Monetisation models in biotech and pharma

Pharma and biotech companies are lagging behind when it comes to squeezing value from their IP assets. Are rights holders missing a trick or are the barriers in this sector much tougher? And are there social costs to this failure?

By **Sherry M Knowles**, **Adrian Dawkes**, **Bill Geary**, **Brent Bellows** and **Karl Normington**

Major IP monetisation deals in the computer, electronics and device sectors have been reaping eye-popping returns for patent holders, while the pharmaceutical and biotech industries look a bit like awkward kids at a high-school dance where everyone else is having a blast and they do not quite get it. These industries are not feeling the love. Some critics say the pharma and biotech industries are fundamentally not structured to benefit from monetisation models, while investors, auctioneers and patent accumulators scratch their heads and wonder whether they are missing hidden gems. Pharma insiders note that industry players would rather abandon pharmaceutical patents that they are not using than attempt to extract value. What is the truth about barriers to monetising pharma and biotech IP assets, and is there a path forward? And – more troubling – what is the current social cost of not monetising pharma and biotech assets?

One might conclude that due to the vast diversity of pharma/biotech products, it is not possible to create pharma or biotech inventions of broad applicability that have great industry-wide monetisation potential. That would be wrong. Ten examples of disruptive patented technologies that have had high monetisation value in the life sciences sector include the following:

- **Cohen-Boyer patents (Stanford/Univ of California)** – these patents covered the process of creating recombinant DNA by molecular cloning, which uses a living cell to produce DNA from another source. The patents, which expired in 1997, generated US$225 million for Stanford University and the University of California.
- **Polymerase Chain Reaction patents (Cetus Corporation/Hoffman LaRoche)** – Nobel prize-winning technology used to amplify DNA outside of a cell was invented by Kary Mullis and developed initially by Cetus and then jointly with Hoffman La Roche, which bought the worldwide rights in 1991 and is still actively commercialising the technology.
- **Cabilly patents (Genentech)** – the Cabilly patents, which have been the subject of much litigation over inventorship and validity, cover the expression of monoclonal antibodies in a host cell. This technology is used to produce leading commercial antibody drugs, including Humira (Abbott Labs), Synagis (MedImmune), Campath (Genzyme), Remicade (Johnson & Johnson) and Rituxan (Genentech/Roche). The Cabilly patent expires in 2018.
- **Winter patents (Medical Research College, United Kingdom)** – these patents cover the technique of humanising antibodies, which allows antibodies created commercially in cell lines to look more like real human antibodies, reducing immune responses when administered to humans. The technology has been licensed to over 50 companies.
- **HCV genome patents (Chiron, now part of Novartis)** – Chiron holds over 100 patents related to the HCV genome, some of which will not expire until

2015. Chiron takes the position that any company that develops a new drug for HCV, or a diagnostic test, needs a licence.

- **Axel patents (Columbia University)** – the Axel patents cover a process to introduce at least two genes into a cell (called co-transfection), which allows one to add both a gene of interest and a marker into a cell so that a researcher can select the cells that have been transformed. The patents have reportedly generated US$790 million for Columbia University.
- **Fluorescent activated cell sorting (Stanford)** – the research of Dr Herzenberg at Stanford provides a means to purify cell populations from a mixture, including sorting cells from small samples of human blood and identifying a small number of cancer cells from a sample. The patents were licensed to Becton Dickinson, which has a line of products used in many areas of research.
- **Human embryonic stem cells (Wisconsin Alumni Research Foundation (WARF) and WICELL)** – WARF owns the early patents of James Thomson covering human embryonic stem cells. These have been licensed to WICELL, a non-profit licensing affiliate.
- **Induced pluripotent stem cells (Yamanaka at Kyoto University and Yu/Thomson at WARF)** – the induced pluripotent stem cell technology provides a process to convert an adult cell into an embryonic cell for research or therapeutic purposes. Dr Yamanaka is the co-recipient of the 2012 Nobel Prize in Medicine for his work in this area.
- **Phage display (Cambridge Antibody Technologies) patents** – these cover the technique of using a virus to insert a gene into bacteria where it can be replicated and identified. The technique has been enormously successful and used to identify a number of therapeutic monoclonal antibodies.

All of these broad disruptive technologies have occurred in the field of biotechnology, not pharmaceuticals, and many are past patent expiration. Given their wide applicabilities, it is unsurprising that the validity of some of these patent positions has been and continue to be litigated. This notwithstanding, they stand as proof that broad dominating patents can be obtained, at least in the biotech space, and serve as encouragement for both researchers and monetisers.

Accurately accessing the value of pharma/biotech portfolios

Any assessment of the value of a pharma/biotech portfolio must take into consideration the comparative size of the company holding the assets as well as the commercialisation potential of the portfolio. The commercialised value of patents in a large company will be a fraction of its holdings, while the opposite may be true of the value of patents in an emerging or development-stage company with a smaller portfolio. For monetisation analyses, it is important to focus on both commercialisation and potentially commercialisable assets.

What percentage of a large pharma/biotech's portfolio is commercially important?

The Intellectual Property Owners Association (IPO) publishes an annual list of the top 300 companies by US patent grants. Table 1 provides data on the top 10 listed pharma/biotech companies. Of note is that the top 2011 pharma US patent grantee, Roche, is far down the list at number 92 out of 300, although it had a healthy 323 new US patents. Table 1 also provides an informal estimate of total US patents in force (taken from the US Patent and Trademark Office's website database) for those same biotech and pharma companies. These estimates do not take into account terminal disclaimers, patent term adjustments, patent term extensions or the like, and patent numbers have been consolidated to include Schering-Plough with Merck, Genzyme with Sanofi-Aventis, Wyeth and Pharmacia with Pfizer, Steifel with GlaxoSmithKline and Amylin with Bristol-Myers Squibb.

To get a sense of how many of these

Table 1. **US patent holdings of pharma/biotech companies**

IPO rank 2011	Company	2011 US patent grants	% change from 2010	US patents in force (estimate)
92	Hoffmann-La Roche Inc	323	0.6	3,145
96	Merck & Co Inc	302	-18.4	3,110
131	Sanofi-Aventis	202	-17.9	1,200
138	Novartis AG	192	4.9	1,875
172	Pfizer Inc	153	-42.0	3,050
180	GlaxoSmithKline	143	-18.3	3,220
195	Merck Patent GmbH	131	-16.9	1,540
197	Amgen Inc	131	-10.9	780
231	AstraZeneca AB	109	-6.0	1,190
248	Bristol-Myers Squibb Co	101	-19.8	2,140
296	Genentech Inc	80	-32.8	1,440

patents cover commercial products, we then looked at the number of approved US drugs and biologics for these top 10 listed pharma/biotech companies. The results are shown in Table 2.

US Food and Drug Administration (FDA) CDER-approved drugs are those drugs approved by the FDA Centre for Drug Evaluation and Research (ie, pharmaceuticals) and FDA CBER-approved drugs are those approved by the Centre for Biologics Evaluation and Research (ie, biotech drugs). According to the 1984 Hatch-Waxman Act, drug companies must provide the FDA with a list of unexpired patents that cover either the product or an approved method to use the product to treat the labelled disorder or disease for all drugs approved by CDER (but not CBER). The list of patents is compiled by the FDA and published in a compendium referred to informally as the Orange Book, and more formally as the Approved Drug Products with Therapeutic Equivalence Evaluations.

The Orange Book indicates how many patents the drug company is using to protect its approved proprietary pharmaceutical drugs. Orange Book-listed patents are a rough indicator of the number of highly significant commercialised pharmaceutical (not biotech) patents at the company. The Orange Book figure does not include process-of-manufacture patents, patents covering pipeline drugs that have not yet been approved or biotech patents. Table 2 also provides the current ratio of approved pharma (CDER) to biotech (CBER) drugs for these 10 companies – all companies other than Amgen and Genentech are currently concentrated in pharmaceuticals (Hoffman-La Roche finalised its purchase of Genentech in 2009, which is set out here as a separate subsidiary).

The comparison of the number of Orange Book-listed patents covering US-approved pharmaceutical drugs to the number of in force US patents is shown in Table 2. The percentage ranges from 0.6% to 5.1%. Even if the Orange Book-listed patent numbers are doubled to account for patents covering unlisted commercial manufacturing processes and biotech drugs, as well as patents covering late-stage clinical trial pipeline drugs, the percentage would still range only from 1% to 10%.

Does the 3% rule apply to pharma/biotech companies?

Art Monk, vice president at UBM Tech Insights, stated in a 2011 *EE Times* article about the Nortel patent auction that "as a general rule of thumb, 3% of in-force patents in any portfolio are truly valuable". Most estimates agree that less than 5% of patents have any apparent commercial value at all – fewer than 1% are litigated (and these are found invalid at a rate of about 50%) – and only a small number of patents are licensed (eg, see Mark A Lemley, "Rational Ignorance at the Patent Office", 95 *NW U L REV* 1495, 1507 (2001) – "[A] relatively small percentage of the 150,000 or so patents issued each year are actually licensed to third parties in exchange for royalties"). Our rough assessment that between 1% and 10% (with an average of 5%) of a large pharma/biotech company's patent portfolio covers commercial products is in line with these accepted numbers in the IT/computer space.

An alternative view of value: amortising the IP value of acquired companies

Since the early 2000s, current accounting standards under both US Generally Accepted Accounting Principles and International Financial Reporting Standards have set out a rigorous process for identifying and valuing intangible assets apart from goodwill when making acquisitions. Intellectual property – including patents, trademarks, copyrights and designs, as well as licences or rights to such property rights – must now be accounted for and amortised over 15 years and can no longer be allocated to goodwill. A number of recent life sciences acquisitions have highlighted the reported value of intellectual property to the acquisition.

Table 3 details five pharma transactions with estimates of the percentage of the acquisition price attributable to intellectual property (adapted from "Industry Voices: The Value of IP in Life Sciences

Table 2. **Number of approved US drugs and biologics for top 10 pharma/biotech patentees**

Company	CDER-approved drugs (pharma)	CBER-approved drugs (biotech)	Orange Book-listed patents	Orange Book-listed versus in-force patents (%)
Hoffmann-La Roche Inc	19	5	19	0.6 (19/3145)
Merck & Co Inc	52	16	77	1.7 (77/4650)
Sanofi-Aventis	58	26	47	3.9 (47/1200)
Novartis AG	79	12	87	4.6 (87/1875)
Pfizer Inc	148	0	73	2.4 (73/3050)
GlaxoSmithKline	87	13	101	3.1 (99/3220)
Amgen Inc	1	9	5	0.6 (5/780)
AstraZeneca AB	33	0	61	5.1 (61/1188)
Bristol-Myers Squibb Co	32	3	47	2.2 (47/2140)
Genentech Inc	3	9	2	0.1 (2/1440)

Figure 1. **Trend in pharma licensing deals**

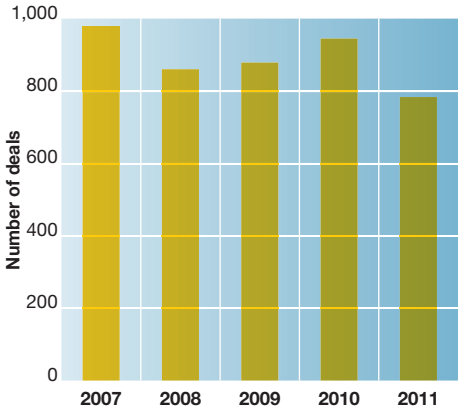


Figure 2. **Trend in total pharma deal value**

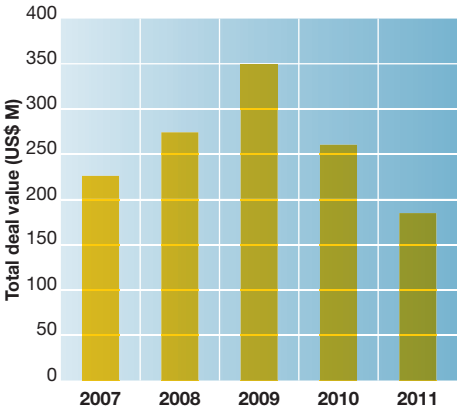
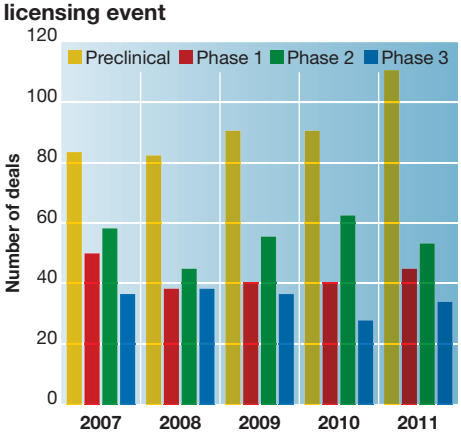


Figure 3. **Trend in clinical stage at licensing event**



Companies", John Kwon and Ryan Starkes, 14th June 2012, *Fierce Biotech*). Intellectual property is defined as including patent and trademark rights related to product/brand rights for commercialised products, as well as rights to patents on compounds in the development pipeline.

The IP valuation figures provided in Table 3 (even taking into account that the valuation includes trademarks, which are not usually a predominant driver of value in early-stage companies) are in stark contrast to the figures in Table 2. The small amount of pharma/biotech intellectual property which is commercialisable constitutes the great majority of the value of emerging and development stage companies, whereas the small amount of pharma/biotech IP which is commercialised constitutes the value of the patents in large companies. Could it really be that the remaining 90%-plus of the commercialisable patents held by large companies are of little value? Unlikely. So how can the value of this remaining 90%-plus of intellectual property be unlocked and used to benefit society as opposed to discarded as a wasted asset?

Pharma/biotech monetisation: in-licensing models

In-licensing of intellectual property, associated development data and know-how has been the lifeblood of the pharma and biotech industries for many years. In the mid 2000s we saw large pharma companies in-licensing drugs in development predominantly at the Phase II stage and beyond, with higher prices being paid for those assets closest to market. The last few years have seen pressure to do deals with pharma under even more rigorous standards, pushed by the lack of liquidity in the investment community, which has cut off venture capital funding from many emerging and development companies. At the same time, large pharmas see the exhaustion of 'low-hanging fruit' opportunities as a motivation to push deal-making activities back in the development timeline. This has forced the pharma players to increase the level of risk of collaborating on earlier-stage drugs and accepting that the in-licensed drug may not reach the market. Values have declined accordingly (in particular with regard to upfront payments).

In addition, fewer successes from expensive in-house R&D efforts have increasingly forced the big players to look outside for new drugs to address the so-called patent cliff faced by all, along with greater competition from generic players. A patent cliff is the precipitous loss of income when patent protection on a drug product is lost. It is estimated that large pharma companies lose about 80% of the market within a few weeks of loss of patent protection. This is a historic year for the pharma industry, because the largest amount of worldwide sales in the history of the industry — 9% — is at risk from patent expirations in 2012. The pharma innovator industry typically sees between 3% and 5% of annual sales at risk from patent expirations or losses. Pfizer lost patent coverage on Lipitor at the end of 2011, which resulted in a 20% fall in Pfizer's first-quarter 2012 corporate income. Other major 2012 patent expirations include Plavix (BMS/Sanofi), Seroquel (AstraZeneca), Diovan (Novartis), Singular (Merck), Actos (Takeda) and Lexapro (Forest Labs). With total pharma sales predicted at approximately US$709 billion in 2012, this means that fully US$67 billion is at risk and US$33 billion is the expected actual loss (EvaluatePharma, "Embracing the Patent Cliff", *World Preview 2018*). The loss of income to large pharma companies from the patent cliffs negatively impacts on the budget

Table 3. **Five pharma transactions with estimates of the percentage of the acquisition price attributable to IP**

Target	Buyer	Status	Proposed/ announced/ closing date	Transaction size (US$ millions)	FDA-approved commercial products	Development pipeline (Phase 1-3 trials)	% of price attributable to IP (estimated)
Human Genome Sciences Inc	GlaxoSmithKline plc	Closed	16th July 2012	3,600	Benlysta	Raxibacumab Mapatumumab	**74%**
ISTA Pharmaceuticals Inc	Bausch & Lomb	Announced	26th March 2012	492	Bromday Bepreve Istalol Vitrase	Prolensa T-Pred Bepomax Beposone Bromfenac Adjunct	**95%**
Stallergenes SA	Ares Life Sciences AG	Closed	28th October 2010	296	Orulair	Actair Stalair Birch Stalair Ragweed	**75%**
Valeant Pharmaceuticals International	ValueAct Capital LLC; Biovail Corporation	Closed	21st June 2010	3,843	Acanya, Atratin Wellbutrin, Cesamet, Nitoman Timoptic, Ocudose (OTC brands)	Dermatology (IDP 107, 108, 113, 118) MC5 Mephyton Retigabine/Ezogabine Lacrisert	**92%**
Cornerstone Therapeutics Inc	Chiesi Farmaceutici SpA	Closed	28th July 2009	74	Curosurf Zyflo CR Factive Spectracef	(minimal)	**85%**

Figure 4. **Number of pharma mergers and acquisitions**

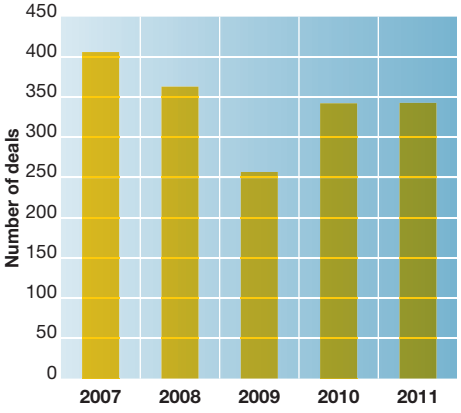
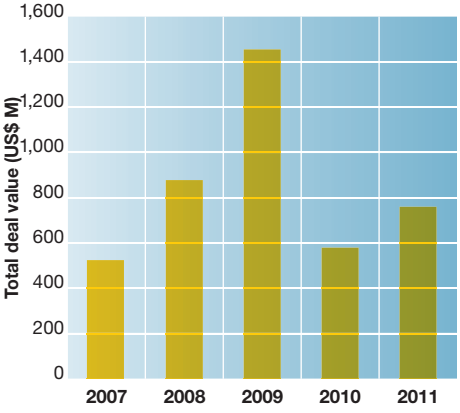


Figure 5. **Value of pharma mergers and acquisitions**



for in-licensing. Further pressures come from increased regulatory requirements and a greater demand from insurance reimbursement providers to limit payments to new drugs that are significantly better than existing medications.

Increased risk is also a result of the fact that the large pharmas/biotechs are competing for the same available licensable assets, so there is a natural tendency to get 'deal drunk' (ie, to pay too much because of the pressing competition) and take on higher-risk opportunities. The increased risk has created more complexity in the deal-making process — as pharmas may take on the risk, but want to protect themselves — leading to more complex deal terms, clawbacks for contingent scenarios and more option deals. As a result, while pharmas are evaluating greater numbers of opportunities than ever before, their choices and their terms have become harder. As a result, we have seen a fall in the number of licensing deals being done over the last four years (Figure 1). In 2011 we saw a 16% fall in the number of deals done compared to 2010 (Figures 1 to 5 adapted from *PharmaDeals Review*, Issue 1, p 15, January 2012).

If we look at the value instead of the number of these deals (Figure 2), we see an even more marked decline, confirming that licensors remain in a strong negotiating position because of the limited financing options available to biotech companies, due to the weak initial public offering market and declining levels of venture capital funding.

The drive towards licensing earlier-stage assets (higher-risk assets) is borne out by the data (Figure 3), with rising numbers of pre-clinical deals and falling Phase III deals.

As licensing is declining in terms of numbers of deals and deal values, how is Big Pharma sustaining growth and returns to stakeholders? Part of this answer is shown in Figure 4, the number of M&A deals in the industry in recent years, and in Figure 5, the value of those deals.

We see an increase in the number of deals following three consecutive declining years up to 2009, with a partial recovery in M&A deal values. The high value of M&A in 2009 despite a lower number of deals was driven by Pfizer's acquisition of Wyeth for US$68 billion and the Merck acquisition of Schering for US$41 billion. In 2011 Johnson & Johnson purchased orthopaedic device company Synthes for US$19.5 billion. Other major 2011 acquisitions are shown in Table 4. Of note was Gilead's purchase of Pharmasset for US$11.2 billion, despite the fact that Pharmasset has no commercial assets. These M&A deals take funds away from in-licensing activity and put further pressure on smaller biotechs.

Pharma/biotech out-licensing: the three hurdles

Even taking into account these licensing and acquisition trends, as Tables 1 and 2 illustrate, large pharma companies carry patent portfolios that include at least nine filings that are never used for each patent that is eventually commercially useful to the company. The patents that do not ever cover commercial products or processes often describe promising research that was never progressed — not because of inherent flaws in the inventions, but because companies are budget constrained. Put simply, large companies invent more than they are able to develop. Some of these patents cover research that has associated pre-clinical or clinical trial data or meaningful know-how. After a certain number of years, the technology begins to get stale because the patent clock is ticking and the odds vanish that a technology can be developed with time to recoup costs and make a profit.

Table 4. **Examples of 2011 pharma M&A deals**

Sanofi/Genzyme	US$17.5 billion
Takeda/Nycomed	US$12 billion
Gilead/Pharmasset	US$11.2 billion
Teva/Cephalon	US$6.2 billion
Grifold/Talecris	US$3.3 billion

Further, the US Hatch-Waxman Act – which grants companies a different form of exclusivity (regulatory data exclusivity – a period during which a generic company cannot rely on innovator clinical trial data to support a drug approval), to make up for the time required by the FDA to grant regulatory approval – has not been updated in 28 years to adjust for the increasing cost of drug development. Embarrassingly, the United States now grants the shortest period of regulatory data exclusivity in the world – five years – which is not even enough time to recover the cost of drug development, much less make the profit required by shareholders. In comparison, Europe grants 10 years of regulatory data exclusivity, Japan eight years, and China, Korea and Canada six years.

This scenario leads to a net loss/loss. The pharma/biotech company carries a larger, more expensive patent portfolio than it needs or could possibly use, and there are few mechanisms to unlock the potential value for the benefit of society. This extra intellectual property could be used to start new companies, support fundraising, create jobs and populate depleted pipelines of other companies.

Budget

In-house patent counsel are under constant pressure to drive down their patent portfolio expenses and minimise headcount. Many patent counsel are given corporate mandates to reduce spending by a fixed percentage and/or are given annual budgets that they cannot exceed. One of the easiest ways to reduce spending quickly is to abandon patent filings. Many large corporations even consider annual patent audits a required best practice, where patent attorneys must review their dockets, converse with R&D personnel and then abandon a given percentage of the portfolio. This creates headroom for new filings for the next year or allows the department to meet corporate goals. When faced with a corporate mandate on budget, there is little patience for an attitude of delaying the portfolio pruning to see whether some of the patents can be monetised.

Risk

Pharma and biotech companies carry enough inherent risk in product development, product liability, generic litigation over patent validity and infringement, and government inspections or investigations to be interested in taking on new risk in the process of monetising patents. These companies are concerned about liability associated with potential

Figure 6. **'Many-to-many' licensing model**

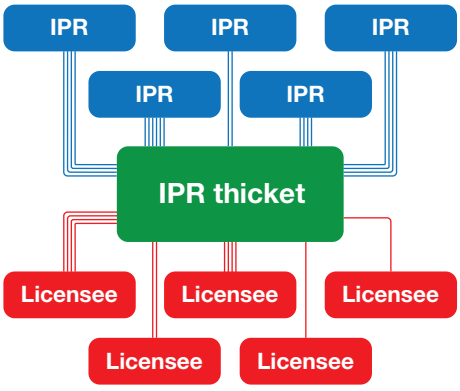
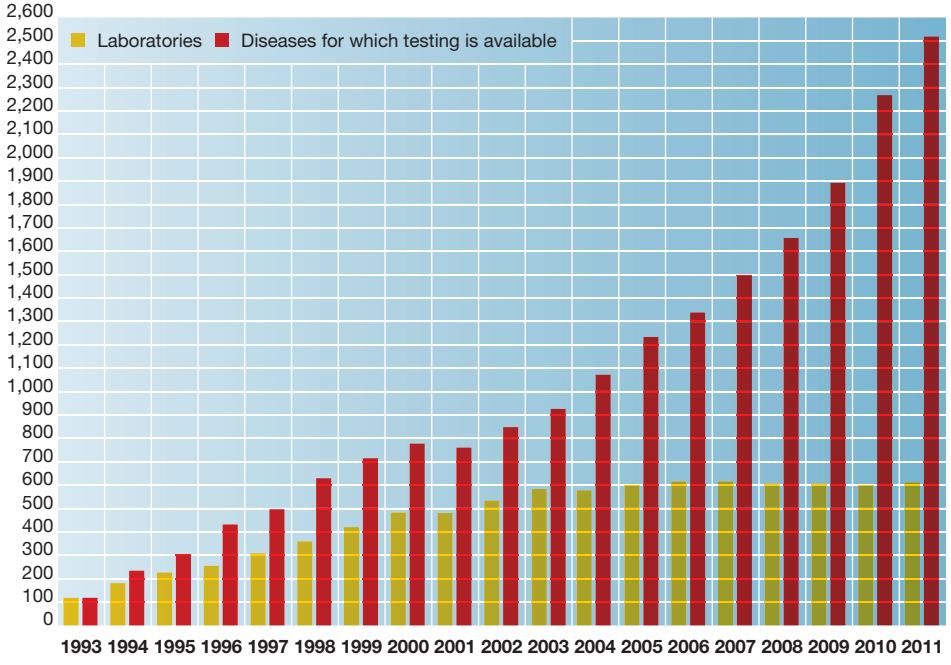


Table 5. **MPEG LA active IT patent pools**

MPEG-2 Programme started in 1997	Started with 8 patent owners 102 patents	• Currently 27 patent owners • 974 patents in 57 countries • 1,888 licensees
ATSC Programme started in 2007	Started with 6 patent owners 41 patents	• Currently 8 patent owners • 236 patents in 27 countries • 151 licensees
AVC/H.264 a/k/a MPEG-4 part 10 Programme started in 2005	Started with 14 patent owners 20 patents	• Currently 29 patent owners • 2,651 patents in 54 countries • 1,460 licensees
VC-1 Programme started in 2007	Started with 16 patent owners 130 patents	• Currently 18 patent owners • 761 patents in 35 countries • 294 licensees
MPEG-4 Visual part 2 Programme started in 2004	Started with 20 patent owners 77 patents	• Currently 29 patent owners • 1,230 patents in 54 countries • 1,128 licensees
MPEG-2 Systems Programme started in 2006	Started with 8 patent owners 161 patents	• Currently 11 patent owners • 237 patents in 29 countries • 199 licensees
IEEE 1394 Programme started in 1999	Started with 6 patent owners 8 patents	• Currently 10 patent owners • 273 patents in 22 countries • 243 licensees
MVC Programme started in 2012	Started with 15 patent owners 112 patents	• Currently 15 patent owners • 917 patents in 40 countries • 14 licensees
Wireless Mesh Programme started in 2012	2 patent owners 37 patents	• 47 licensees

Figure 7. **Growth in availability of new diagnostic tests**



Source: **GeneTests database (2011) www.genetests.org**

problems in the patent portfolio itself or mistakes in clinical trial data or know-how during monetisation. It is often the case that abandoning assets (even without any knowledge of actual problems) is an easier dismissal of risk than a transfer of rights.

Time

Monetising assets is not the day job of pharma and biotech companies. Companies faced with headcount pressure and lay-offs focus on their main directive — to obtain, maintain and litigate patents on commercial assets. For the largest pharma and biotech companies, with a few exceptions, the money at stake in protecting commercial assets dwarfs any money that they have seen in monetising assets. The old adage "follow the money" is appropriate here.

Should Congress or other national legislatures help?

Notwithstanding these three hurdles, jettisoning researchers' time and nascent medical discoveries is a cost to society. This is manifested in the potential loss of new jobs and/or companies by not unlocking these assets — not to mention new drugs, diagnostics and devices that could be created to enhance quality of life. Can the three hurdles be overcome through appropriate structures and protections? If we agree that it is in society's best interests to do so, it is reasonable to suggest that new laws are needed. Congress or corresponding national legislatures should consider well-designed plans and new legal frameworks to achieve this goal as a jobs creation vehicle. We suggest a few proposals below. Readers will likely have others.

First, we recommend that Congress amend the US Hatch-Waxman Act to increase the period of data exclusivity to a length of time that is long enough to motivate the commercialisation of drugs with insufficient patent protection, similar to what has been done in Europe. This would give a longer time period for pharmas to monetise assets without having those assets go stale.

In addition, if we assume that pharma/biotech-focused monetisation companies are created as vehicles to unlock the potential of unused patents and assets at large pharma and biotech companies, how can we lower the three hurdles to use such vehicles successfully?

In one structure, pharma/biotech patent portfolios offered for monetisation are designated as such and held by the pharma/biotech company during a set monetisation period (perhaps two years). In another structure, the portfolios are transferred to the monetisation company. In both scenarios, the monetisation company could create a public website listing the assets and advertise monetisation opportunities. This is not substantially different from what the World Intellectual Property Organisation (WIPO) is doing with the charitable patent pool for neglected tropical diseases (Re:Search), which is gaining momentum.

Corporate cost of carrying a portfolio and allowing third parties to review it

We assume that the pharma/biotech costs of carrying large patent portfolios are currently viewed as business tax deductions. To date, however, these deductions have not been a sufficient incentive for companies to carry portfolios for the purpose of monetising these inventions.

With the disclaimer that none of the co-authors is a tax expert, one might imagine a new tax structure to incentivise pharma/biotech companies to carry designated patents for a certain time to allow consideration and due diligence by potential acquirers. In this approach, the pharma/biotech company could designate yet continue to hold patents for potential monetisation for a set time and the monetisation company would be responsible for marketing. The pharma/biotech company and the monetisation company would split any income according to a set

ratio, and the pharma/biotech company would receive a sufficiently incentivising tax advantage (over and above what it already gets) for holding and caring for the designated assets during the set time.

Using this approach, the pharma/biotech company might have several in-house or, more likely, contract patent attorneys handle the portfolios so that the assets are separated from the remaining portfolio. Costs such as headcount and disbursements might be taken as additional tax deductions (which would be duplicative, but could act as at least an incremental incentive). In addition, pharma/biotech companies might take an additional charitable deduction based on some proportion of the income retained by the monetisation company. The structure could be reconsidered after several years to see whether it works as intended.

In another approach, the designated patents would be simply transferred to the monetisation company and the biotech/pharma company would get an immediate fair-market value charitable deduction for transferred portfolios, even though the monetisation company is a for-profit concern.

Compare: tax treatment of patents for donations

Before 2004, corporations were allowed to use fair-market value determinations as a taxable deduction for donations of intellectual property. Examples include DuPont, which gave away patents it valued at US$64 million to Penn State, the University of Iowa and Virginia Tech in 1999; Caterpillar, which gave away US$50 million in patents to Mid-America Commercialization Corp in 2001; and Kellogg, which gave away US$49 million worth of patents to Michigan State in 2002.

In 2004, as part of the American Jobs Creation Act, Congress amended the charitable deduction provision by eliminating the fair-market value standard for contributions. The 2004 legislation limits the initial charitable deduction of any type of intellectual property to the property's tax basis. Often, the donor's tax basis in intellectual property is very small; in many cases, the donor's basis is zero because development costs are often deducted when incurred. To encourage charitable giving of intellectual property, Congress did grant donors of intellectual property future charitable deductions based on the income received by the charity receiving the donation. Specifically, the donor can take a deduction for up to 10 years for gifts of royalty-producing intellectual property to public charities (but not other companies, including emerging companies that could use the patents to raise money for development of the other research, or large pharmas that would likely need such an incentive to unlock further resources).

In general, as discussed above, without an immediate tax advantage gained from donating or holding unwanted intellectual property, abandonment is often the easier solution, as it achieves the desired effect of eliminating the ongoing expenses associated with maintaining the intellectual property. Affirming a fair-market value method would restore the incentive to give intellectual property as a charitable donation and perhaps give an incentive for monetisation initiatives which stimulate the economy, create jobs and improve health.

Contract waivers

Whatever structure is used, the patent portfolio and associated assets would have to be transferred on an 'as is — no warranty' basis, with full waiver of liability to the pharma/biotech company.

Role of the monetisation company

The monetisation company would be responsible for maintaining the website, marketing, negotiating the deal and handling the contracts, with input from the pharma/biotech company, in a manner that minimises the burden on the time of large pharma employees.

Pharma/biotech monetisation – spin-offs

Pharma/biotech companies have a history of using asset sales as a means to monetise intellectual property. Typical asset sales are focused on clinical development candidates or already marketed products, and are often available as a result of a merger or change in

> "Without an immediate tax advantage gained from donating or holding unwanted intellectual property, abandonment is often the easier solution"

Table 6. **Initial patent contributors to Librassay**

• Johns Hopkins University
• Ludwig Institute for Cancer Research
• Memorial Sloan-Kettering Cancer Center
• National Institutes of Health
• Partners HealthCare
• The Board of Trustees of the Leland Stanford Junior University
• The Trustees of the University of Pennsylvania
• University of California, San Francisco

direction of the selling company.

Is there a successful model for spin-off companies when large pharmaceutical companies stop work in therapeutic areas or drop a drug? A historic example is Triangle Pharmaceuticals, which was created after Glaxo and Wellcome merged in 1995. Glaxo Wellcome terminated Wellcome's licence with Emory University for an antiviral drug for the treatment of HIV, which was picked up by Triangle. Triangle was purchased by Gilead in 2003 and the drug, approved as Emtriva, is now a cornerstone in Gilead's HIV franchise, used in four HIV combination therapies and earning billions for Gilead.

In early 2010 GSK announced the shutdown of its neuroscience and psychiatric research programmes and facilities, directly leading to infrastructure savings of US$785 million. Approximately 30 independent programmes were identified for possible spin-outs, leading to two successes to date. In October 2010 Convergence Pharmaceuticals was launched, with US$35 million and a Phase II-ready compound for pain management. In August 2011 Autifony Therapeutics was launched, with a focus on drugs targeting voltage-gated ion channels, which promise to treat hearing loss and tinnitus.

Pharma/biotech monetisation: asset purchases

Given the number of pharma/biotech mergers in the last few years, along with the prolific reorganisations, it is unsurprising that just the last few months of 2012 have seen a number of asset sales, including:

- Cell Therapeutics' agreement to acquire pacritinib, a highly selective JAK2 inhibitor, from S*BIO (April 2012).
- MEI Pharma' acquisition of S*BIO's exclusive worldwide rights to Pracinostat, an investigational, potential best-in-class, oral histone deacetylase (HDAC) inhibitor (August 2012).
- Synergy Pharmaceuticals' agreement with Bristol-Myers Squibb to acquire the assets related to FV-100, an orally available nucleoside analogue, in development for the treatment of shingles (August 2012).
- Omega Pharma's acquisition of non-core OTC brands of GlaxoSmithKline in Europe for €470 million in cash.
- Forest Laboratories' acquisition from Janssen Pharmaceutical for all US patents and other US and Canadian intellectual property for Bystolic (nebivolol), which is currently approved in the United States for the treatment of hypertension (March 2012).
- Steifel's worldwide asset purchase agreement for Toctino from Basilea Pharmaceutica in (June 2012).

Pharma/biotech patent pools

Pharma/biotech patent pools were traditionally created for reasons wholly different from, and structurally unrelated to, IT patent pools, which were usually organised to handle patents that cover industry standards. Pharma/biotech patent pools were first created for charitable purposes as a vehicle to allow access to technology for under-researched medical needs. The UNITAID patent pool was founded in 2006 by Brazil, Chile, France, Norway and the United Kingdom as an international drug-purchasing organisation to assist people with HIV/AIDS, malaria and tuberculosis in developing countries. In 2011 UNITAID announced its first agreement with a pharmaceutical company, Gilead Sciences, for the distribution of a number of HIV products in least developed countries and some developing countries for a 5% royalty. Around 2003, there was an attempt to create a SARS patent pool that would group together patents related to the SARS virus (www.who.int/bulletin/volumes/83/9/707.pdf). Interest was driven by public health concerns about how to clear a perceived patent thicket to allow different organisations to gain access to the patents they needed to efficiently develop SARS vaccines (www.who.int/intellectualproperty/events/en/JamesSimon.pdf).

In 2009 GlaxoSmithKline created a patent pool for neglected tropical diseases and offered access to 800 of its patents, and more importantly, corporate know-how, via a website listing. Soon thereafter, Alnylam Corporation joined the pool and BioVentures for Global Health was selected to administer the pool. In May 2010 the South African Ministry of Science and Technology became the first government agency to seek access to the pooled assets. Other companies joined and a further major step occurred in 2011, when WIPO became the umbrella coordinator of the neglected disease initiative (Re:Search). These charitable pools demonstrate the willingness of corporations to step up to the plate and participate in world health issues with actions that are largely, or sometimes fully, the opposite of asset monetisation.

What about using commercial patent pools to facilitate the development of pharma/biotech products? We can learn from patent pools in the electronics industry, which are typically formed around an industry standard having one or more

patent thickets involving multiple patent owners and multiple licensees. The normal structure is the licensing model shown in Figure 6. Patent pools can provide an efficient licensing mechanism compared to negotiating multiple one-to-one bilateral licence agreements. In the pharma/biotech space, this model may most easily be applied to medical diagnostics, biomarkers and related pharma-research tools.

MPEG LA is credited with creating the first modern IT patent pool after obtaining a business review letter from the US Department of Justice in 1997 for its MPEG-2 pool (www.justice.gov/atr/public/busreview/215742.pdf). This determined that the proposed pool structure was pro-competitive based on a number of features such as openness to adding new patent owners, the inclusion of 'essential' patents and the availability of bilateral licensing alternatives to the pool licence. This pool structure was different from older patent pools and became the template for other modern patent pools. Today, MPEG LA manages IT licensing programmes comprising 6,000 patents in 74 countries, with 159 licensors and some 5,000 licensees. A summary of these licensing programmes is provided in Table 5 (data as of 17th September 2012).

Commercial patent pools for the pharma or biotech industries?

Pharma and biotech companies are not governed by industry standardisation of the type seen in the IT industry. In the areas of medical diagnostics there are often approved or accepted clinical markers, or optimal methods of analysis common to a range of tests. There has been a significant amount of research in the biomarker space, and a number of these biomarkers can serve as the basis for research, diagnostics or personalised medicine therapies.

A 'biomarker' is a protein, lipid or other biological material that is highly correlated with a target cell, condition or change in condition. One use of biomarkers is to determine which patients will experience an undesired side effect from taking a drug. By pre-screening patients, the drug can be prescribed more safely. The National Institutes of Health (NIH) established the Genetic Testing Registry (GTR), which collects information on the association between specific genes or mutations and various disease or metabolic conditions (www.ncbi.nlm.nih.gov/gtr/). The requirement for the use of specific diagnostic tests by regulatory agencies prior to drug administration or during therapy, or the endorsement of such testing by professional associations, may suggest the need for multiple non-exclusive licensing activities.

Another factor which supports commercial patent pools for diagnostics is the increasingly common complex diagnostic tests involving a large number of biomarkers. This is especially true in the case of tests derived from whole exome or genome sequencing. Complex tests being developed now involve dozens or hundreds of biomarkers, many of which are covered by patents owned by a multitude of different parties.

Rapid growth in the number of diagnostic tests

Not only are new diagnostic tests becoming more complex, but many more new diagnostic tests are being developed and offered to the market. Figure 7 shows that the number of diseases for which diagnostic testing is available has tripled in the last 10 years.

Because of the rapid changes in diagnostic testing technology and scientific knowledge underlying these tests, and the need to license many patents from multiple owners, a many-to-many licensing model can provide an efficient solution.

Companies that need access to multiple

Table 7. **Current Librassay coverage (~400 patents)**

Diseases/conditions	Cancer subgroups
Cancer	• All types
• Ageing	• Some potential concentrations in:
• Allgrafts	– Breast
• Autoimmune	– Colorectal
• Cardiovascular	– Endometrial
• Central nervous system	– Epithelial
• Gastrointestinal	– Oesophageal
• Genetic disease	– Lung
• Infectious disease	– Ovarian
• Kidney disease	– Pancreatic
• Metabolic disease	– Prostate
• Neuropsychiatric	– Renal
• Opthalmology	– Tumour associated genes, eg,
• Pulmonary	– tumour rejection antigens
• Reproductive health	– MAGE
• Speech disorders	– SSX
• Stroke	– Certain biochemical pathways
Other	– TGF-beta -> MAD genes
• Devices	
– Microfluidics	
– Arrays	
• Imaging	
• Next generation sequencing	
• Computer modelling	

Action plan

Players in the life sciences industries should:

- Initiate discussions about the social benefit of pharma and biotech patent monetisation to create innovative new drugs to treat diseases, new companies and new jobs to stimulate the economy and improve healthcare.
- Create solutions to the three hurdles:
  - Provide legal mechanisms to compensate for the cost of maintaining patent portfolios during monetisation activities.
  - Transfer the substantial time burden associated with marketing and monetisation activities away from the patent holder to an asset commercialisation vehicle, which also benefits from the transfer.
  - Create contracts which assure that patent and associated asset monetisation occur without legal risk to the transferor. The buyer must take as is, without any warranties.
- Involve tax experts to determine feasible and meaningful tax advantages for the patent holder and the commercialisation vehicle to motivate the formation of these structures sufficiently.
- Start conversations with legislators about the need for new laws to unlock identified potential medical discoveries.
- Consider participating in commercial pools for diagnostics, biomarkers and research tools.

patented technologies to offer a proprietary diagnostic testing platform, including those involving many different multiplexed biomarker assays, may prefer to take less expensive and less difficult to obtain non-exclusive de-blocking pool licences. The goal of licensing each component exclusively could be virtually unobtainable in practice, even if delays caused by negotiating the myriad of exclusive licensing deals could be tolerated during the fast pace of development.

A patent pool for diagnostics and personalised medicine

Perhaps the first example of a commercial patent pool in this area is the MPEG LA's Librassay, which recently announced a landmark collaboration with the NIH and other leading healthcare innovators (see Table 6). It is now providing one-stop worldwide access to diagnostic discoveries for personalised medicine. Starting with about 400 patents, Librassay provides access to medical diagnostic patent rights from some of the world's leading research institutions to any potential licensee through a non-exclusive licence. It is expected to be of particular benefit in connection with emerging multiplexed diagnostic tests for disease and other health conditions, including whole genome sequencing, for which patent rights belonging to many different parties may be needed.

The initial contributors of patents are shown in Table 6. MPEG LA is in active discussion with other institutions and patent owners to offer their patents through Librassay.

The field of use for the Librassay licence is diagnostics and research tools. The licence does not cover drugs or purely therapeutic applications, which typically demand exclusive licences to encourage and justify the significant investment required to bring the drug to market.

In addition to a royalty-bearing licence, Librassay provides a royalty-free licence for educational purposes and for experimental, developmental or research work funded by a governmental entity or non-profit organisation, to the extent that there is no payment or reimbursement for discrete products or services.

The 400 patents in the pool currently encompass the disease conditions and technologies shown in Table 7. Each category may contain multiple sub-categories, as demonstrated by the cancer sub-group shown on the right of Table 7. Librassay coverage will expand as more patents are added, and there may be bundles of complementary patents around particular tests for which licensees would take a licence to the entire bundle just as they would a pool of essential standards patents. The value of widely dispersed patents may be realised when associated and offered with other complementary patents in a single efficient transaction.

Of course, in the United States, potential pool licensees will be closely monitoring future judicial interpretations of the recent US Supreme Court decisions in *In re Bilski* and *Mayo Collaborative Services v Prometheus*. In the meantime, Librassay appears to address licensing issues in diagnostics and personalised medicine in a manner that some advocates claim to be aligned with the public policy goals of access. If the income is sufficient, such pools will motivate further innovation and patenting. In the press release announcing Librassay, Director of the National Institute of Health (NIH) Office of Technology Transfer Mark Rohrbaugh said: "The NIH's policy is to disseminate its technologies as broadly as possible to promote commercialization and improve public health. This agreement promotes our policy by permitting MPEG LA and Librassay to pool patented technologies contributed by NIH with complementary technologies from other sources, and to grant non-exclusive, commercial licenses from the pool for in vitro diagnostics and personalized medicine" (www.librassay.com/ Media.aspx).

Industry expansion

The possibility exists to develop many more innovative drugs, create new jobs and stimulate the economy by unlocking innovative assets in large pharma and biotech patent portfolios. The added income to large companies could be used to support further in-licensing and research opportunities. The advent of commercial pharma/biotech pools in the areas of biomarkers and diagnostics may likewise expand these industries. We all win when the result is a better quality of life. *iam*

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