IP & Licensing Strategies for Commercialization of Biotechnology Products:
Example: Therapeutic Antibodies:
17 Years with J&J’s Remicade®:
University/Start Up Collaboration to
>$6B WW Annual Sales and
Record $1.7B Patent Infringement
Jury Verdict

Kevin Townsend
Special Counsel
Faegre & Benson
April 27, 2011

Disclaimer

• All information in presentation is publicly available

• Comments and opinions expressed are solely those of author and are not attributable to any other company, firm or person.

• Comments and opinions are not basis for any legal advice or counsel and cannot be relied on as such.
Background

- B.S., M.S. (Physics, Chemistry, Biochemistry, Molecular Biology)
- J.D. (Intellectual Property/Licensing/Regulatory)
- 5 years post graduate research at the NIH
- >10 years of Device/IT/Biotech/Pharma/Chemical, IP and Licensing at law firms
- > 10 years in house IP and Licensing at Eli Lilly and Johnson & Johnson (Centocor Ortho Biotech, Janssen, Ortho Clinical Diagnostics)
- > 15 years licensing experience
- > 100 major (>100M) licensing/acquisition due diligences, negotiations and drafting
- > 3000 agreements

Agenda

- Critical Importance of Patents and Exclusivity
- Patent Filing, Prosecution and Issuance
- Proactive Third Party Patent Licensing Acquisition
- Freedom to Operate
- Example of Biotechnology Product: Remicade ($>6B WW sales)
- University/Start Up Collaboration to >$6B Annual Sales and Record $1.7B Patent Infringement Jury Verdict
Critical Importance of Patents and Exclusivity

- Protect/Recoup investment ($500M-1.7B/product)
- Provide maximum exclusivity and market share for commercialized products (up to millions of $/day) to provide reasonable profit.
- Cover own product, indications, manufacturing, formulations, combinations, administration.
- Cover competitors’ to block, obtain royalties and/or cross license patents relating to competitors’ competing or non-competing products, indications, manufacturing, formulations, combinations, and administration.
- Use pediatric, data, and regulatory exclusivity provisions and regulatory and patent office patent term extension provisions to extend patent term, obtain data exclusivity, and block generics.

Patent Filing, Prosecution and Issuance

- File, prosecute and issue patents on your product, all potential label indications including combinations, manufacturing, formulations, modes of administration, devices, potential combination products.
- File, prosecute and issue patents on your competitors’ products, all potential label indications including combinations, manufacturing, formulations, modes of administration, devices, potential combination products.
- Consider for patenting all types of competing products: full antibodies, other biologics (antibody fragments, alternative scaffolds, receptor fusions, antagonist proteins and mimetics, DNA or RNA products (e.g., siRNAs), etc.), as well as small molecules.
Antibody Related Patent Subject Matter; Target/Antibody Component/Derivatives

- **Antibody Target**: protein, family, class, type, sequence, activity; epitope (sequence, linear, conformational, and method of determination), etc.

- **Antibody Component**: antibody portion or fragment (CDR, FR, Fab, HC or LC, variable, heavy chain); Mab fragments and fusions (enzyme digest, CH-1, -2, -3, hinge, IgG, IgA, sequence, portions), etc.

- **Antibody Derivatives**: Component fusions, PEGylated, protein engineering (e.g., random v. designed sequences), affinity maturation, glycosylation/cleavage site engineering, solubility, constant region immune functions, immunogenicity, etc.


- **Antibody Target Company Examples**: Genentech, Amgen, HGS, Medarex, Elan, Immunex, Regeneron, Zymogenetics, Wyeth, Genetics Institute, NIH, etc.

- **Antibody and Component Company Examples**: Genentech, Amgen, HGS, Medarex, Immunex, Merck, Regeneron, Zymogenetics, Elan, Wyeth, Genetics Institute, Biogen, etc.

- **Antibody Derivatives Company Examples**: Applied Molecular Evolution/Lilly, Protein Design Labs, Dyax, Genentech, Amgen, HGS, Medarex, Elan, Immunex, Regeneron, Zymogenetics, Wyeth, Genetics Institute, etc.
Antibody Related Patent Subject Matter:
Discovery/Screening/Engineering

- **Antibody Discovery Technologies**: phage display, transgenic mice, humanization, CDR grafting, protein engineering, alternative scaffolds, non-rodent/primate mammalian (camel, etc).

- **Antibody Screening Technologies**: protein or ELISA screening, phage display screening, Western blot screening, cell based screening,

- **Antibody Engineering/Modification**: protein engineering (e.g., random v. designed seqs), affinity maturation, glycosylation/cleavage site engineering, solubility, constant region immune functions, immunogenicity, etc.

Antibody Related Patent Subject Matter:
Discovery/Screening/Engineering

- **Antibody Discovery and Screening Technology Companies**: CAT, MRC, Morphosys, Dyax, Xoma, Biosite, Abgenix/Amgen, Amgen, Medarex/GenePharm, Genentech, Scripps Inst., Stratagene, PDL, Wyeth/Immunex/Amgen, Genetics Institute, Biogen-Idec, etc.

- **Antibody Engineering/Modification Companies**: Applied Molecular Evolution (AME)/Lilly; CAT, MRC, Morphosys, Dyax, Xoma, Biosite, Abgenix/Amgen, Amgen, Medarex/GenePharm, Genentech, Scripps Inst., Stratagene, PDL, Immunex/Amgen, Genetics Institute, Wyeth, immunex, Biogen-Idec, etc.
Third Party Patent Acquisition and Licensing Program Important

- Active Third Party Patent Evaluation, Acquisition and Licensing Program will:
  - reduce royalty burden by getting rights early and at reduced cost;
  - provide freedom to operate at lower cost/royalties;
  - provide cross-licensing of patents for later negotiations for other licenses, disputes, settlements or litigations;
  - help maximize market share with broader patent portfolio; and
  - Help mitigate common problems associated with (late) entry into existing or crowded markets.

Freedom to Operate (FTO)

- FTO: Complex matrix of types of patents and patent applications, for:
  - evaluation,
  - design around,
  - opinions,
  - due diligence,
  - negotiations,
  - licensing,
  - reexamination,
  - oppositions, interference, appeals, and/or litigation,
  - to minimize royalty burden and provide freedom to operate.
Types of Patents Potentially Affecting Freedom to Operate

- Potentially Relevant Patents that may or may not be licensable for License Fees and/or Royalties:
  - Antigen: proteins and amino acid sequences
  - Antibody: generic, Mab type, affinity, DNA, AA sequences
  - Mab Generation: phage, CDR grafting, humanization, engineering, transgenic animal, non-human, non-rodent, fusions, modifications
  - DNA/RNA: regulatory element/selection sequences, single/multichain vectors, HC/LC, bacterial/mammalian elements, etc.
  - Vectors: bacterial, mab fragment encoding, selection, combinations
  - Host Cells: mammalian, bacteria, yeast, plant, CHO, Sp2/0, etc.
  - Methods of Expression: batch, perfusion, reactors, fermentors, non-animal derived media components, soluble/insoluble, etc.
  - Methods of Purification: protein A, chromatography, solubilization, viral inactivation/removal, size exclusion, etc.
  - Formulations: sugars, buffers, salts, stabilizers, surfactants, solutions, lyophilization, reconstitution, concentrations, ratios, etc.
  - Administration: IV, IM, SC, inhalation, nasal, (oral, transdermal)
  - Indications: oncology, immunology, neurological, dermatology, infectious disease, mabs, proteins, antagonists

Potential Royalty Stacking Hypothetical

<table>
<thead>
<tr>
<th>Patents</th>
<th>Expiry</th>
<th>Subject Matter</th>
<th>Potential Royalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target/antigen</td>
<td>2015</td>
<td>Protein, DNA, Target, epitope, CDRs</td>
<td>A %</td>
</tr>
<tr>
<td>Target Mabs</td>
<td>2015</td>
<td>Target, epitope, CDRs</td>
<td>B %</td>
</tr>
<tr>
<td>Mab Indications</td>
<td>2016</td>
<td>IMID, Oncol, etc.</td>
<td>C %</td>
</tr>
<tr>
<td>Mab Technology</td>
<td>2017</td>
<td>grafted, transgenic, phage, engineered</td>
<td>D %</td>
</tr>
<tr>
<td>Expression System</td>
<td></td>
<td>promoter, selection, vector, cell line, culture system</td>
<td>E %</td>
</tr>
<tr>
<td>Purification</td>
<td>2019</td>
<td>protein A, chromatography</td>
<td>F %</td>
</tr>
<tr>
<td>Formulations</td>
<td>2019</td>
<td>lyophilized, solution, etc.</td>
<td>G %</td>
</tr>
<tr>
<td>Combination</td>
<td>2020</td>
<td>Other drugs</td>
<td>H %</td>
</tr>
<tr>
<td>Mode of administration</td>
<td>2021</td>
<td>IV, IM, SC, inhalation, transdermal, oral</td>
<td>I %</td>
</tr>
<tr>
<td></td>
<td>2024</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Potential Royalties: 12-30%
Remicade®

- J&J’s largest product (~$6B/year WW)
- Therapeutic engineered chimeric (mouse/human) antibody against tumor necrosis factor (“TNF”) (IgG2, huConstant/ muVariable).
- 15 label indications, including rheumatoid arthritis, Crohn’s disease, psoriasis, psoriatic arthritis, ulcerative colitis, etc.
- Made by recombinant biotechnology, cDNA expressed in synthetic media of cultured, transformed, mammalian cells (Sp2/0, CHO-GS), via reperfusion continuous cell culture and batch cell culture.
- Administration is by intravenous perfusion every 6-8 weeks.
- First drug ever approved for regression of a chronic disease (RA).

Origins of Remicade®

- Collaboration research between NYU Medical Center (NYC) and start up biotech company: Centocor (Malvern, PA).
- NYU discovered high affinity mouse antibody against TNF.
- Centocor isolated cDNA encoding mouse variable region and engineered chimeric with human IgG2 constant region to reduce immunogenicity.
- First CIP/PCT patent application included 130 potential label indications, as well as alternative types of antibodies having similar properties including affinity, competitive binding, epitope mapping, human, chimeric, etc. Patents co-owned by Centocor and NYU Medical Center.
First Work with Remicade

-1992: 3 years out of NIH, 2nd year evening law school, 2nd year as patent agent
-First month at patent boutique firm, Browdy and Niemark, LLP, Washington, D.C.
-Writing 4-5 patent applications per month for NYU Medical Center and prosecution/appeals (e.g., Fiers v. Sugano v Revel, Federal Circuit Interference Appeal, biotechnology reduction to practice (RTP), constructive RTP, enablement, and written description).
-Given NYU/Centocor PCT/CIP to draft:
  -Questions I repeatedly asked inventors for enabling disclosure on:
    -What is potential competition (other antibodies, fusion proteins, human, chimeric)?
    -What are properties of antibody that could encompass competing products?
    -What are potential label indications (markets) based on mechanism of action?
    -How could competing proteins be made or discovered?
    -What are the potential modes of administration?
    -What are the potential devices used?
  -Review of prior art and analysis for disclosure and claims to distinguish.

Continued Work with Remicade

-1992-1994:
  - Additional 6 CIPs/prosecution: 130+ label indications, human, engineered and fusion proteins, characteristics, methods of making, etc.
  - International Filings: EU, Japan, Canada, Australia, etc. (35 countries, not China)
  - Managing international prosecution

-1994-1998:
  - Transferred prosecution to Hamilton, Brook, Smith and Reynolds, Concord, MA

-1998-2000:
  - Centocor acquired by Johnson & Johnson in multibillion dollar deal
  - Remicade® approved 1998, sells in US, Schering Plough Markets in rest of world (e.g., EU, Australia, etc. (except China), Mitsubishi Tanabe sells in Japan.
J&J Acquires Centocor/Remicade®

- 2000: Join J&J, first patent/licensing attorney to support Centocor.
  - Centocor has 10 products in development including 3 lead products besides Remicade®: Simponi® (human TNF antibody); and Stelara® (IL-12 antibody), now on the market.
  - Remicade® Worldwide Prosecution:
    - Directly manage prosecution in US by Hamilton Brook
    - Directly manage prosecution of international filings: EU, Japan, Canada, Australia, etc. (35 countries, not China).
    - Begin setting up and analyzing potential EU and Japanese oppositions, appeals.
  - Review patent licenses relating to Remicade® and other products.
- Abbott Labs acquires Knoll Pharmaceuticals, including TNF and IL-12 antibodies in phase II/III (Begin getting regular phone calls from Abbott’s Chief Patent Counsel).
- Centocor’s Remicade® is marketed in US, EU and Japan by 2001. Predicted to be multi-billion dollar product.
- Peptech, a small Australian issues EU patent out of opposition relating to TNF antibodies binding specific epitopes for human TNF.


- PCT Application filed 1992
- 1994: National Stage Filings: 35 Countries, not China
- 1994-2001: Foreign prosecution initiated, difficulty in EU, Japan
- 2000-2001: take over direct management of prosecution, projected multi-billion product:
  - Review original application disclosure and claims: instruct foreign associates to base all claims on original disclosure and claims;
  - Review cited and know prior art; identify issues to address with future claim amendments and strategy
  - Looked at potential competing products and potential claims
  - Reviewed all Office Actions and draft responses, input on claims and priority application support, with view to potential litigation
  - Began setting up with foreign associates in EU and Japan to plan on conducting interviews with Examiners.
- 2001-2007: Directly manage WW prosecution: provide instructions to foreign associates, phone conferences, review draft responses (in translation if not English) and approve amendments and arguments before filing to assure consistent arguments for claims and cited art. Issue patents in >30 countries.
- Milestones: 2004-2008: EU patent granted, opposed, appealed and issued, covering product, label indications, modes of administration, devices, as well as some potential competitors.
- 2004-2007: Work with Japanese patent counsel, file multiple divisional applications, hire new Japanese patent counsel, conduct telephone interviews with JPO Examiner, in house patent counsel at Tanabe, Travel to Japan to conduct in person interviews with Examiner, meet with in house patent counsel for Mitsubishi Tanabe. Appeal to JPO Board on three cases.
Peptech and Centocor/Remicade: 2000-2004

- 2000: Peptech, a small Australian Biotech issues EU patent out of opposition relating to TNF antibodies binding specific epitopes for human TNF.

- 2000: Peptech Press Release that Peptech contacting J&J for license for Remicade, then detailed technical, business, and legal analysis relating to potential EU and WW licensing, litigation, nullity actions, preliminary injunctions, experts, etc.

-2000: Australian Press and Peptech press releases report that negotiations with Peptech results in WW patent license relating to Peptech's EU and potential other WW issued patents relating to TNF antibodies.


-2002: Analysis results in press stories in Australia announcing that J&J has decided to stop paying royalties.

-2003-2004: Australian Press reports that Peptech and J&J will arbitrate infringement under license agreement.


Potential Infringer of WW Patent Infringement

- US: Reexam, interference, arbitration, declaratory judgement (DJ), litigation.

- EU/EPO: opposition/appeal (can move to enter after initiated); nullity action, UK contract interpretation, submarine action (Italy), arbitration, litigation.

- Issue of preliminary injunction in Netherlands (can be 3-6 months for injunction, which can be carried to other EU countries, then 1-2 years for infringement trial).

- Japan: opposition/appeal; arbitration, litigation. Communication issues with Japanese counsel; Arbitration will be preferred to litigation. Settlement negotiations take many 1-2 week meetings over months and months.

- Early and Comprehensive Preparation: novelty/obviousness prior art, validity, enforceability, experts for generating data and evidence of non-infringement and for refuting patent data and infringement evidence data, reverse doctrine of equivalents, lack of enablement, lack of written description/lack of priority support (EU), utility, claim construction, choice of venue (e.g., E.D. Texas, W.D. Wisconsin), local counsel, timing, etc.
Potential Accuser of WW Patent Infringement

- US: Statutory Disclaimer, Reexam, interference, arbitration, declaratory judgement (DJ), litigation.
- EU/EPO: opposition/appeal (must be fully supported); UK contract interpretation, arbitration, litigation.
- Issue of preliminary injunction in Netherlands (can be 3-6 months for injunction, which can be carried to other EU countries, then 1-2 years for infringement trial).
- Japan: opposition/appeal; arbitration, litigation. Communication issues with Japanese counsel; Arbitration will be preferred to litigation. Settlement negotiations take many 1-2 week meetings over months and months.
- Early and Comprehensive Preparation: novelty/obviousness prior art, validity, enforceability, experts for generating data and evidence of non-infringement and for refuting patent data and infringement evidence data, reverse doctrine of equivalents, lack of enablement, lack of written description/lack of priority support (EU), utility, claim construction, choice of venue (e.g., E.D. Texas, W.D. Wisconsin), local counsel, timing, etc.

EPO Oppositions/Appeals Centocor: 2000-2008 (14 Total)

- 5 EPO Oppositions and Appeals for TNF antibodies, 14 total, including third party granted TNF patents and Centocor EPO TNF patent. Preparation and diligence is critical. Oral hearings are critical and must be argued very carefully. There is misconception that if you win at opposition then you will likely win on appeal. This is a very bad assumption.
- All issues must be carefully analyzed and briefed. The EPO Board will make a preliminary determination based on initial briefs prior to oral hearing. Poor briefs can be outcome determinative against you. Technical experts and declarations are very important to avoid decisions based on attorney arguments. Briefs must be extremely concise (generally 4-5ks shorter than US briefs). Long briefs will be held against you.
- During oral hearings, EPO Board members will tend to side with attorneys they are more used to hear arguing, who tend to make new, baseless, technical arguments, but for which the other side has failed to provide a technical expert declaration. The experts are expected to be at the hearings and the declarations may be discounted if they are not present. However, the experts are often not questioned during the hearing.
- Highly recommend using very experienced European Patent Attorney with long and continuous experience arguing at oral hearings for oppositions and opposition appeals (fluent in German also helps as hearings can be conducted in German at request of patentee), including arguing for technical area of patent.
- DO NOT rely on experienced European Patent Attorneys who have prosecuted patents but who do not have long and continuous oral hearing experience. Plan on hiring an experienced oral hearing attorney at least 6 months prior to first hearing of opposition and plan on retaining for appeal.
- Clients should be warned about likelihood of appeal and aware of budget required, including retaining technical experts for both opposition and appeal. Settlement negotiations with opponents may require concessions to not sue them under issued patent out of appeal, if not going well for patentee.

- Drafted and filed 7 US CIP Applications 1992-1994, (9 CIPs and 65 applications total through 2008)
- 1992-2001: usual difficulty with prosecution, 4 patents limited to sequences, with two “chimeric” treatment patents
- 2000: take over direct management of prosecution, projected multi-billion product, monthly and bi-monthly in person meetings with Hamilton Brook:
  - Review original application disclosure and claims: instruct to base all claims on original disclosure and claims;
  - Review cited and know prior art: identify issues to address with future claim amendments and strategy
  - Looked at potential competing products and potential claims
  - Reviewed all Office Actions and draft responses, input on claims and priority application support, with view to potential litigation
  - Began setting up interviews with Examiners.
- 2001-2006: continued management and participated in 3-5 in-person Examiner interviews per year:
  - Main Examiner eventually started agreeing on broad claim language (competitive binding and epitopes)
- Milestones: 2004-2008: > 30 Broad patents issue, covering product, labels indications, modes of administration, devices, as well as potential competitors

Remicade® WW Sales: 2004-2010

- 2004: US$ 2.1B
- 2005: US$ 2.5B
- 2006: US$ 3.0B
- 2007: US$ 3.3B
- 2008: US$ 3.7B
- 2009: US$ 4.3B
- 2010: US$ 4.9B

[From E.D. Texas Opinion 11/4/09 (“Op.”): (2:07-CV-139-TJW); and public information]

- 2000: Abbott Labs acquires Knoll Pharmaceuticals/BASF, including TNF (Humira®) and IL-12 antibodies in phase II/III (developed with CAT using phage display).

- 2002: Abbott Labs: signs cross licensing agreement with Centocor relating to TNF antibodies.


- 2005: “...Centocor conducted competition testing with Humira and cA2 to determine whether the pending claims directed to human antibodies cover Humira, and that after finding that Humira and cA2 compete for binding as required by the pending claims...” (Op. p 21)

Centocor v Abbott ED Texas Infringement Case

- Filed 2007 for infringement of Abbott’s Humira® claims 2, 3, 14 and 15 of Centocor/NYU US patent 7,070,775.


- May, 2009: Equitable issues bifurcated from jury issues (inequitable conduct, prosecution laches, and indefiniteness).

- June, 2009: Jury Verdict of valid and infringed: $1.67B (1.17B lost profits, 0.5B reasonable royalty).

- November, 2009: Opinion on equitable issues all in favor of Centocor.
Centocor v Abbott ED Texas Infringement Case

Inequitable Conduct:

- First, the Court finds that Abbott has failed to provide clear and convincing evidence of any material misrepresentation or omission during prosecution of the applications in the '775 patent family.
- Second, the Court finds that Abbott has also failed to provide clear and convincing evidence that Centocor withheld any material information from the Examiner. The disputed reference was before the examiner, was not a reference that was withheld from the USPTO, and thus the examiner was free to accept or reject the prosecuting attorney's arguments.
- Third, the Court finds that Abbott has failed to provide clear and convincing evidence that Centocor had a sample of MAK-195 and that Centocor had a duty to obtain and test a sample of MAK-195 in these circumstances.
- Fourth, the Court finds that Abbott has not proven by clear and convincing evidence that Centocor had a duty to cite to the Examiner prior rejections in the parent applications of the '775 patent, when the file history of the patent applications was already before the examiner.
- Further, the Court finds that Abbott has failed to prove by clear and convincing evidence that the inventors, attorneys, or anyone else associated with the prosecution of the '775 patent or patent family intended to deceive the USPTO by their alleged misrepresentations or omissions of material facts. Abbott has not shown any direct evidence of intent, and instead asks the Court to infer intent. The Court finds that Abbott has not proven that inference of intent is appropriate under these circumstances. Abbott has not shown by clear and convincing evidence that the inventors or attorneys knew that any arguments made to the USPTO were false or misleading. As noted above, evidence has been presented showing that these arguments were not false or misleading. Deceptive intent is not, in this case, the "single most reasonable inference." Thus, because the Court has found that Abbott has not satisfied its burden of proving that Centocor made material misrepresentation or omissions during prosecution of the '775 patent family or deceptive intent by clear and convincing evidence, inequitable conduct cannot be found in this instance. See Star Scientific, 537 F.3d at 1365-67.


Laches:

- Centocor also argues that in July 2002 when it filed claims directed to chimeric and human anti-TNFα antibodies that it had begun development of its own human anti-TNF antibody. Centocor argues that it was not until August 2005 that Centocor conducted competition testing with Humira and cA2 to determine whether the pending claims directed to human antibodies cover Humira, and that after finding that Humira and cA2 compete for binding as required by the pending claims, Centocor notified the patent office that the claims cover Humira. Centocor argues that it is not unusual or improper to draft claims to cover a competitor's product, as long as there is a basis in the pending application.

- “The Court has considered the totality of the circumstances in this case, including the prosecution history of all the applications leading to the '775 patent, and finds that Abbott has not met its burden of proving that there was any unreasonable delay by Centocor in the prosecution of the applications in the '775 patent family. . .”

- “Centocor provided reasonable explanations for its lengthy prosecution of the applications in the '775 patent family. Indeed, Centocor was successful in obtaining numerous patents from the applications leading to the '775 patent. Further, the Court finds that Abbott, in contrast to Centocor, presented no evidence regarding what practices are considered reasonable in the prosecution of life sciences patents. . .”

- “The Court also finds that Abbott did not meet its burden to show that Centocor used delay tactics in presenting claims directed to human antibodies. It is not unusual or improper to draft claims to cover a competitor's product, as long as there is a basis in the pending application. See Kingsdown, 863 F.2d at 874 ("there is nothing improper, illegal, or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market"). . .”

Centocor v Abbott ED Texas Infringement Case

- Indefiniteness:
  - "... The Court interpreted the claim language "competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF-α" to mean an antibody must "compete[] with A2 (ATCC Accession No. PTA-7045) for binding to human TNF-α" in order to infringe the claims. Abbott argues that as defined, the limitation does not permit a person of ordinary skill in the art to "understand the bounds of the claim." Abbott raised this issue at claim construction and the Court ruled on it in its Markman Order, adopting Centocor’s claim construction. ...

The Court first notes that it has already rejected Abbott’s arguments that the “competitively inhibits” language is indefinite in its Markman Order in this case. The Court again finds that Abbott has not shown by clear and convincing evidence that those skilled in the art would not understand the bounds of the claims or that the claims are “insolubly ambiguous.” Abbott has failed to prove that the results of competition testing will change depending on the assay conditions. Further, the Court finds that the evidence adduced during the jury trial shows that those skilled in the art would understand the bounds of the asserted claims. For example, Abbott's expert relied on antibody competition testing done by a different retained expert to support his conclusions about invalidity in this case. Abbott's expert also did not contest the protocols used by a Centocor scientist to show antibody competition or the quality of the results. Thus, the Court finds that Abbott has failed to show by clear and convincing evidence that the claim term "competitively inhibits" is "insolubly ambiguous," and thus the Court finds that the '775 patent is not invalid for indefiniteness.

Centocor v Abbott Federal Circuit Appeal

- Filed early 2010 after 11/9/2009 ED Texas Opinion on inequitable conduct, laches and motions by Abbott
- Opinion Issued yesterday February 23, 2011
- “Reversed” ED Texas Verdict of valid and infringed
- Sua Sponte Lack of Written Description
- Reasoning shows Fed. Cir.’s overlap with lack of enablement and appears to reject constructive reduction to practice and require actual reduction to practice.

“At bottom, the asserted claims constitute a wish list of properties that a fully-human, therapeutic TNF-α antibody should have: high affinity, neutralizing activity, and the ability to bind in the same place as the mouse A2 antibody. The specification at best describes a plan for making fully-human antibodies and then identifying those that satisfy the claim limitations. But a “mere wish or plan” for obtaining the claimed invention is not sufficient. ... At the time the 1994 CIP applications were filed, it was entirely possible that that no fully human antibody existed that satisfied the claims. Because Centocor had not invented a fully-human, high affinity, neutralizing, A2 specific antibody in 1994, a reasonable jury could not conclude that it possessed one.

- Likely will be asked for hearing en banc
- Likely will be appealed to Supreme Court
Questions, Comments

Thank You!

• Kevin Townsend,
  Special Counsel
• Faegre & Benson
• ktownsend@faegre.com
• 1-303-607-3636