



Wolf Greenfield

SPECIALISTS IN INTELLECTUAL PROPERTY LAW

Amgen, Inc. v. F. Hoffman-La Roche Ltd. *(D. Mass., Judge William Young)*

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Massachusetts Biotechnology Council

May 29, 2008

Status

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- **Amgen sued in 2005 on four EPO patents**
- **October 2007 – jury found patents infringed and valid**
- **Judge denied post-verdict JMOL motions**
- **Court now considering allowing Roche to sell infringing product**

Background

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- **Amgen sells patented products, Epogen[®] and Aranesp[®], to treat anemia in patients with chronic kidney disease**
 - ~50% of Amgen's revenue
- **J&J (Ortho Biotech) sells Procrit[®] (EPO for purposes other than dialysis/diagnostics) under 1995 license from Amgen**
- **Roche sells Mircera[®] (peg-EPO) in Europe**

Fact Issues – Clinical & Dosage

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- **Mircera® differs from Amgen products**
 - FDA allows less frequent dosing
 - Active ingredient identical, however
 - No medical advantage to Mircera®
 - Amgen – frequency of dosing unimportant
 - Dialysis - frequent dosing anyway
 - Simply convenience factor, not medical need
- **One-for-one substitution**

Fact Issues – Financial

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- **\$\$ Savings**
 - **Dispute whether Mircera® would be priced higher or lower than Amgen products**
 - **Amgen – higher reimbursement rates**
 - **Roche – competitive discounting will follow, possibly saving billions**

Permanent Injunction

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- **General rule – injunctions should issue**
- **EBay (May 2006) – Plaintiff must establish 4 factors:**
 - 1) **Irreparable injury**
 - 2) **Monetary remedies inadequate**
 - 3) **Balancing of hardships**
 - 4) **Public interest**

Judge Young's Approach

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- **February 29, 2008 – Undecided on permanent injunction, but**
 - **Would eventually decide and write opinion**
 - **In meantime: Preliminary Injunction**
- **Findings**
 - **Valid and infringed**
 - **Less than permanent injunction would inadequately compensate Amgen**
 - **Balance of hardships favors Amgen**
- **Undecided as to public interest factor, but “no disservice” from preliminary injunction**

Kicker

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- **If neither party appealed, court might amend preliminary injunction to allow Roche sales if Roche agreed to:**
 - Pay 22.5% royalty
 - Sell at price equal to or lower than both Amgen's products for life of patents
 - Provide certain additional data on dose conversion factor
 - Fund independent agency
 - Continue to provide Mircera[®] at same price to patients

Kicker *(cont.)*

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- **Roche indicated agreement, but appealed preliminary injunction anyway**
- **Federal Circuit denied expedited treatment of appeal**

Would Court Refuse Injunction? Would Refusal be Affirmed?

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- **Post EBay – competitive situations – always enjoined**
- **Encourage more infringement**
- **Congressional resistance to compulsory licensing**
- **Patent system – investment incentives**

Would Court Refuse Injunction? (*cont.*)

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- **Amgen – can sue for damages anyway?**
 - **89% profit margin**
 - **Willful infringement**



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