; positively impacting upon the accessibility to life-changing intervention. The touch paper was lit at an engaging and instructive debate at the British Orthopaedic Meeting, involving an experienced and authoritative panel on the topic of generic implants. It revealed the controversy and uncertainty involved in this area of orthopaedic practice^[14].

INTELLECTUAL PROPERTY

Intellectual property refers to a concept which has some tangible or concrete manifestation that is assigned to specific owners^[15]. In orthopaedics and medicine in general intellectual property rights are protected by means of patents and copyright.

PATENT

Patents allow the inventor of an orthopaedic implant the right to prevent others from manufacturing, selling that creation without the inventor's consent^[16]. In effect the

originator has the exclusive right of manufacture and sale. The patent can be owned by corporations, a group of people or an individual. Rights under patent can also be transferred or sold. An application must be made for the patent to be applied nationally or internationally. In the United Kingdom patents applications are made to the Intellectual Property Office. National patents will only protect the invention in the nation in which the patent is applied. However it does not prohibit reproduction of the implant abroad. International patents provide protection overseas. A single application can be made under the Patent Cooperation Treaty provides patent covering 140 countries. Application made under European Patent Office covers 30 European nations^[17].

Patents have a finite lifespan. They do not exclude others from imitating the product indefinitely. There has been global harmonisation following implementation of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement)^[18]. Hence patents last for 20 years^[16]. Once this period has expired any manufacturer can create the equivalent products. Globally there are in excess of 1 million hip arthroplasties are implanted annually^[19]. Stryker, DePuy Synthes and Zimmer Biomet Holdings sequester over 75% of the worldwide market for hip and knee implants^[20].

PATENT EXPIRY AND FINANCIAL SEQUELAE

The exclusivity provided by patents confers to the manufactures considerable control on the price and availability of the product. This was highlighted in Lord Carter's report where he identified that the variation of the cost of primary hip prosthesis from £788 to £1590^[10]. Further there was little correlation between the number of prostheses used by trusts and cost. However, very recently the patents protecting the Exeter and Corail hip arthroplasty systems both expired; allowing other providers to produce equivalent implants. This impacts directly upon cost and accessibility of products. The ultimate ramifications for healthcare provision with regard to orthopaedic devices are extensive and pervasive.

Experiences with bisphosphonates are instructive. The patented form of alendronic acid, Fosamax was produced by Merck Sharp and Dohme Limited. It was given US Food and Drug Administration (FDA) in 1995^[21]. In 2004 the price of the drug in the United Kingdom was £300/year. The patent expired in 2008. Currently the price of generic alendronic acid is £14/year^[22]. This represents a 95% fall in price with the advent of generic alendronic acid. This had considerable ramifications with regard to accessibility. Prior to the introduction of generic bisphosphonates, this class of drug was not included in the national guidelines in the United Kingdom or Europe for the treatment of osteoporosis due to the prohibitive effect of costs^[21,23,24]. In the same year the in NICE 2080 guidance it became firmly established as the cornerstone of management^[25]. A similar pattern was observed in the rest of Europe^[26].

Most economic models show that once a patent expires the entry of generic products into markets results in "price decay" which is a fall in the price of the product. This stabilises at around 2%-10% of original patented drug price by 3 years^[27]. Price depreciation is slower if there are fewer competitor manufacturers of the product or it is of a sophisticated design. However, similarly precipitous declines in the cost of orthopaedic implants could potentially transform healthcare provision. In the United Kingdom according to the National Joint Registry 88763 primary hip arthroplasties were performed in 2014^[3]. NICE determined in their latest hip arthroplasty guidance the weighted mean cost of a total hip replacement was £2571 including the cost of cement^[28]. The net expenditure on cement, based on the percentage of cemented, uncemented, hybrid and reverse hybrid fixation is £111. Hence the mean prosthetic cost is £2460. Extrapolating from these figures, the introduction of generic hip implants could potentially save the NHS near £200 million annually if the price equilibrium nestled at 10% of innovator cost. This is a significant proportion of Lord Carter's target saving for orthopaedics of £283 million. The effect may even have a significant impact on private healthcare making it more accessible by reducing the cost of private hip arthroplasty in the region of 20%^[29].

GENERIC ORTHOPAEDIC IMPLANTS

The patent application process requires the applicant to explicit the features of the implant which make it unique and efficacious. These are then protected for the term of the patent. However, the details of any patent are publicly available. If it were not, corporations would not know if they were potentially infringing upon patents when

introducing new design. Indeed patent is derived from Latin *patere* “lay open or bare” for public view. Hence when the patent expires other manufacturers can use the content of the patent application as a blueprint to imitate the design. In addition to the information available on the patent, a process known as “reverse engineering” is employed to produce an identical product. This involves extracting the structure and design from the product itself, in part by means of high resolution 3 dimensional computer assisted analysis using computerised tomography for example^[30].

The current pioneer and protagonist in the orthopaedic imitation implants is Orthimo^[31]. The company was founded in and is based in Switzerland with satellite offices in Europe. The first challenge faced by Orthimo was to determine which of the implants on the market to duplicate. However, the solution produced the safest but also most profitable device. The corporation interrogated national joint registries including that of England and Wales, Australia, and Sweden to determine the most durable prosthesis. The England and Wales NJR revealed the implants with the best survivorship were the cemented Exeter V40 stem/contemporary cup (Stryker) dyad with ceramic on polyethylene bearing surface and the uncemented Corail with ceramic on polyethylene interface. The 10-year revision rates were similar for both at 2.70% (1.72-4.21) and 2.19% (1.40-3.41) respectively^[32]. The longevity of the Exeter contemporary and Corail systems were also confirmed in oldest joints registries including the Swedish (est. 1975)^[33], New Zealand (est.1998)^[34] registries. This paid testimony not only to the durability of the implants but also the reproducibility amongst surgeons. The reference implants Orthimo selected were the Exeter cemented stem (Stryker), Charnley Elite Plus LPW (Depuy), Corail uncemented stem (Depuy) and Trident uncemented cup (Stryker). The generic Exeter prosthesis is named the Optistem XTR and Opticup^[31]. The uncemented Corail equivalents are the Optistem CRL and Opticup TDT.

APPROVAL OF GENERAL DEVICES

In the pharmaceutical industry expiration allows manufacture of the same drug. The FDA determines the generic drugs formulation on the basis of studies submitted to it. The confidence interval for the generic's bioactivity must be between 75% and 125% of the innovator product. This is often misconstrued as meaning FDA allows drugs with 75% of the bioefficacy of the innovator. This is not the case the range represents the statistical confidence interval of bioactivity on the basis of studies submitted to FDA^[21].

With regard to orthopaedic implants the generic implants must first comply with international standards of metallurgical composition and metal grain size required for all orthopaedic implants laid down by the International Organisation for Standardisation^[35]. With regard to the US FDA there are two modes of approval. The first is the premarket approval process^[36]. The FDA has provided prescriptive criteria to which, for example, hip^[37], knee and shoulder implants must comply^[38]. This requires extensive and comprehensive evaluation of the device with robust clinical trials showing that the implant is safe for use in patients. This is a protracted, exhaustive and expensive process. It may last up to two years excluding the time expended for the essential laboratory pre-clinical trials and subsequent clinical trials. The expense is in the region of \$250000^[39]. However for devices based on patents there is a second pathway: The 510(k) approval process^[40]. Here the FDA will approve an implant that is “substantially equivalent” to a device that is previously approved. The applicant must satisfy the FDA that new device: “has the same intended use as the predicate; and has the same technological characteristics as the predicate; or has the same intended use as the predicate; and has different technological characteristics and the information submitted to FDA; does not raise new questions of safety and effectiveness; and demonstrates that the device is at least as safe and effective as the legally marketed device.”

The FDA goes on to state that: “A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility, standards, and other characteristics, as applicable.” Generic implants would fall into this category. However the 510(k) approval process has received much criticism as it is the process by which the much maligned and now withdrawn ASR hip was approved. Although the ASR hip is distinct from generic implants, given that it was submitted as an implant that was substantively different to other implants^[40].

In the EU and United Kingdom a similar “approval for marketing” paradigm is

operative for implants. Manufacturers must prove conformity with EU Medical Devices Directive (MDD) (Council Directive 93/42/EEC) and Medical Device Regulations 2002. They are then awarded a certificate indicating "Conformité Européenne" (CE)^[41,42]. In the EU the process of approval is delegated to authorised bodies known as "notified bodies". The fee charged by the notified bodies can range from £2240 to £4100^[43]. In the United Kingdom notified bodies are approved and accredited by the Medical and Health Products Regulatory agency (MHRA)^[44]. Each member state will have its own notified body accreditor. Applicants for the CE certification within the EU are free to apply to any notified body within the EU.

There is no expedited 510(k) pathway. However proof of equivalent design to an established prosthesis will inevitably accelerate the process. As part of the approval pathway the notified body is required to sample the applicant company's devices. To ensure that these comply with the design specifications alleged by the company; which in turn must adhere to the requirements of the EU MDD. If these are identical to the design specifications of an approved but patent-expired stem such as the Exeter or Corail and the generic manufacturer's implants are found to meet this specification, it is difficult to see how any regulatory body be it the FDA or EU can decline approval. If it were to decline approval it is not clear on what grounds such refusal could be made. However the failure of the EU approval process to eliminate the ASR hip has raised concern in the EU with regard to the rigour with which notified bodies evaluate proposals. Recent legislative amendments have been implemented with a view to making the review process more robust and transparent.

In the United Kingdom there exist additional strata of regulation for implants in the form of NICE and Orthopaedic Data Evaluation Panel (ODEP). NICE in their 2014 guidance on hip arthroplasty recommend that only implants with survivorship of 95% or greater at 10 years should be used^[30]. Their guidance also suggests that implants with over 3 years of follow-up can also be used; if on extrapolation of the survivorship figures, their 10 years estimates are equivalent to or superior to the 95% benchmark. NICE in addition make reference to ODEP. They provide the NHS with a rating on implants in the United Kingdom depending on the duration of follow-up and implant survival. The optimum rating is 10A* for implants with greater than 10 years follow-up and very strong clinical evidence of 90% or greater survival at 10 years^[45]. New devices are given one two ratings, Pre-entry and Pre-entry A*. The latter is reserved for those introduced under the auspices of "Beyond Compliance". This independent body provides support and guidance for manufacturers; facilitating the safe and incremental introduction of new implants into the United Kingdom^[46]. Orthimo Optistem, and Opticup were awarded the Pre-entry A* rating by ODEP^[47] and at the safest, Level 1 risk rating for Beyond Compliance. This is the safest risk rating and usually reserved for a branded product line extension. Orthimo use the same manufacturer for their prosthesis as Corail. There is only one outlet for polyethylene cups use by Corail Exeter and Orthimo.

POINT OF ENTRY OF GENERIC IMPLANTS INTO HEALTHCARE SYSTEMS: SAME OLD OR BRAND NEW?

The point of entry of generic implants such as the Orthimo Optistem depends on it is deemed to be a substantively new implant or only new in name alone (nominally new). Given that Orthimo manufacture the Optistem to the same design specification as the Exeter and Corail, with the same manufacturer as the latter, it is difficult to argue it is a materially different implant. This is a fortiori if it passes the necessary audits of the EU MDD confirming conformity with design specifications. One could theoretically pursue a line of argument that this is substantively different device. However, a necessary sequitur from that would be that whenever Stryker or DePuy change or add a different manufacturer for their prostheses they too would have treat prostheses from this new manufacturer as a new device and follow the same catenation of steps for approval and produce new 10-year data. This is even if the new manufacturer used the exact same design specifications. Most would consider this to be over-zealous. However, this is effectively the requirement which Orthimo Optistem must meet. Nonetheless some degree of caution is required. The difference between hip prosthesis and much other patented technology is that most other devices were created by design. In the case of the hip prosthesis most of the favourable features that endow longevity, be it nature of the taper or the polished stem, were discovered by serendipity^[48]. They were not conceived *ab initio*; rather their significance was often only appreciated where new designs deviated from the originator and failed rapidly^[48]. Hence it is conceivable that another factor (factor X), *outside* of the design specifications, that differ between manufacturers may have an

adverse or even favourable effect on outcome, that is hitherto unanticipated. This possibility is increased by the fact that only a limited number of parochial manufacturers produce hip prosthesis. The manufacturing process has not been exposed to heterogeneity of production milieu; as would be the case if there were globally distributed production centres. Consider two manufacturers produce implants to the exact same specification. However in one unit but not the other, the process is coincidentally exposed to another factor be physical, chemical, biological, synthetic or organic, that is thought not to affect prosthesis longevity and hence is not covered by the manufacture process specification. This factor then impacts upon implant survival. This can happen as the parameters which determine longevity or precocious failure have not been exhaustively elucidated. It is only in hindsight that flaws of the Capital and ASR systems are apparent^[49-51]. The role of factor X may be less relevant with generic implants as currently there exists only one outlet for polyethylene cups. However, Orthimo and Exeter use different manufactures for the stems. This may be science fiction. However, it would also be hubris to regard Exeter data as complete vindication of the Optima Stem. Where generic stems are used patients must be appropriately counselled and consent.

If Orthimo prostheses successfully achieves a 3A* rating it is not clear if other manufacturers would see this as catholic vindication of generics and not feel so obliged to pursue such a deliberate process in the implant market. 3A* rating satisfies the NICE guidance for arthroplasty both in the context of osteoarthritis and hip fracture^[30,33]. Further, the success of the implant with regard to longevity of Orthimo may make surgeons more accepting of generic implants as a species.

However evaluation of survival at 3 years may be in some ways premature. It is likely that that in its infancy the generic prostheses will only be predominantly implanted by experienced surgeons. Hence a more robust test of reproducibility of results will be 10-year data. In a BOA debate on generics Mr T. Nargol one of the key researchers involved in elucidating and communicating lessons from ASR hip advocated a co-ordinated system of implant retrieval and examination for failed generic implants^[13,52]. This allows the mode of failure to be determined and compared with that of well characterised prostheses. It also permits the expeditious detection of systematic structural failings that may precipitate premature implant failure.

PATENT TROLLS AND THE ABUSE OF INTELLECTUAL PROPERTY PROTECTION

Patent system is open to abuse. Increasingly in recent years nefarious and undesirable practices have started to emerge. There exist what has been termed Non-Practising Entities (NPE). These bodies purchase patents with *no* intention of producing or developing the product^[53]. Rather they search or wait for others to do so and then initiate legal proceeding claiming their patent rights have been infringed with a view to compensation. Universities have become a fertile ground for NPEs to operate by purchasing patents right from researchers affiliated to these institutions. NPE's are also pejoratively referred to as "patent trolls". The most high-profile commercial case involved Apple's Siri. A team from Rensselaer Polytechnic Institute (RPI) created a means of computer processing computer, assigning their patent to the institute. Marathon Patent Group who had no involvement in the genesis of this system learn of the patent, acquired part of the rights and filed a suit on behalf of RPI against Apple. They contend that Siri constituted infringement of copyright. The case was settled for out of court for £17million^[54]. Orthopaedic industry has become nubile territory for patent trolls with some of the most dominant manufacturers repeatedly falling prey to this form of strategic litigations. In 2013 a subsidiary company of Acacia Research Corp, an NPE, purchased 150 patents relating to orthopaedic technology. They made no attempt to develop the patents but rather issued proceeding against Biomet for infringement of copyright. The latter settled out of court^[55]. Orthophoenix a subsidiary to NPE, Marathon Paten Group acquired patents form Medtronic relating to kyphoplasty technology^[56]. It proceeded to take similar action against Stryker but was unsuccessful^[56]. Indeed the orthopaedic industry is so lucrative that an NPE, Wi-Lan has a subsidiary named Orthopedic Innovations whose sole purpose to purchase and sequester orthopaedic patents or "build of an orthopaedic patent portfolio" to use industry jargon. Like other NPEs; there is no intent to develop the patent but rather merely issue proceeding when others who produce devices even of tangential similarity. As an insight into the tenacity and intrepidity of NPEs, Orthopedic Innovations brought a simultaneous multiparty suit against orthopaedic market giants Stryker, DePuy, Zimmer, Biomet, ConforMIS and Medacta all for allegedly infringing their copyright for distal femoral cutting blocks

and flexion/extension gap evaluation^[57]. DJO Global medical devices manufacturer settled out of court with Orthopaedic Innovations for an undisclosed amount following a similar earlier suit^[57]. The definitive outcome of the lawsuits against the other firms is less clear. NPE use the legal system to the advantage. In the United States the process of defending against litigations that can be so financially exacting that it in many cases it may be more cost-effective to settle even where claims of infringement are tenuous or the merits of the case questionable^[53]. Proposed new legislation in the US in the form the Innovation Act and Protecting American Talent and Entrepreneurship Act of 2015 are aimed at curbing the predatory litigation of patent trolls^[53]. They require litigants to precise the exact patents allegedly being infringed rather than allowing the formulation of nebulous claims from widely-defined patents. This introduces new modes of disputed resolution where the merits of case be evaluated prior to formal legal proceedings in court. Hence the proposed legislation gives US Patent and Trademark Office greater discretion to require that parties initially present their dispute to a new administrative body the Patent Trial and Appeal Board. The aim is to curbs cost and make the process more expeditious. Initial evaluations of infringement claims will occur such that frivolous claims are dismissed in limine.

All orthopaedic surgeons in research or innovation can be a target for patent trolls, seeking to acquire the rights to their patents. The proposals can be superficially appealing with the prospect of immediate remunerations and the added incentive of further gains in event of any other group attempting to develop the product or innovation. However, anyone succumbing to such advances of patents trolls effectively blocks their own contribution to healthcare improvement while creating financials hurdles for anyone else wishing to do.

Intellectual property has a profound effect on healthcare provision, which is not immediately apparent. The expiration of key patents potentially allows healthcare systems to take advantage of highly effective devices that become financially more accessible. However, cost saving cannot come at the expense of patient safety. Vigilance, surveillance and traceability remain essential for all new generic devices. The emergence of equivalent implants may herald a commercial renaissance for global healthcare and present a significant opportunity for pioneers such as Orthimo. However, the market is fiercely competitive; even Orthimo struggling to establish itself against competitors who have monopolised the market for decades with an audience of surgeons who can be conservative^[58]. Similarly the original "magic circle" of Orthopaedic industry faces tangible threats from generic devices but also relentless patent trolls. They must innovate and evolve or risk extinction.

CONCLUSION

Arthroplasty and much of orthopaedics involve life-changing surgery. Given that the patents for the most durable implants have now expired, there is a unique opportunity to increase access, as financial constraints slacken. The cardinal question, however, remains how receptive the orthopaedic community will be to generic design equivalents. The purpose of patent law is to promote innovation and creativity. However the system is open to manipulation; as the 21st Century has seen the rise of the enigmatic patent troll, who patents inventions and yet does not develop them. However they lie in wait for the unsuspecting inventor and claim their intellectual property rights when the original idea has been realised. Caveat inventor.

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