# BIO Advanced Business Development Course

# Intellectual Property

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# What are we going to cover?

- Intellectual Property
  - what it is and what it does
- IP Due Diligence
  - how you do it and what to watch out for

# Intellectual Property

- laws differ from country to country
- basic types of intellectual property
  - patents
  - copyrights
  - trade marks
  - trade secrets
  - data exclusivity

# Intellectual Property

- Patent types (EP)
  - European patent
  - National patent
  - and now potentially the Unitary Patent & Unified Patent Court
- Patent types (US)
  - Utility patents cover any “new and useful process, machine or composition of matter”
  - Design patents cover any “new, original and ornamental design for an article of manufacture”
- Patent Cooperation Treaty (PCT)

# Intellectual Property

- Patents – duration of protection
  - 20 years from filing date
  - maintenance/annuity fees must be paid periodically during the life of a patent in the U.S. and EP to keep the patent or application in effect
  - can be extended for pharmaceuticals (and can be adjusted e.g. for delay in USPTO)

# Intellectual Property

- Patent basic requirements in EU
  - invention must be novel
  - must be capable of industrial application
  - must not be obvious
  - not excluded (e.g. surgical techniques)

# Intellectual Property

- Establishing Rights – patent rights arise only after filing an application on a country by country basis and being granted a patent after an examination process
  - Timing – absolute novelty requirement in Europe, grace period in U.S. (12 months from disclosure)
  - Priority – (EP & ROW), first to file wins. (U.S.) – first to invent (historically)
  - but now US moving to first file under the America Invents Act (as of March 2013)
- Remember 9 month opposition period in Europe (following grant) and the new post grant proceedings in the US from March 2013

# Intellectual Property

- Owner – (U.S.) Filing is made in the name of the inventor who then assigns the patent application to a company, if obligated to do so. (EP) The right to a European patent belongs to the inventor or his successor in title. If the inventor is an employee this right is determined in accordance with the law of the State in which the employee is mainly employed (Art. 60(1) EPC)
- Co-ownership – watch out for this. Different rules in different countries e.g. in U.S. each co-owner can exploit and license without consent, in UK, can't license without consent.

  E.g. Ethicon v US Surgical Corp (lab technician inventor on one claim), Schering Corp v Roussel (combination drug case)
- Getting ownership right is key – lots of deals go wrong on this point e.g. Southampton University case in the UK.
- Also note Yeda v Rhone Poulenc re rights to Erbitux
- Stanford v Roche (2012 US Supreme Court)

# Intellectual Property

- Enforceability
  - Patents give the owner the right to exclude others from using the claimed invention, but not the right to practice the invention if this would infringe an earlier patent
  - (EP & US) Basis for infringement – a patented invention will be infringed when an unauthorised third party uses the patented invention or an [equivalent thereof]
  - (EP) Damage awards can be based on a reasonable royalty, lost profits, or infringer's profits; no increased damages for wilful infringement
  - (US) Damage awards can be based on a reasonable royalty or on lost profits and can include prejudgment interest; treble damages and attorneys fees are available in cases of wilful infringement
  - (EP & US) Injunctive relief may be granted e.g. Amgen v Roche
  - but just because you have a granted patent doesn't mean its valid e.g. recent Mayo v Prometheus case in the US
  - plus challenges to patentability e.g. in India re Glivec and grant of compulsory licences e.g. Nexavar in India

# Intellectual Property

- Patents – enforceability
  - can be very powerful
  - but not always e.g. Celltech v MedImmune and Cargill v Monsanto
  - note also research exemptions in particular U.S. Bolar exemption and now EU equivalent of Bolar
  - EU Bolar implemented in different countries in different ways
  - increases the uncertainty e.g. difference in UK v German approach on clinical trials
  - but generally courts arrive at similar conclusion – 90% of the time according to EU Pharma Sector Inquiry
  - Generally EU national courts try to follow EPO but not always e.g. recently in MedImmune v Novartis in the UK

# Intellectual Property

- Building a valuable patent portfolio
  - composition of matter, e.g., biologics, compounds
  - method of use, e.g., indication, regiment, etc
  - process of manufacture, intermediates, etc.
  - formulations
  - delivery devices
  - biomarkers, e.g., in combination with therapeutics

# Intellectual Property

- Building a valuable patent portfolio
  - follow the business objectives and regulatory approval strategy
  - support the proposed valuation, e.g., duration of market exclusivity
  - have sufficient options to address “uncertainty”
  - Support “barrier to entry”

# Intellectual Property

- Patent thickets – a good thing?
  - old/current model = file lots of patents
  - composition of matter
  - process of manufacture
  - formulations
  - dosages
  - delivery devices
  - new “improved” versions etc

# Intellectual Property

- Patent thickets
  - EU Commission looking at this very carefully
  - Industry facing great uncertainties
  - Enforcing “bad” patents can cost e.g. Servier v Apotex
- EU Commission Inquiry into pharmaceutical sector – the so called “toolbox”
- note also the recent AstraZeneca decision – very easy to be in a dominant position if you are first to market
- and now recent activity by the Italian anti-trust authorities against Pfizer
- see also EGA papers at www.egagenerics.com for the generics side of the argument

# Intellectual Property

- Trade marks

  What may be protected?

  - (EU) any signs capable of being represented graphically, particularly words, including personal names, designs, letters, numerals, the shape of goods or of their packaging, provided such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings
  - (US) extends to any “work, name, symbol or device” which acts as an indication of source for products or services, including slogans, sounds and container shapes

  Duration of Protection

  - (EU) ten years from the date of filing of the application/ may be renewed for further periods of 10 years; can be indefinite if continuously renewed
  - (US) can be indefinite

# Intellectual Property

- Benefit
  - can be very valuable for the innovators e.g. Nexium, Avastin etc.
  - can help protect market share when patent expires particularly in countries where “substitution” is not permitted
  - can be used to stop infringing goods – can be very powerful e.g. counterfeit seizure rights of customs
  - 10% of medicines counterfeit (WHO)

# Intellectual Property – Trade Secrets

- Trade Secrets
  - facts, know-how etc. not generally known
  - can be very valuable
  - some companies now using know-how more and more
  - particularly useful for technology platforms/research tools?
  - problems with enforceability of "reach through" claims
  - need to assess when and when not to patent
  - once the cat's out of the bag … !

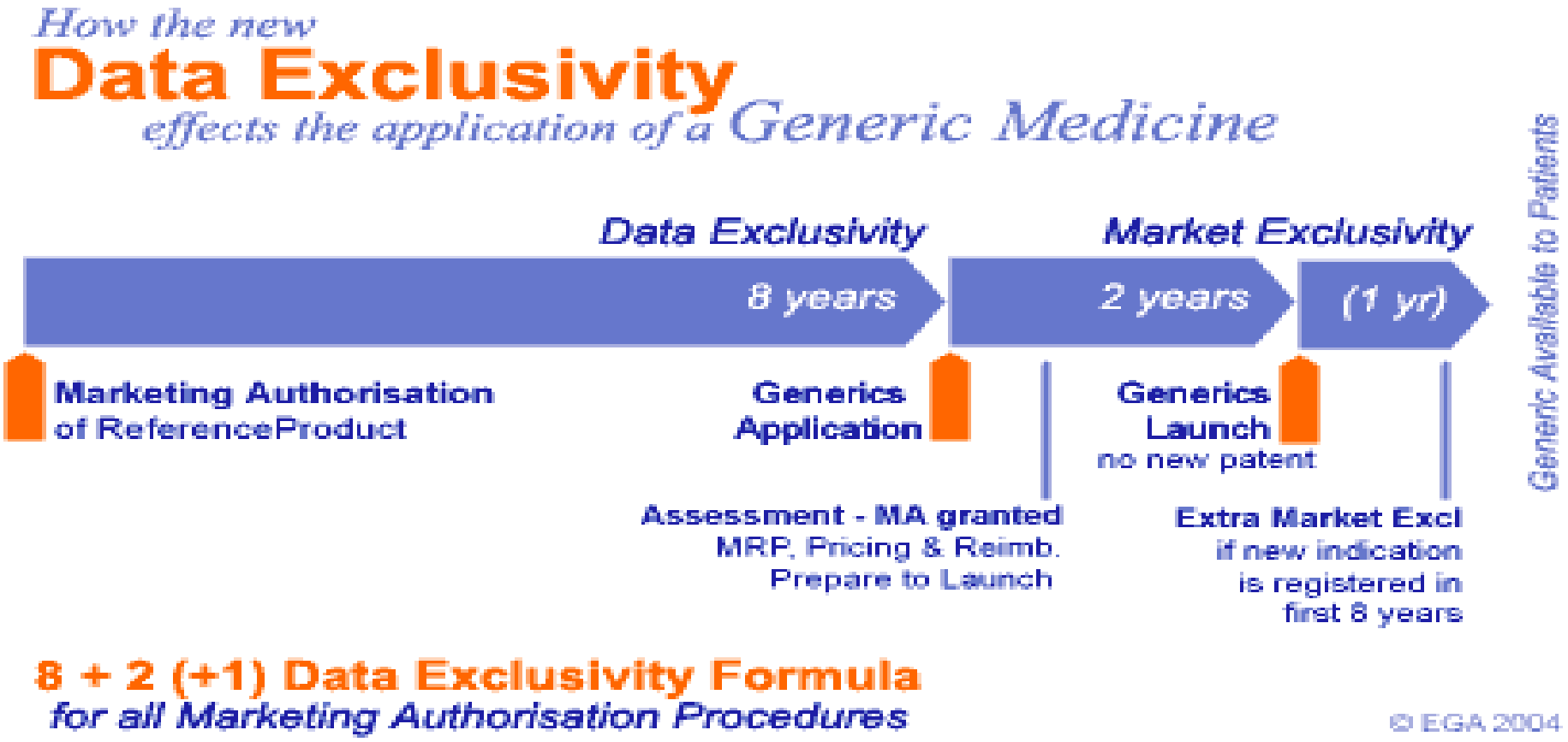
# Trade Secrets

- Ownership – make sure employee assignments are in place and that all contracts with customers, suppliers, collaborators etc protect information from disclosure
- Infringement – new employees should be advised not to disclose or use prior employers' trade secrets
- many cases involve employees joining new companies
- misuse of a third party's trade secrets can get you into trouble e.g. Emisphere Technologies v Lilly (U.S. case) and recently Tekmira v Alnylam
- Complexity in making some drugs can be a barrier to generic entry e.g. biosimilars, also GSK's Serotide and note recent FDA statement about Teva's version of Wellbutrin which had been on the market for 6 years before FDA finally decided not bioequivalent

# Data Exclusivity in Europe

- Data exclusivity can be very valuable
- More valuable than patents?
- “the 8 + 2 + 1 rule”

# Data Exclusivity in Europe



# Data Exclusivity in Europe

- exclusivity for Paediatric Use Marketing Authorisations (PUMAs) – 10 years for generic product with an exclusive use in Paediatrics
- orphan drug market exclusivity (10+2) (5 in 10,000 people or investment not likely to be recovered) (or in the US – Orphan Drug Act 1993 (less than 200,000 patients)
- data exclusivity is very valuable
- therefore lots of issues around interpretation of the laws e.g. single enantiomer protection versus racemate

# Data Exclusivity in the U.S.

- 5 year exclusivity for new chemical entities
- no ANDA can be submitted in that 5 years except can do if after 4 years if certification of patent invalidity or non-infringement
- 3 year exclusivity for previously approved drugs when new clinical investigations carried out
- 7 year exclusivity for approved orphan drug
- 6 month "tag on" for paediatric exclusivity
- and now 12 years for biologics drugs – (the Patient and Affordable Care Act 2010)

# Supplementary Protection Certificate (EU; Regulation 1768/92 EEC)

- Intended to compensate for long time line for development of a drug
- Must be separately applied for by patent holder in each Community State within 6 months from grant of marketing authorization or of patent, whichever is later
- Is granted in respect of "basic patent" in force in that State
- Basic patent may be to a product, process or use
- Duration – for a time period corresponding to the time period that elapsed between the filing date of the basic patent and the date of the first marketing authorisation of the product in the Community, reduced by 5 years; maximum duration is 5 years; starts from the expiry date of the basic patent

# Supplementary Protection Certificate (EU; Regulation 1768/92 EEC)

- Basic requirement:
  - a basic patent protecting the product (i.e. the active ingredient or combination of active ingredients) must be in force in that State
  - a valid marketing authorisation for the product must have been granted in that State
  - the product must not have already been the subject of an SPC; and
  - the marketing authorisation must be the first marketing authorisation in that State

# Supplementary Protection Certificate (EU; Regulation 1768/92 EEC)

- extra 6 months protection for carrying out paediatric studies (Paediatric Regulation)
- lots of problems around interpretation of the SPC regulation
- 20 years after the regulation came in questions still being raised
- e.g. Daiichi's case re levofloxacin against Generics UK
- note also AZ's "SPC abuse" of a dominant position

# Patent term extension in the U.S.

- Four human drugs extension

  $$= \frac{(\text{testing period})}{2} + (\text{time for approval of NDA})$$

- Capped at 5 years
- Extension is reduced if applicant did not act with due diligence during regulatory review
- Must be submitted within 60 days after product approved for commercial sale or use

# IP DD – when and why do it, how do you do it and what do you really need to watch out for?

- When do you do it?
  - M&A deals
  - VC investments
  - Licences/collaborations
  - IPOs
- Different deals – different drivers e.g. big pharma co will have different approach to a VC
- VC will often have less money/time to spend on doing the job a big pharma co will do
- Need to understand the key drivers right from the start
- Exercise will be costly/time consuming so focus!

# Why do it?

- could just rely on the warranties/indemnities (!)
- but that's very risky
- your eyes need to be open
- you need to ask for the right warranties/indemnities (plus they are often capped/time limited)
- information is power – could help to reduce the price
- could lead to deal structure modification e.g. to allocate risks
- you may not have any warranty protection (of any substance) depending on the deal (e.g. academic spin out investment or acquisition of a listed company)
- could identify deal breakers

# How do you do it?

- Depends on your organisation
- A large pharma – often have large teams, well briefed, "turn over every stone" approach, rely on external help to a lesser extent than a VC. VC - will not have the resources to do the same detailed DD job as a large pharma co – will often rely on FTOs already prepared by target company (sense checked by external counsel) and will focus on specific areas plus use more outside counsel support
- VC – can the company pass the "big pharma" test
- Pharma Co - does the company have the exclusivity required to support the investment needed?
- IPO – important that IP due diligence is done and done well – getting it wrong for a public company can cause tremendous problems e.g. Oystertec PLC in the UK and recent litigation against NUMIS

# What are you looking for?

Let’s focus on patents:-

- Ownership issues
- Infringement issues/freedom to operate
- Validity issues
- Scope of protection (IP and regulatory)
- And these days – antitrust issues?

# Ownership Issues

- Chain of title
  - is it complete? Any breaks? Have all the relevant assignments been entered into? (can be a real problem, particularly if IP originated in an academic setting)
  - any co-inventors/co-owners? (see cases mentioned earlier such as Ethicon v US Surgical
- Linked to title – are any of the rights licensed?
  - if yes, need to review all background licences (including all amendments)
  - pay particular attention to sublicense rights
  - what happens if licence terminates for breach/insolvency?
  - will you get rights to second generation/improvement products (e.g. Amgen v J&J and recently Bayer v Onyx)

# Ownership Issues (cont.)

- do you have to hand back improvements?
- is there a clear right to sublicense? (don't rely on an implied one)
- who controls IP prosecution and enforcement? Watch out in particular for SPCs and Hatch Waxman time limit problems
- are the financial provisions clear (e.g. CAT v Abbott)
- change of control/right to terminate issues
- field carve outs/restrictions
- can be very complex!

# Ownership Issues (cont.)

- Security interests
  - has the target company secured borrowings against IP?
  - quite common in smaller companies
  - restrictions under the borrowing documentation on what the target can/can't do can be severe
  - searching registers may throw up some information but not all
- Have all assignments been registered? If not can have enforcement consequences
- Look at employment contracts to make sure proper IP assignment provisions are included
  - remember local laws can vary on employer/employee invention ownership e.g. Germany has some quite unusual laws on this issue
- Inventor compensation can be a residual liability – see GE case in the UK

# Ownership Issues (cont.)

- If there is a head licence (i.e. you are a sublicensee) – can you protect against/what is the consequence of licensee insolvency?
  - what does the licence say?
  - does the local law protect you?
  - In Germany and the US sublicense survives
  - In UK sublicense would not survive
- What about licensor insolvency?
  - US Bankruptcy Code versus Europe
  - European laws (vary from country to country) e.g. Italy and Germany where insolvent licensor may disclaim a licence leaving licensee with only a claim in damages
  - Note recent case in relation to Qimonda AG
- Is the IP otherwise encumbered e.g. licences out to third parties?

# Freedom to operate

- What are client's short and long term business objectives?
  - existing products/services to be acquired/licensed
  - future products in development
- Which of the target's products/technologies is key for achieving these objectives?
- This will determine the requirements for FTO searching and analysis

# Freedom to operate (cont.)

- Obtain detailed description of the products from the target
  - amino acid and nucleotide sequences for biological products
  - details of formulations
  - details of manufacturing process
- Initiate FTO search
  - instruct specialist patent searcher to conduct independent search (costly, and must allow sufficient time for evaluating results)
  - compromise if timescale and budget don't allow? Can you use searches/opinions provided by target?
  - waiver of privilege issues

# Freedom to operate (cont.)

- Analysis of results
  - reality check – it's not unusual to identify FTO issues
  - check status and construe claims of third party patents
  - compare target products/technologies against construed claims
  - evaluate infringement risk
- Can infringement risk be mitigated?
  - is the third party patent valid?
  - can client design around?
  - can client license or acquire problem patents?

# Scope of protection

- Evaluating scope of protection provided by target's IP
- Breadth of claims
  - consider scope of claims in granted patents and claims likely to issue from pending applications
  - do they cover target's key products and technologies?
  - are they too broad/difficult to enforce? e.g. recent UK case of HGS v Eli Lilly
- Check status and territorial coverage
  - extent and status of each patent family should be independently verified – don't rely on list provided by target
  - a variety of database tools are available, and many Patent Offices maintain online registers, but some information may have to be obtained from local agents
- Term of protection
  - accurate determination of expiry dates can be extremely important, especially for deals concerning pharma patents
  - safest to confirm with local agents in each territory, especially in case of patent term extensions/SPCs

# Scope of protection (cont.)

- Are there other barriers to competition besides target's patent rights?
- Regulatory data exclusivity?
  - powerful barrier against generic competition
  - will often extend beyond expiry of the patent (and SPC)
  - some investors may attach more importance to this than the patent (and SPC) term

# Validity Issues

- Objective: determine if the target's key patents are valid and enforceable
- Process:
  - identify relevant prior art
  - assess validity/patentability in view of prior art
  - identify any other validity issues – sufficiency, added matter
  - and any issues that could affect ability to enforce patents, e.g. US case law on inequitable conduct
  - claims too broad?

# Validity issues (cont.)

- Prior art base for validity assessment
  - clear boundaries are needed, but have different levels of risk associated
- Consider only prior art from file histories?
  - essential when assessing scope of claims likely to issue from a pending application (or a granted patent under opposition/appeal)
  - less helpful if patent has been granted – unless the Examiner has made a mistake
  - and even less so if patent has been maintained over the cited art in opposition/appeal

# Validity issues (cont.)

- What more could you do?
- Search for inventor's own prior art
  - especially conference posters and abstracts, can be a good source of relevant art
- US file histories
  - also a useful source due to information disclosure requirement
- Include searches carried out by the target or documents from FTO searches
- Conduct extensive independent prior art searching
  - may be worthwhile for key platform technology patents, or early stage applications, if budget and timescale allows – need to search technical literature as well as patents

# You can't do EVERYTHING!

- What level of risk is the investor/buyer/licensee willing to accept?
- What can be done within budget and timescale?
- Boundaries must be set and agreed by parties and advisors
- Ensure everyone understands what is being done and what is **not** being done - and the **level of risk** in not doing it

# Antitrust Issues?

- TTBE in Europe? R&D B/E?/Patent misuse in the US?
- AZ decision plus recent Commission Inquiry and follow up raids
- Has the target engaged in practices which might be in breach of Article 102?
- "Excessive patenting"
- Very difficult to advise given current uncertainties
- Settlement agreements, particularly with generics
  - case law uncertain in the US but recent victory for the FTC
  - Commission clearly looking at as part of their inquiry
  - e.g. case against Lundbeck re Citalopram

# Presenting the findings

- Again different companies have different styles
- Some want all the detail
- Some just want the “big issues”
- Defining what is “big” in the context
- There is real value created in an experienced lawyer/patent attorney drawing out only those points which are important in the deal context

# Presenting the findings (cont.)

- Executive summary should recommend what action should be taken
  - further enquiries?
  - warranty/indemnity? (what's the difference?)
  - corrective action? (pre or post completion?)
  - condition precedent? E.g. a key assignment, key amendment to a licence, consent to assignment from head licensor etc.
- Useful to have a system to differentiate e.g. traffic lights or show dragger/show stopper terminology
- Oral presentation often required so focus on the key findings
- Make sure the report is acted upon!

# What if you are acting for the target?

- Hopefully it's all in order …
- Make sure you have a clear IP policy which is implemented e.g. invention disclosure by employees, monitoring of third parties, when to patent and when to not?
- IP due diligence positions your IP portfolio for success
- Ask the hard questions now
  - and answer them –
  - before the acquiror's counsel asks them
- Prepare the portfolio for due diligence

# What if you are acting for the target?

- Are the files in good order?
  - have all maintenance fees and annuities been paid up to date?
  - have assignments been recorded?
- Preparation for FTO analysis
  - assemble technical information to enable the suitor to conduct effective FTO
  - do you know which are the problem areas and are you prepared to answer tricky questions on them when asked?
  - decide whether to make opinions available to suitor (remember privilege issues in the U.S.)
- Scope, validity, enforcement
  - what information will be made available to the suitor, e.g. file histories for US applications not open to public inspection, internal records, lab notebooks etc?
- Make sure all relevant agreements are available (check disclosure restrictions) and redacted if necessary/desirable

# QUESTIONS & ANSWERS