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Institution **Harvard Law School**
Course / Session **F21 Fisher Patent Law**
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Exam Mode **TAKEHOME**
Section **All** Page 1 of 21

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Count (s)	Word (s)	Char (s)	Char (s) (WS)
Section 1	98	501	598
Section 2	99	527	625
Section 3	499	2725	3220
Section 4	1299	6883	8171
Section 5	1994	11741	13697
Total	3989	22377	26311

Answer-to-Question- _1.1_

No. When a patentee sells a product, it exhausts all rights, regardless of the location of the sale or any restrictions the patentee purports to impose (*Lexmark*). A licensee's sale is treated as the patentee's sale, even if the licensee imposes a restriction on purchasers. The narrow *General Talking Pictures* exception holds that a licensee's *unauthorized* sale does not exhaust patent rights, but here, Laurent made an authorized sale within Italy -- the license agreement did not require Laurent to inform purchasers of the importation bar (and even if he had, Max could not be enjoined by Kara).

Answer-to-Question-_1.2_

Old novelty rules apply. Nathan overcomes the public-use bar, because Olivia's use was confidential: he asked her to keep the sales secret, and she told no one about the mousetrap. No formal NDA is necessary (*Barry*). There is no confidentiality exception to the on-sale bar, so Nathan's sale to Olivia is excused only if "experimental." There are no indicia of experimentation (e.g. supervision, control, recordkeeping, *see Loff, Polara*), and the sale does not seem "incidental to experimental use," so the application should be rejected due to the on-sale bar (Nathan sold the mousetraps prior to the one-year grace period).

Answer-to-Question- _1.3_

The prior art includes anything “inherent” in the listed art (*Toyota*). The PHOSITA here is probably someone with a bachelor’s degree in molecular pathology or a similar field. The necessary inventive step here is not too high, because biotechnology is an unpredictable field (Lemley & Burk).

Challenger argues that the prior art teaches toward the invention and that the invention was “obvious to try” (*KSR*). The *Nature* article and PhD dissertation both teach production of monoclonal antibodies; the 3 patents teach using *polyclonal* antibodies for sandwich assays; and the YouTube lecture and textbook teach using assays for different purposes. Thus the inventive step taken here seems to be using a *monoclonal* antibody for the particular type of assay at issue. Arguably the prior art can be combined by a PHOSITA to reach this result (*SRAM, Nabisco*).

However, this case seems closest to *Toyota*. Both cases involve prior art that teaches a similar approach (here, the textbook teaches the use of sandwich assays for *different purposes*; cf. catheter instead of screen), along with prior art that helps lead to the scientific approach (here, the *Nature* article and the PhD dissertation teach the production of monoclonal antibodies). But nothing here teaches using *monoclonal* antibodies for sandwich assays (the other patents use *polyclonal* antibodies, and the

YouTube lecture uses monoclonal antibodies for a different assay).

I'd inquire whether the sandwich assays in the textbook are polyclonal or monoclonal, but overall I think the invention is nonobvious. As a humanities major, I'm unsure whether the dissertation affinity is 10 liters/mole (with typo exponent) or 10 billion liters/mole, but either way the dissertation arguably teaches *away* from the invention, which claims substances over 108 liters/mole -- if the dissertation teaches 10, the 108 is significantly higher; if the dissertation teaches 10 billion, the 108 is far lower, so PHOSITA likely wouldn't test at that level (*Actavis*). See *Chemours* (holding that prior art of 24 g/10 minutes taught away from 30 +/- 3 g/10 minutes).

Between the "teaching away" issue and the fact that the nonobviousness threshold is low for biotechnology (Lemley & Burk), along with the fact that *Toyota* was a close case (though ultimately finding obviousness), I'm inclined to find this invention nonobvious, especially when avoiding the temptation of hindsight bias (*KSR*). I would also like to gather more information pertinent to secondary factors: e.g. was there commercial success with a nexus to the invention; applause; copying by others; and did the invention address a long-felt unsolved need (e.g. does this assay approach provide a breakthrough in life-saving treatments). On the other hand, I'd want to know if there was parallel independent invention, which would counsel against nonobviousness.

On a separate note, this invention may fail an enablement challenge (especially because the enablement threshold is high for biotechnology, Lemley & Burk), because it purports to claim any antigenic substance over 108 liters/mole. If there is some antigenic

substance above that number that the invention fails to address, there is an enablement issue (*Regeneron*).

Answer-to-Question- _1.4_

a)

To determine subject matter eligibility, we use the *Alice* test as applied to AI. Under Step 1, the claim is directed to a combination of a machine (the processor and memory) and a process (the operations of the processor). But under Step 2A, the claim is directed to the “abstract idea” of using AI to compare and contrast images (*cf.* geolocation example, comparing person’s preferences with nearby locations; *Electric Power Group*, holding that “collecting and analyzing information” counts as “abstract idea”). And under Step 2B, the claim does not include an “inventive concept” that adds “something more” to the judicial exception: the mere use of a computer to accomplish the process is insufficient (*Alice*), and the claim does not characterize the invention as actually improving the functionalist of a computer (and more cynically, it fails to use lots of technical jargon, which can sometimes help protect eligibility). Thus on first glance, the patent should fail *Alice*.

Alice caused the invalidation of thousands of software patents. It is especially hostile to AI patents, which almost always involve an “abstract idea.” As a result, the U.S. suffers from an “AI Gap” where it lags severely behind China and Korea in AI patents. The NSC has recommended closing this gap, including by granting more AI

patents. Similarly, the 2019 USPTO guidelines try to help AI by breaking *Alice* Step 2A into two parts. Under 2A(1), the invention here still recites the judicial exception of “abstract idea,” but under 2A(2), it is “integrated into a practical application” (i.e. the very specific task of preventing dental insurance fraud). Thus these guidelines could help Claim 1 survive an eligibility challenge. For example, *McRo* held eligible AI claims that allowed the “automation of further tasks”; here, the claimed technology allows automation of dental imagery comparisons. USPTO examples may also help FB (e.g. because FB didn’t recite the actual mathematical concepts, and the steps are not practically performed in the human mind). The ultimate outcome may turn on whether the court views the guidelines as consistent with *Alice*.

In addition to subject matter eligibility, 35 U.S.C. 101 includes the utility requirement. The invention here would easily survive a utility challenge. It has general/operable utility (all parties agree that it works -- indeed, BDIC wants to use it), specific/practical utility (it has the practical application of preventing dental insurance fraud), and beneficial utility (it benefits insurance companies by preventing fraud, and likely benefits consumers whose premiums may decrease if fraud is less prevalent).

b)

New novelty rules (“first-to-file-or-disclose”) apply, because this was filed after March 16, 2013. Frank disclosed the invention to Samantha (and perhaps offered to sell it) five months before the filing date, but this does not destroy novelty because it’s disclosure by the inventor during the one-year grace period. Samantha disclosed the

invention in January 2020 (through the “printed publication” of the presentation, or by making the invention available to the public), but this also does not destroy novelty, because it was derived from the inventor (indeed basically stolen, since Frank asked her not to disclose), and perhaps also because it followed public disclosure by Frank to Samantha (though this may not be “public” -- this is unresolved and perhaps will be decided in *Helsinn*). Claim 1 would thus survive a novelty challenge.

c)

Unlike novelty (which concerns only prior art references including all elements of the claim), prior art for nonobviousness includes anything “reasonably pertinent to the particular problem” and anything “inherent” in that art (*Toyota*). Since the AIA, the scope of prior art includes any art up to the filing date (February 1, 2020). Thus our search for prior art should be very broad. First, we should examine prior art related to methods of dental imagery and decisionmaking on insurance claims (which relate to “obtaining” the first radiograph image and “determining” that there is potential fraud). Second, we should collect prior art on AI programs, especially those that use ConvNet or other Deep Learning algorithms, which compare different images -- similar programs are surely used by law enforcement for facial recognition, by tech companies like Google for image matching, and many other purposes. Third, we should examine prior art that creates digital signatures and adds and compares them with an ongoing database -- such art likely exists in various fields, including blockchain and other fintech. Fourth, we should collect prior art on presenting stored information on a GUI -- countless examples of this come to mind (e.g. Apple). All this prior art can consist of patents, articles, video, or any other

form of art. Overall, we want to collect sufficient prior art to show that a PHOSITA (likely someone with a bachelor's or graduate degree in computer science -- though arguably, the PHOSITA should be an "AISITA") would be able to make the inventive step of combining those references, along with anything "inherent" in them, to create the patented invention. This will be a strong argument, because the Federal Circuit often finds software patents obvious unless the patent covers the first ever program to perform a given function (Lemley & Burk).

d)

If BDIC uses FB's exact technology, it will be liable for literal infringement under § 271(a). And no defenses (other than invalidity) seem tenable, except perhaps if FB intentionally withheld material information about the invention from the USPTO (*Therasense*).

First, the court will award monetary damages to FB. FB will likely seek lost profits (i.e. compensatory damages for the lost sales of the technology due to BDIC's infringement). It will need to show that there was demand for the product (which is likely), that there were no acceptable noninfringing substitutes in the market (also likely, given that insurance companies lack capacity for human examiners, and given that there's no sign that BDIC was "ready and able" to produce a noninfringing substitute itself), that FB was able to exploit consumer demand, and the amount of profit it would've made. (FB may also seek consequential damages, e.g. through the EMV Rule for any components it would have sold along with the technology, such as computers). Lost

profits may be rejected if FB is unable to show that it could fully exploit consumer demand, e.g. because its licensing fee was too high.

More often, the patentee resorts to receiving a “reasonable royalty,” usually measured through a “hypothetical negotiation” to determine the amount BDIC would have paid as a royalty to FB use the product. The court will consider the clumsy and redundant *Georgia-Pacific* factors, and might indirectly consider BDIC’s profits (*Lucent*).

FB may also seek prejudgment interest. Also, it may seek enhanced damages of up to three times the regular damages (§ 284). It will argue that BDIC’s conduct is “egregious” (e.g. willful) by a preponderance of the evidence (*Halo*). After *Halo*, enhanced damages are granted 55% of the time when infringement is found, and FB will have a strong case here because BDIC knew of the patent but chose to infringe rather than pay the license fee.

FB will likely request preliminary and permanent injunctions under § 283, but this will likely be rejected, because injunctions are difficult to obtain under *eBay*. FB would struggle to prove irreparable injury and that monetary damages are inadequate; additionally, the public interest may be disserved by an injunction (which would decrease the availability of the invention to insurance companies, thus causing more fraud and perhaps increased premiums for consumers). An injunction is especially likely if FB is a non-practicing entity (Kennedy concurrence in *eBay*). If the injunction is denied and BDIC wishes to continue using the technology, the court may encourage FB and BDIC to

negotiate a semi-voluntary license fee. If this is unsuccessful, BDIC will need to pay an “ongoing royalty” (which on average is 1.66 times the reasonable royalty, *see* Sidak) to FB.

Answer-to-Question- 2

Why eBay Was Wrong

In the 2006 decision *eBay Inc. v. MercExchange, L.L.C.*, the Supreme court held that the traditional four-part test for injunctive relief should be used when determining whether to grant an injunction against patent infringement. Courts thus now require patentees to show that 1) they suffered irreparable injury, 2) legal remedies are inadequate to compensate the injury, 3) the balance of hardships favors the patentee over the infringer, and 4) an injunction does not disserve the public interest (*eBay*). This holding sharply limited the availability of injunctive relief to prevailing patentees (Gupta & Kesan).

eBay was wrongly decided, but not because injunctions should be widely available for patentees. Rather, *eBay* represented a missed opportunity to frame the injunction inquiry in terms of the cultural view of patent law. The availability of injunctive relief should chiefly depend on its impact on global equity and distributive justice.

I. *eBay* Falls Short Under the Utilitarian, Fairness, and Personality Theories

The dominant theory of patent law is the incentive theory, which is part of the

utilitarian (or welfare) view. Under this theory, inventions are naturally underproduced public goods; patent law exists to incentivize innovation toward the socially optimal level. While *eBay* purports to advance this theory, its actual utilitarian impact is unclear.

The utilitarian argument in favor of *eBay* is that injunctions are harmful, especially when patentees are socially pernicious non-practicing entities (NPEs), because they give patentees holdup power and lead to inefficient “royalty stacking” when negotiating post-injunction licenses (Lemley & Shapiro). Another possible benefit of *eBay* is that it creates a “lottery effect” by decreasing the probability of the maximum payout of an injunction, which could incentivize innovation among overoptimistic creators who love skewness (Crouch).

Critics of *eBay* note an empirical absence of patent holdup and royalty stacking (Barnett) and argue that sophisticated businesspeople can efficiently negotiate licenses (Elhauge). And arguably, *eBay* worsens a public goods problem that other patent doctrines have already exacerbated. Patent availability has been limited by various other rules in recent years. For example, subject matter eligibility has contracted in the 21st century, particularly in the realms of tax strategies (eliminated by AIA), medical procedures (*Mayo*), genetic sequences (*Myriad*), and software and business methods (*Alice*), especially those derived from artificial intelligence (at least until the 2019 USPTO Guidelines). The new novelty rules allow various actions in other countries (such as sale and public use) to destroy novelty, where the old rules limited the knowledge and use exception to domestic activities. The nonobviousness threshold has risen (*KSR*), and biotechnology inventions must surpass high disclosure and utility requirements, though

lower a nonobviousness bar (Lemley & Burk).

In addition to those substantive doctrines related to patent validity, the advent of inter partes review (IPR), has made it more difficult for patentees to retain their patents once granted. IPR allows challengers to mount a much faster attack on patent validity, and to prevail much more often. Furthermore, even where patents are granted and survive challenge, the *Lexmark* decision sharply limits the benefits patentees can reap. Under *Lexmark*, sale of a patented product triggers complete exhaustion, regardless of the location of sale or any restrictions the patentee purports to impose; this decision prevents patentees from engaging in differential pricing, thus sharply limiting the economic benefits they can derive from patents. Other patents have reduced economic value because of their duration -- in particular, pharmaceutical patents only have a commercial life of approximately twelve years (due to time spent in preclinical testing, clinical testing, and FDA review), even with a five-year extension added by the Hatch-Waxman Act.

Patentees, therefore, will argue that these various doctrines already make patent prosecution difficult and patent exploitation harder still. By limiting injunctive relief, *eBay* limits their economic rights even further. For example, *eBay* may increasingly enable “efficient breach” by infringers who deem it worthwhile to intentionally breach patents to build a market share, then diverge -- this was Samsung’s strategy, and it proved successful despite eventually losing the vast majority of suits in *Apple v. Samsung*. Evidently, then, while *eBay* has some utilitarian support, it has ample downsides under the incentive theory too.

If the welfare outlook is inconclusive, the fairness and personality frameworks seem irreconcilable with *eBay*. The fairness theory, associated largely with Locke, emphasizes that inventors have natural rights to the fruits of their intellectual labor. By markedly shifting patent law from property rules toward liability rules, *eBay* undermines this notion of moral desert, thus destroying the “essential foundation” of the “liberal political order” of excluding others from one’s property (Mossoff; cf. Gorsuch dissent in *Oil States*). Additionally, injunctions are consistent with the U.S. culture of lauding innovation (though arguably inconsistent with the equally strong cultural preference for competition, *see* Bill Lee lecture). The personality theory, which is more Kantian and Hegelian, emphasizes that intellectual products are extensions of inventors’ personalities; therefore, inventors should retain considerable control over such products. Ample access to injunctive relief is consistent with both of these theories, and thus *eBay* appears contrary to their aims.

In summary, *eBay* is an insufficient response to the utilitarian, fairness, and personality frameworks of patent law. In the next section, I turn to the cultural theory. The *eBay* Court’s true failure, I argue, was missing an opportunity to frame the injunction inquiry in terms of distributive justice.

II. A Cultural Framework for Patent Injunctions

The cultural view of patent law recognizes the existence of deep global inequities, and posits that patent law should seek justice. Patent law should support the search for the

“good life,” including values such as life, health, and competence, and should further the causes of distributive justice and global equity. *eBay* missed an opportunity to frame the injunction test around this cultural view.

One area where redistributive justice is sorely needed is the global health crisis. The leading causes of death in many low-income countries, predominantly in the Global South, are infectious diseases such as HIV/AIDS, tuberculosis, and malaria. Pharmaceutical companies are economically incentivized to focus their research on “me-too” drugs and medicines for the U.S. market; meanwhile, they neglect to spend sufficient resources researching breakthrough drugs, central nervous system (CNS) diseases (Choi), vaccines, and treatments for neglected infectious diseases (Fisher & Syed). Conflicts and gaps between the incentive, quality, and access functions of government have exacerbated these inequities and led to an influx of substandard drugs, especially in sub-Saharan Africa (Fisher, Okediji & Sampath). TRIPS arguably exacerbated these issues by making some developing countries (with exceptions related to least-developed countries and TRIPS “flexibilities”) grant patent protection for foreign pharmaceutical products, thus undermining the development of local pharmaceutical industry.

A culturally-oriented injunction framework could help ameliorate this problem. Injunctions should be granted for patents on breakthrough and CNS drugs, vaccines, and treatments targeting neglected infectious and parasitic diseases; injunctions should be denied, however, for me-too drugs, other low-value medicines, and perhaps some antibiotics, where a prize system might be more effective (Lander). To make this happen, *eBay* could have defined the injunction test in terms of global equity; this would

contribute to “de-biasing” pharmaceutical firms’ skewed incentives (Fisher & Syed). Perhaps the inquiry could even consider DALYs or another metric that would incentivize the development of live-saving and pioneering drugs. Finally, this approach would also help serve the cultural framework’s aspiration of “competence,” by helping developing countries build local capacity to address pressing public health crises (*cf.* Fisher, Okediji & Sampath).

An injunction test focused on distributive justice would also support increased protections for traditional knowledge. In particular, injunctions for patents derived from traditional knowledge should only be granted if such patents are fully compliant with prior and informed consent and access and benefit-sharing (PIC/ABS) principles under the Nagoya Protocol. In PIC/ABS agreements, such as the one used for the development of Prostratin, indigenous groups can be named as inventors and will share the benefits of the patent. The ability to enforce such patents through injunctions will incentivize firms to negotiate fairly with indigenous groups, and will increase the benefits shared with those groups. Distributive justice will be served by this framework, because indigenous groups lag significantly behind non-indigenous people on various socioeconomic metrics -- for example, over forty percent of Native Americans suffer from food insecurity. Meanwhile, patents not fully compliant with PIC/ABS principles should likely be invalidated (often due to biopiracy) but certainly should not receive the benefit of injunctive relief. The cultural framework will thus help ensure that patents serve the interests of indigenous groups who have been severely harmed by patent law’s failure to protect traditional knowledge.

This framework could still alleviate the concerns underlying Justice Kennedy's concurrence in *eBay*, which argued that we should hesitate to grant injunctions for patents on business methods or components of complex products, particularly when the patentee is an NPE. The cultural framework will deny injunctions for NPEs (because by not practicing the invention, NPEs fail to contribute to distributive justice), and will limit injunctions to only those business method or fintech patents that actually further societal equity (such as P2P lending platforms, which increase access to credit for low-income borrowers). This approach is consistent with the Federal Circuit's applying patent doctrines differently in different industries (Lemley & Burk). It strikes a middle-ground between Prospect Theory (Kitch) and Cumulative Innovation (Merges & Nelson) by rewarding only the most beneficial patents with injunctions, while deterring satisficing behavior by inventors of less valuable innovation.

Arguably, distributive justice could instead be sought by making the beneficial utility requirement more robust. But while this approach would discourage inventors from developing harmful inventions (e.g. due to deception, *see Juicy Whip*, or environmental harm, e.g. acid-wash jeans), it would not incentivize truly life-saving creations like breakthrough vaccines, unless the beneficial utility bar was set extremely high (thus rendering many moderately beneficial inventions unpatentable). By reframing the injunction test around the cultural framework, however, we can fine-tune inventors' incentives such that greater economic benefits accrue to pioneering innovations that drive equity. And unlike beneficial utility, which is primarily considered during patent prosecution, injunctions allow courts to shape distributive justice more flexibly than in twenty-year cycles (*cf.* Judge Prost, noting that judicial discretion allows judges to adapt

to technological change).

Admittedly, *eBay* creates uniformity by using the same four-factor test that is used in other legal fields. But the Federal Circuit exists to leverage its expertise on patent law specifically, and to design and implement standards that aim to balance incentives for innovation with the public interest. To that end, judges in IPR courts throughout the world should receive continuous training, including on the cultural framework of patent law (*cf.* IPI & USPTO, Comparative Study of Specialized IP Courts). Additionally, granting more injunctions would align the U.S. with other countries such as Japan, Germany, and China (e.g. in China, victorious patentees are granted injunctions in 90% of cases when sought). Doing so would be consistent with the Paris Convention, the PCT, and TRIPS, which have sought to harmonize treatment of patents across countries, through mechanisms like national treatment (Paris and TRIPS), the most favored nation principle (TRIPS), and mandatory subject-matter coverage (TRIPS Art. 27), though the principles of territoriality and independence of patents remain. More cynically, a rule friendlier to injunctions would also incentivize more patentees to bring initial suits in the U.S., giving American courts an advantage in shaping the law (*cf.* SSOs, SEPs, and anti-suit injunctions).

Of course, the fourth prong of the *eBay* test does mention public interest, offering a foothold for distributive justice considerations. But by including the other three requirements, and by placing the burden on the patentee, *eBay* demonstrates an unnecessary hostility toward injunctions that finds no firm grounding in the welfare, personality, fairness, or cultural theories of patent law. *eBay* missed an opportunity to

frame the injunction inquiry chiefly around the public interest in distributive justice and global equity.