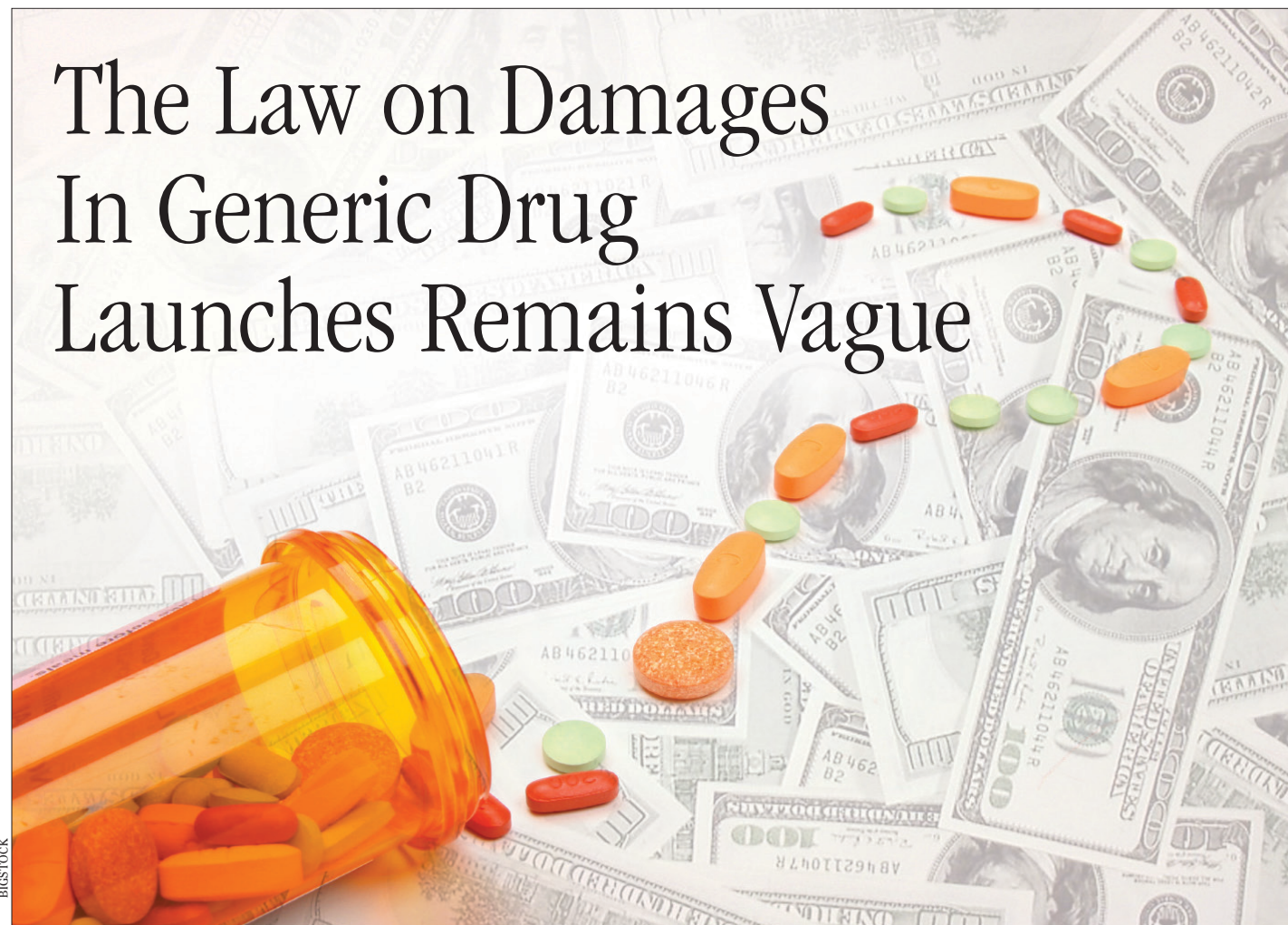


Intellectual Property

The Law on Damages In Generic Drug Launches Remains Vague



BY DAVID MANSPEIZER

It was a stunning number, purportedly the largest patent settlement in history. During trial, defendants Teva (\$1.6 billion) and Sun (\$550 million) agreed to pay plaintiffs Wyeth and Nycomed a combined \$2.15 billion to settle litigation stemming from their “at-risk” launches of generic versions of Wyeth and Nycomed’s Protonix product.

At-risk launches have become a popular tactic by generic companies over the last 10 years. As a result, counsel for branded and generic companies are increasingly litigating highly complex damages issues. However, the law on patent damages as applied to the interactions between generic and branded products in the pharmaceutical marketplace remains largely undeveloped.

Before 2002, the idea that a generic company would begin selling its product before a favorable decision from the U.S. Court of Appeals for the Federal Circuit seemed only a theoretical possibility. The risk that a product launch would result in damages exceeding its profits, together with the purpose of the Hatch-Waxman Act itself, appeared to mean that no generic company would launch before such certainty (generic drugs are typically sold at a substantial discount to the brand). That changed in June 2002, when Geneva Pharmaceuticals began selling a generic version of the popular antibiotic Augmentin after winning summary judgment of patent invalidity. Geneva’s decision provided a new paradigm for generic companies, one that quickly morphed. Soon, generic companies were no longer waiting for even a district court victory to begin selling. Rather, they were actively positioning their cases to be in a position to launch at the end of the Hatch-Waxman imposed “30-month stay” on FDA’s approval of a generic drug. Aided by the Federal Circuit’s shifting standard for preliminary injunction,¹ the threat was reinforced in settlement negotiations. Faced with the potential sudden loss of a large chunk of revenue, many cases were settled. But,

ity of the patentee to satisfy the demand, and the quantum of lost profits.³ Showing demand for the patented product seems not to be an issue, to date, in such cases. After all, the branded product’s sales show that demand and probably the ability to satisfy demand as well. However, any history of manufacturing issues affecting the ability to supply the market will likely be cited as evidence of an inability to meet demand.

A patentee must also prove the quantum of profit it would have received “but for” the infringing sales, typically relying on actual historical sales and forecasts of future sales for this proof.

at least 26 times since Geneva’s actions, generic companies have followed through on the threat. Until Protonix, only three had gone to trial, and none yielded any significant case law guidance for some of the unique issues presented by patent damages in the pharmaceutical marketplace. Settlement likely disappointed those seeking more clarity on potential measures of patent damages, including lost profits and reasonable royalty.

To recover lost profits, a patentee must show it would have received that profit “but for” the infringement.² The lost profits analysis typically includes four *Panduit* factors: proof of demand for the patented product or feature, an absence of acceptable non-infringing alternatives meeting that demand, the abil-

ity of the patentee to satisfy the demand, and the quantum of lost profits.³ Showing demand for the patented product seems not to be an issue, to date, in such cases. After all, the branded product’s sales show that demand and probably the ability to satisfy demand as well. However, any history of manufacturing issues affecting the ability to supply the market will likely be cited as evidence of an inability to meet demand.

Determining if there are acceptable non-infringing alternatives first requires defining the marketplace. No case law answers that question definitively for this unique market. The patentee will likely seek to confine the market to that branded product itself. It will argue that the generic copy is a direct substitute for the brand, and that this defines the market—when a prescription is written for Prozac, the pharmacist cannot substitute another anti-depressant absent the doctor’s permission. Because most states mandate generic substitution, generics can quickly capture up to 90 percent of branded sales. The patentee will also point to the defendant’s business model, a model based on substitution for specific brands. Finally, the patentee will cite the Hatch-Waxman statute, and argue that there can be no non-infringing alternatives under its framework. On the other hand, the generic defendant will argue for a broader marketplace, in which, by definition, non-infringing alternatives exist. Thus, for a drug like Protonix, defendants may argue that the marketplace is all proton pump inhibitors, or even all anti-ulcer medicines. While the presence of non-infringing alternatives does not completely deny the availability of lost profits, it can consign the patentee to a damages award based on market share.⁴ Under a market-share theory, a product with 20 percent market share would capture

20 percent of the generic’s sales. The plaintiff might thus receive a lost profits award limited to only 20 percent of the infringing sales—even though the generic captured 90 percent of branded sales. Existing law has not yet addressed the equities of this scenario.

Branded companies sometimes respond to an at-risk launch by selling an “authorized generic” version of the drug, competing with the infringing generic product on somewhat even grounds, and mitigating loss to some degree. But the generic defendant may argue that the patentee’s authorized generic version of the drug is a non-infringing substitute. The grant of a patent license to a third party, which then sells a product covered by the same patent, can create a non-infringing alternative in the marketplace.⁵ It is unknown, however, whether the Federal Circuit would apply that case law to this particular market. A defendant may also argue that the “authorized generic,” although launched in response to the defendant’s actions, has accelerated the loss of brand sales, and that it should not be responsible for such self-inflicted harms. The response by the patentee: “But for your infringement, I would not have launched my own generic product, and I would have continued to sell at least at prior levels and prices.”

A patentee must also prove the quantum of profit it would have received “but for” the infringing sales, typically relying on actual historical sales and forecasts of future sales for this proof. Of course, the historical accuracy of the forecasts will be contested. But the issues go far beyond. For example, an infringer may point to factors outside of the brand-generic interplay, attempting to place blame for loss of sales elsewhere. It might argue that sales would have declined anyway because a competitor brand



Copyright Trends: Substantial Similarity in the Age Of Electronic Music

BY MICHAEL R. GRAIF AND JASON GOTTLIEB

Driven by technical advances in electronic music production, an increasing amount of popular music lacks several traditional markers that courts use to determine whether one song is “substantially similar” to another: melody, harmony, rhythm, and lyrics.

Instead, the creativity inherent in electronic music centers on the “texture” of the sound being produced. But can a sound texture be protected by copyright? This article provides a road map for lawyers and judges alike to navigate substantial similarity in non-traditional forms of music, with a particular focus on electronic music.

The Traditional Framework

To establish copyright infringement, a plaintiff must demonstrate access to, and copying of, the elements of the work that are original.¹ When a court compares works with both protectible and unprotectible elements, the court’s inspection will be “more discerning,” and the court will ask “whether the protectible elements, standing alone, are substantially similar.”²

The ground rules for evaluating substantial similarity in traditional music are familiar. From Bach through Britney Spears, Western musical compositions traditionally embodied a limited set of features. As Nimmer on Copyright put it: “It has been said that a musical work consists of rhythm, harmony and melody—and that the requisite creativity must adhere in one of these three.”³ Courts expanding beyond that limited ambit do so rarely and tentatively, and focus on traditional elements of musical composition: “melody, motifs, melodic contours, tonality, pitch emphasis, bass line, tempo, generic style, rhythm, ornamentation, harmony and lyrics.”⁴ Courts will also examine combinations of these elements: the same melody line in the same rhythm,⁵ or a similar melody with similar words.⁶

Not all of those elements are necessarily copyrightable. Unprotectible aspects of a song include a common motif in the particular idiom,⁷ a clichéd lyric or a sim-

plistic melodic line,⁸ or a common key signature and rhythm.⁹

The commonality of many songs follows from the structure of Western music. There are only 12 notes in a chromatic scale (i.e., each note on a piano, which repeat every 12 notes).¹⁰ As a result, there are only 12 major and 12 minor keys, and a limited number of possible melodies or chord progressions within each key. Thus, most Western songs have used “tonal-functional harmony at their core, and have a traditional songlike melody.”¹¹ Courts are “mindful of the limited number of notes and chords available to composers and the resulting fact that common themes frequently reappear in various compositions, especially in popular music.”¹² The limited nature of traditional Western music (particularly commercially-oriented music) thus favors the party seeking to copy it.

How Electronic Music Differs

While much electronically produced music contains traditional

When a court compares works with both protectible and unprotectible elements, the court’s inspection will be “more discerning,” and the court will ask “whether the protectible elements, standing alone, are substantially similar.”

elements of music, an increasing (and increasingly popular) amount uses those elements sparingly, or not at all. Yet only the stodgiest would deny that it is music, or that electronic music is a “work of authorship” under the Copyright Act.¹³ Indeed, courts have made this same point about music in other styles. “For the uninitiated, much of rock music sounds the same, and a hasty comparison...could result in a finding of superficial similarity.”¹⁴

The Copyright Act does not define “music.” At base, music is simply a collection of sound waves arranged in a particular manner. When an object is vibrated, that vibration displaces molecules, which produces sound. The molecules travel in waves, until the energy created by the vibration dissipates.¹⁵ The sound takes a particular waveform, depending on its volume, frequency (i.e., pitch), and timbre (i.e., the character of the sound). Differing timbres are critical to music: Such differences allow a listener to distinguish between a violin and a trumpet playing the exact same pitch.¹⁶

The Evolving Hurdle of Patentable Subject Matter

Decisions bring uncertainty to financial services, software and data processing industries.

BY SCOTT D. LOCKE

Last spring, in the much publicized and much criticized case, *CLS Bank International v. Alice*,¹ the Court of Appeals for the Federal Circuit set out to resolve how to apply the standard of patentable subject matter to claims that were directed to certain methods for conducting business, and computer-readable media and systems that implement these methods.

However, rather than providing clarity, the Federal Circuit

introduced more uncertainty into what was already a murky area of patent law, rendering five separate opinions, none of which were signed by a majority of judges. When read in combination, the five opinions suggest that inventors and practitioners who counsel them should be prepared for there to be a hurdle of increased height with respect to the patent eligibility requirement of the patent law.

Shortly after deciding *CLS*, the Federal Circuit issued *Ultraercial v. Hulu*,² in which it appeared to shrink the shadow cast by *CLS*, adopting the reasoning of a minority opinion from that case. However, refusing to embrace the precedent of *Ultraercial*, this fall the Federal Circuit perpetuated the ambiguity in this area of the law, when

in its decision, *Accenture Global Services v. Guidewire Software*,³ it embraced the sentiments of a different opinion from *CLS* than the *Ultraercial* panel did. These three cases form a trilogy that highlights the degree to which the patent system was ill-prepared to confront inventions of the Information Age, and unfortunately have left innovators, particularly those within the financial services, software and data processing industries with challenges when trying to protect their creativity.

Background

The heyday of the Information Age began in the 1990s. Consistent with society’s celebration of innovation relating to ways by which to process and analyze

data, in a pair of now abrogated cases, *State Street Bank & Trust v. Signature Financial Group*⁴ and *AT&T v. Excel Communications*,⁵ the Federal Circuit fully embraced a policy in which there was in effect almost no limit to the types of inventions that were patent eligible. In the decade that ensued, applicants increased the rate at which they filed for patent protection with the U.S. Patent and Trademark Office (USPTO), and the USPTO continued to issue patents that were directed to methods for processing data, as well as to systems and the media on which they were processed.

As the number of these types of patents increased, so too did the number of parties that could infringe them, and this gave rise to the increased prominence of the non-practicing

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10 Can Jurisdiction Over Infringers Be Manufactured?

BY PAUL I. PERLMAN, CYNTHIA GIGANTI LUDWIG AND MELISSA N. SUBJECK

Music

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After several hundred years of music made by a limited set of instruments, any sound can now be created with little more than a laptop and software. Modern electronic synthesizers can manipulate waveforms to recreate traditional instruments, alter them, or create virtually any other kind of sound wave imaginable. The waveforms can take on other characteristics as well, depending on their amplitudes, frequency, phase, and other features, all of which combine to make the particular soundwave that a listener hears.¹⁷ The versatility of music software is such that a modern-day musician can apply a multitude of different types of effects (chorus, reverb, delay, compression, distortion, modulation, etc.) to existing sounds, and in the process create an entirely new sound.

Not all synthesized sounds are original, but even unoriginal sounds can be adapted into original works. Music production soft-

ware comes with a wide array of pre-created, license-free “sample” sounds. Electronic musicians often mix and match these samples, or combine them with other sounds, to create original musical compositions.¹⁸ They may also alter the samples significantly so as to create entirely new sounds, also forming original musical compositions.

Particularly given the “newness” of electronic music, artists should exercise diligence in protecting their copyrights. After all, someone was the first person to chant “it’s your birthday” in a hip-hop song, and someone was the second.

A composition that results from such a creative endeavor may not have the traditional elements of melody, harmony, chord progressions, or lyrics. But it represents a creative effort, the likes of which the Copyright Act is designed to protect. A court attuned only to the traditional elements of music may miss what makes electronic music protectible.

Towards a New Framework

Successful prosecution or defense of an electronic music copyright case depends on understanding electronic music—both its method of creation and the commonly used expressions of the genre.

Plaintiffs must be aware of the characteristics comprising electronic music beyond the traditional markers: synthesizer settings and combinations; timbre; tonality; rhythmic disruptions; and other computerized effects.

Defendants should consider the common or unoriginal elements of the music. Most producers use one of a limited number of digital audio workstations or commercially-available sound sets.¹⁹ As a result, many sounds used in modern electronic music contain (or simply are) those “presets.” Two songs may sound similar, but only because their creators used the same unoriginal license-free presets, or a similar method of creating the song.²⁰

Both sides should encourage their clients to articulate the creative process behind their respective work, the legal relevance of which even the artist may not fully appreciate. The creative process in electronic music is not just knob-twiddling or pressing computer buttons. The computer is a musical instrument, and the process of composing can be used to explain why the resulting composition is protectible.

Particularly given the “newness” of electronic music, artists should exercise diligence in protecting their copyrights. After all, someone was the first person to chant “it’s your birthday” in a hip-hop song, and someone was the second. Once the hundredth person uses

outside the traditionally qualified senior professor with a long list of publications, professional accomplishments, and experience with expert testimony. While there are professors who teach modern electronic music, the phenomenon is new enough that there are relatively fewer senior academics. Some courts have recognized the necessity of practical experience in a particular style. One district court considering two rap songs accepted as an expert an ethnomusicologist, rather than a more traditional professor of composition or music theory.²³ That expert, however, was also a full professor at the University of Toronto Faculty of Music, trained in musical analysis and transcription, and had previously served as an expert witness in music copyright cases—so not much of a stretch.²⁴

Courts also should allow a greater tolerance for experts

The Daubert standard²⁵ and Federal Rule of Evidence 702 need not be relaxed, just reconsidered. The world’s foremost expert to analyze synthesized sounds for similarity may not be a tenured professor in a prestigious music department, but instead a 28-year old DJ or producer who may not be able to read sheet music. Courts should be cautious not to disqualify experts for a lack of academic status or publications. Practical expertise in the field is key.

Conclusion

It is a cliché that parents believe the music that their teenagers enjoy to be “just noise.” Certainly, music that avoids centuries of fundamental composition techniques may well be mistaken as such. But courts should not dismiss the creativity inherent in these works, particularly when, as several circuit courts have noted, substantial similarity analysis takes into account the particular audience for whom the work is intended.²⁶

Senior lawyers and judges, perhaps not the target audience for electronic music, might not immediately appreciate its original, and protectible, elements. But a particular composition should not be unprotectible just because it does not conform to the typical guideposts for assessing substantial similarity.

Courts examining only traditional elements such as melody, harmony, chord progressions, and lyrics in evaluating the substantial similarity of electronic music compositions could potentially undermine this thriving area of the musical arts. At best, courts would find no substantial similarity between two

electronic compositions, because both lack any traditional elements to compare, and at worst, courts may find no protectible elements at all. As a result, electronic music would be easier to copy, and more difficult to protect, undermining the fundamental, constitutional purpose of copyright law.

It is therefore incumbent upon courts and scholars alike, when analyzing and comparing modern-day music, to depart from traditional comparisons of melodies and lyrics largely absent in electronic music, and instead focus on elements such as timbre and texture that make this evolving musical art original and protectible.

1. *Feist Publ'ns v. Rural Tel. Serv.*, 499 U.S. 340, 361 (1991). A plaintiff can prove musical copying without evidence of access to the original work by showing that the compositions are “strikingly similar,” such that copying is the only plausible explanation of the similarities. See *Fogerty v. MGM Grp. Holdings*, 379 F.3d 348, 351 (6th Cir. 2004); *Three Boys Music v. Bolton*, 212 F.3d 477 (9th Cir. 2000).

2. *Knitwaves v. Lollytogs*, 71 F.3d 996, 1002 (2d Cir. 1995) (citations omitted).

3. I Melville B. Nimmer & David Nimmer, *Nimmer on Copyright* (hereinafter *Nimmer*) §2.05[D] (Matthew Bender, Rel. 83 Pub. 485 2010).

4. Sergiu Gherman, “Harmony and its Functionality: A Gloss on the Substantial Similarity Test in Music Copyrights,” *Fordham Intellectual Property, Media and Entertainment L.J.* 19:2 (2008) (hereinafter *Gherman*) at 487. See also, e.g., *Three Boys*, 212 F.3d at 485 (analyzing lyrics, rhythm, pitch, cadences, instrumental figures, the verse/chorus relationship, and a “fade” ending); *Ellis v. Diffie*, 177 F.2d 503, 506 (6th Cir. 1999) (phraseology, lyrics, rhythms, chord progressions, “melodic contours,” structures, and melodies); *Cottrill v. Spears*, No. 02-3646, 2003 WL 21223846, at *9 (E.D. Pa. May 22, 2003) (pitch, chord progression, meter, and lyrics); *Tisi v. Patrick*, 97 F. Supp. 2d 539, 543 (S.D.N.Y. 2000) (structure, melody, harmony, and rhythm); *McKinley v. Raye*, No. 3:96-CV-2231-P, 1998 WL 119540, at *5 (N.D. Tex. March 10, 1998) (lyrics, melodies, and song structure); *Intersong USA v. CBS*, 757 F. Supp. 274, 280 (S.D.N.Y. 1991) (chord progress, structure, pitch, and harmony).

5. *Bright Tunes Music v. Harrisongs Music*, 420 F. Supp. 177 (S.D.N.Y. 1976).

6. *Three Boys Music*, 212 F.3d at 477.

7. See *Lil' Joe Wein Music v. Jackson*, 245 Fed. Appx. 873, 878 (11th Cir. 2007) (hip-hop phrase “Go [name], it’s your birthday,” not protectible because it was a “common hip-hop chant”); *Currin v. Arista Records*, 724 F. Supp. 2d 286 (D. Conn. 2010) (Pharrell and the Neptunes’ “I’m Frontin’” had no similarity to another song called “Frontin’” other than the name and an unprotectible “hip hop idiom”).

8. *Johnson v. Gordon*, 409 F.3d 12, 21-22 (1st Cir. 2005) (the lyric “You’re the One” an unprotectible cliché; the “life is but a dream” melody from “Row, Row, Row Your Boat” also would not be protectible).

9. *Cottrill*, 2003 WL 21223846 (Britney Spears’ “What U See Is What U Get” did not share substantially common elements with a song called “What You See Is What You Get,” outside the very common A-minor key signature and 4/4 rhythm, and the clichéd title).

10. This generalization excludes music employing microtonalities, or tones whose frequency is “between” the notes on a piano, a technique employed rarely.

11. *Gherman* at 509.

12. *Gaste v. Kaiserman*, 863 F.2d 1061, 1068 (2d Cir. 1988); see also *Tisi*, 97 F. Supp. 2d at 548 (“The striking similarity test...is applied with particular stringency in cases...involving popular music”).

13. 17 U.S.C. 102.

14. *Tisi*, 97 F. Supp. 2d at 543; see also *Lil' Joe Music*, 245 Fed. Appx. at 880 n.7 (same point regarding hip-hop music).

15. See, e.g., *The Physical Principles of Sound*, available at <http://www.jiscdigitalmedia.ac.uk/guide/the-physical-principles-of-sound>.

16. See also American National Standards Institute, “USA Standard Acoustical Terminology,” 51.1-1994 (R1999) (“Timbre is that attribute of auditory sensation in terms of which a listener can judge that two sounds similarly presented and having the same loudness and pitch are dissimilar”).

17. *Id.*

18. For example, one particular synthesizer sound (often called “Hoover” or “Dominant”) appears on numerous electronic songs with minimal, if any, alteration. See, e.g., <http://www.synthmania.com/Famous%20Sounds.htm> (including samples of three such songs).

19. <http://www.musicradar.com/us/tuition/tech/the-15-best-daw-software-apps-in-the-world-today-238905/>.

20. See, e.g., *Watt v. Butler*, 744 F. Supp. 2d 1315, 1323 (N.D. Ga. 2010) (granting summary judgment for defendants; the creator of the allegedly infringing song testified that “[t]he keys on the [computer] keyboard were right beside each other. And that’s how the tune came about”) (alteration in original).

21. *Lil' Joe Wein Music*, 245 Fed. Appx. at 878.

22. See, e.g., *ZZ Top v. Chrysler*, 54 F. Supp. 2d 983, 986 (W.D. Wash. 1999) (“While the reduced version of the riff may...be an appropriate representation of ‘how the music actually sounds’ or is ‘perceived,’ it is not an accurate representation of the written notes that are subject to copyright protection”).

23. *Watt*, 744 F. Supp. 2d at 1320.

24. *Id.*

25. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

26. See, e.g., *Kohus v. Mariol*, 328 F.3d 848, 858 (6th Cir. 2003); *Lyons P’ship v. Morris Costumes*, 243 F.3d 789 (4th Cir. 2001); *Whelan Assocs. v. Jaslow Dental Lab.*, 797 F.2d 1222, 1233 (3d Cir. 1986); *Atari Games v. Nintendo of Am.*, 975 F.2d 832, 844 (Fed. Cir. 1992); *Computer Assocs. Int’l v. Altai*, 982 F.2d 693, 713 (2d Cir. 1992).



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