

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

ELORAC, INC.,)	
)	
Plaintiff,)	
)	
v.)	Case No. 16 C 11522
)	
RICK HENSON, et al.,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

Pharmaceutical company Elorac, Inc. ("Elorac"), a company that specializes in the development, marketing and sale of treatments for skin diseases, characterizes its 2014-introduced prescription work removal treatment "UltraSal[®]-ER" as the only such treatment in the United States that has a patented¹ extended-release formulation of its active ingredient, salicylic acid. Elorac also asserts that other UltraSal[®]-ER ingredients provided documented virucidal activity. Elorac has sued four defendants -- KMM Pharmaceuticals, LLC ("KMM"), Rick Henson, Stayma Consulting Services, LLC and BioComp Pharma, Inc.² -- charging that the product (the "KMM Product") that was originally marketed and sold as "Salicylic Acid 28.5%" was then, without any change in ingredients, relabeled "Salicylic Acid 28.5% Extended Release." And that label change has assertedly created a false portrayal that has sharply undercut the market for UltraSal[®]-ER

¹ Elorac is allegedly the exclusive licensee from the patent holder.

² Those three first-named defendants are the only targets of Elorac's opening-gun prayer for preliminary injunctive relief, so they will collectively be referred to as "Defendants" in this memorandum opinion and order.

because the KMM Product has consequently been perceived as a much cheaper generic equivalent of Elorac's product.³

Because Elorac viewed that situation as not adequately redressable by any remedy at law, it has moved for preliminary injunctive relief. And because Elorac's Complaint satisfies the Twombly-Iqbal "plausibility" requirement both substantively and in terms of the inadequacy of any remedy at law, this Court responded favorably to Elorac's prayer for preliminary injunctive relief -- not in terms of granting a preliminary injunction as sought by Elorac (a remedy that requires an evidentiary hearing), but rather in terms of granting a temporary restraining order ("TRO").⁴ Such a solution, however, is at odds with the literal language of the Fed. R. Civ. P. ("Rule") 65(b) format for such a remedy, which prescribes a limited 14-day life for a TRO with a similarly limited 14-day renewal provision -- requirements that, in any case posing more than modest evidentiary demands, may make it infeasible to have a seamless transition from TRO status to the entry of a preliminary injunction, instead leaving a gap of indeterminate length while the parties are gearing up for a full-blown preliminary injunction hearing to allow the Court to decide the contested issues and find whether a preliminary injunction decree is appropriate.⁵

If a District Court seeks to bridge that gap by extending a TRO beyond the literal Rule-65(b)-prescribed timetable referred to in the preceding paragraph, the caselaw (not Rule 65(b) itself) teaches that such an extension must be supported by appropriate findings of fact and

³ Neither UltraSal[®]-ER nor the KMM Product has been approved by the Federal Food and Drug Administration for distribution.

⁴ It should of course be emphasized that this Court has not engaged in any fact-finding -- instead it has appropriately accepted the well-pleaded allegations of the Complaint as true for current purposes.

⁵ See Appendix.

conclusions of law -- and that of course can create a Catch-22 situation, for those are the same types of findings and conclusions that are needed to support the preliminary injunction toward which the TRO is aimed as an interim measure. Federal courts have been wrestling with that dilemma for more than a half century -- see the discussion by the Court of Appeals for the Second Circuit in Pan Am. World Airways, Inc. v. Flight Eng'rs' Int'l Assoc., FAA Chapter, AFL-CIO, 396 F.2d 840, 842-43 (2d Cir. 1962).

In all events, however, the formulation of an appropriate TRO presents difficulties of its own. Defendants have advanced a contention that seeks to make light of the seemingly suspicious circumstance that their initial promotion of the KMM Product lacked the term "Extended Release" (one of the two featured focal points of Elorac's assertedly patent-supported claim), but then later turned up on the KMM Product label even though no change at all had been made in its ingredients. To say the least, that has given rise to substantial concern on the part of this Court.

Each side has now tendered to this Court a competing version of a "Proposed Temporary Restraining Order," based on this Court's oral exposition at the time of the parties' initial presentation. Although the litigants have tendered different proposals for action by this Court, their statements en route have presented much the same picture (though defendants' submission has unsurprisingly been marked by advocacy for their legal position as well). Just as Elorac's plausible allegations in its Complaint may and should be credited at this threshold stage of the litigation, paragraphs 1 through 12 of its Proposed Temporary Restraining Order fairly set out what should be treated *arguendo* as a predicate for dealing with the case at this point. Hence those paragraphs have been annexed as Ex. 1 and are incorporated as part of this opinion.

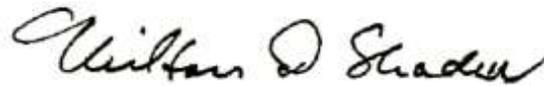
Where then does that leave the matter? It may well be that the essential final aspect of preliminary injunctive relief -- the requirement of an appropriate bond to be posted by Elorac against the possibility that such a remedy has been improvidently granted, measured against the necessary assurance that Elorac can be made whole in damages if a preliminary injunction is improvidently denied -- might tip the scales. That information as to both sides' financial situation would appear to be the appropriate first line of inquiry, requiring the least effort in terms of discovery and factual development, to assist this Court in the decisional inquiry.

In the meantime the position advanced by defense counsel, relying on a kind of semantic word play that appears to assert, in Gertrude Stein fashion, "salicylic acid is salicylic acid is salicylic acid," oversimplifies the matter dramatically. Anyone who is subjected to the television commercials that hawk products of all kinds is familiar with the endless litany of potentially dangerous consequences that, if taken literally, would contraindicate ever buying the product that is being hawked. No indication whatever is given in those commercials as to the potential incidence, however minute, of the perils involved in the laundry list rattled off by the hawkers. Just so here -- the fact that the KMM Product also contains some salicylic acid substance does not necessarily correlate with the "extended release" feature that Elorac claims is the key advantage of its product. At the same time this Court believes, as defense counsel has sought to invoke in his oral presentation, in a freely competitive market. But such free competition should be based on an informed presentation, rather than the type of nonjudgmental disclosure that is apparently provided by First DataBank and like drug information databases (see Ex. 1 ¶ 5). That view has led this Court to the conclusion articulated in the rest of this opinion.

First, as stated earlier, both sides must promptly disclose their financial situations to enable this Court to engage in the competitive analytical decision referred to above. To avoid prejudice to either side, that may be done under seal on a counsel's-eyes-only basis until further order of court.

Next and vitally, to create the level playing field essential to free market competition, the drug information databases such as First DataBank should be apprised promptly of the facts that there is litigation pending in this Court in which a challenge has been made to the claimed generic equivalence of the KMM Product to UltraSal[®]-ER and that this Court has that issue under consideration and is in the process of receiving the input of counsel for the parties to that end. That information, when made available publicly to everyone involved in the process (such as physicians, drug wholesalers, distributors, pharmacies and pharmacists) will enable them and the consuming public to reach their respective decisions on an informed basis -- something that is not possible today because of the manner in which First DataBank and other drug information databases function.

Finally, this action has earlier been set for a status hearing at 9:30 a.m. March 16, 2017. At that time the litigants' counsel should come prepared to address what has been set out here.



Milton I. Shadur
Senior United States District Judge

Date: March 13, 2017

APPENDIX

This Court has long been puzzled at the manner in which Rule 65(b) has been structured, forcing the federal judiciary that is called on to deal with it to operate without the informed guidance that the Rules of Civil Procedure were intended and designed to provide. Most importantly, it is bizarre that the Rule deals in detail with the permitted duration of the infrequent TRO that is granted without notice, while remaining totally silent as to the temporal limits and related procedures applicable to the far more common TROs that are entered with both plaintiffs and defendants having their say in a contested proceeding.

That drafting gap has given rise to what essentially amounts to a judicial amendment that often tends to apply the identical time limits (14 days plus a possible 14-day extension) to that much more common situation as well. And as the text of this opinion has said, the result has typically been to render preliminary injunctions of lesser utility unless the relationship between a lawsuit's adversaries results in a mutual agreement to allow the TRO greater life in order that the preliminary injunction process can generate a considered decision on a developed evidentiary record. And absent such mutual agreement, a court is forced to demonstrate a justification for a TRO's extended life that has to be based on a factual showing too often dependent on the very underpinning that is ultimately needed to support the preliminary injunction itself (the Catch-22 problem referred to in the opinion's text).

This Court has not been privy to any consideration that the Advisory Committee on the Rules of Civil Procedure may have given to the problem and potential dilemma briefly addressed here -- its own service by way of designation by the Judiciary Conference has been its 10-year tenure (the last 3 years as Chairman) on the Advisory Committee on the Federal Rules of Evidence. But it does seem astonishing that an important part of federal practice, that involving

TROs, is addressed by Rule 65(b) solely in terms of the comparatively rare TRO issued without notice (just look at the Rule and its subparts) and that the Advisory Committee Notes give no indication that the limited focus of Rule 65(b) as originally generated has ever been the subject of any potential revision that would provide Rule-directed guidance on the subject.

~~Cir. 1988). To succeed on its request for a TRO or preliminary injunction, the moving party must demonstrate that: (1) its case has some likelihood of success on the merits; (2) no adequate remedy at law exists; and (3) it will suffer irreparable injury if preliminary relief is denied. *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 11 (7th Cir. 1992); *see also Ragold, Inc. v. Ferrero, U.S.A., Inc.*, 506 F.Supp. 117, 123 (N.D. Ill. 1980) (explaining that the criteria for determining whether injunctive relief is appropriate are applicable to TROs where a defendant receives notice and is afforded an opportunity to be heard). Once these conditions have been met, the Court must balance the harm that the non-moving party will suffer if the injunction is granted against the irreparable harm to the moving party, in addition to the public interest in denying or granting the injunction. *Id.* at 11-12. A plaintiff need not show that each and every factor weighs in its favor for an injunction to be granted; rather, an injunction is appropriate where the balance tips in the plaintiff's favor. *Id.* at 12.~~

~~The declarations submitted in support of Plaintiff's motion for preliminary injunction support the following conclusions of law and fact:~~

1. Elorac is pharmaceutical company headquartered in Vernon Hills, Illinois that specializes in the development, marketing, and sale of treatments for skin diseases. In 2014, Elorac introduced its prescription wart removal treatment, UltraSal[®]-ER. UltraSal-ER is the only prescription wart removal treatment in the United States that has a patented extended-release formulation of its active ingredient, salicylic acid, which is exclusively licensed to Elorac by the patent holder. UltraSal-ER also contains ingredients with documented virucidal activity.

2. KMM Pharmaceuticals, LLC ("KMM"), is a Georgia-based company that, in conjunction with Henson and Stayma (collectively, "Defendants"), and BioComp Pharma, Inc. ("BioComp"), manufactures, markets, distributes, and sells a product known variously as "Salicylic Acid 28.5%" and "Salicylic Acid 28.5% Extended Release" (the "KMM Product")

3. Unlike branded drug companies, generic companies like KMM do not market their products to physicians. Rather, they convince drug wholesalers, distributors, pharmacies, pharmacists, and national drug databases that their products are equivalent generic substitutes for brand-name drugs. A pharmacist presented with a doctor's prescription for a brand-name product, like UltraSal-ER, may fill that prescription by dispensing the product prescribed or substituting a "generic" version of the product. In fact, many states require pharmacies to substitute generic drugs when a brand name is prescribed.

4. A minimum standard for appropriate generic substitution of products at the pharmacy level is "pharmaceutical equivalence." Products are considered to be pharmaceutical equivalents if they contain the same ingredient(s) and the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration. To identify generically equivalent products, many pharmacists use information provided by large drug information databases such as First DataBank ("FDB"). These databases assign a generic code number to drugs in their systems based on label information produced by drug manufacturers or marketers. Products with the same clinical formulation are not necessarily therapeutically equivalent, but they do have (among other things) the same particular active ingredient(s) and are "linked" in the databases. Some pharmacists rely solely on these codes in deciding whether to substitute a prescription drug.

5. When Defendants began marketing the KMM Product in approximately June 2015, the product label stated that the KMM Product was a "film-forming virucidal solution," but Defendants did not include the phrase "extended release" in the name or labelling. Nonetheless, Defendants represented to FDB that the KMM Product had extended-release delivery and was a generic equivalent to UltraSal-ER, causing pharmacists to substitute the KMM Product when filling prescriptions for UltraSal-ER.

6. In July and August 2015, shortly after FDB began identifying the KMM Product as a generic equivalent to UltraSal-ER in its database, Plaintiff informed FDB, as well as Defendants, that the two products were not equivalent. FDB, relying, in part, on the label of the KMM Product, as well as its drug listing with the U.S. Food and Drug Administration (“FDA”) (which, at that time, did not include any claims of having extended-release properties), stopped identifying the KMM Product as a generic equivalent to UltraSal-ER. As a result, many, but not all, pharmacists and health care professionals stopped substituting the KMM Product for prescriptions of UltraSal-ER.

7. In May 2016, Defendants changed the label of the KMM Product, adding the phrase “extended release” below the product name and in the product description, while continuing to represent that the KMM Product had virucidal properties. Defendants submitted this new label to the FDA. Defendants did not change the National Drug Code (“NDC”) number for the KMM Product when they changed the label to add the “extended release” claims. Rather, the NDC number, 52187-522-10, is identical for both versions of the KMM Product label. Furthermore, Defendants admittedly did not materially change the formulation of the KMM Product, which does not have extended-release properties or ingredients with demonstrated antiviral activities, contrary to the KMM Product’s label claims.

8. Following Defendants’ mislabeling of the KMM Product as “extended release,” FDB again “linked” the KMM Products to UltraSal-ER as UltraSal-ER’s generic equivalent. Since then, substitution of the KMM Product for UltraSal-ER has dramatically increased at the pharmacy level, and sales of UltraSal-ER have plunged dramatically.

9. Plaintiff is reasonably likely to prove at trial that Defendants violated Section 43 of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), and the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2, by deliberately misleading drug databases and

pharmacies into believing that Defendants' product is an extended-release salicylic acid product with virucidal properties that is pharmaceutically equivalent to, and a substitute for, UltraSal-ER. As a result, substitutions of the KMM Product by pharmacists filling UltraSal-ER prescriptions have significantly eroded UltraSal-ER's revenues.

10. Plaintiff is likely to suffer irreparable harm in the absence of preliminary relief. Defendants' claim that the KMM Product is an extended-release salicylic acid with virucidal ingredients has harmed, and will likely continue to harm, Plaintiffs' sales of UltraSal-ER, by causing wholesalers, distributors, and pharmacies across the country to purchase the KMM Product with the intent to dispense it as a generic substitute for UltraSal-ER prescriptions. Plaintiff also has a well-founded fear that Defendants' conduct is likely to injure the goodwill of UltraSal-ER in the market. UltraSal-ER's extended-release formulation allows the active ingredient, salicylic acid, to be released slowly and steadily, extending its activity and reducing irritation. The KMM Product does not offer this therapeutic advantage. Additionally, UltraSal-ER contains documented virucidal ingredients that reduce reinfection risk and prevent viral contamination of the product under normal use. The KMM Product, however, contains no virucidal agents that confer this added benefit. As a result, doctors and patients may have negative experiences with the KMM Product and may later associate their dissatisfaction with UltraSal-ER, further harming UltraSal-ER sales and Elorac's goodwill and reputation.

11. The balance of potential harm to Defendants of a TRO being issued is far outweighed by the potential harm to Plaintiff if it is not issued. The Court does not recognize as a "harm" to Defendants any consequence resulting from an injunction that requires them to compete truthfully, fairly, and lawfully.

12. The public interest favors issuance of a temporary restraining order. False advertising disserves the public interest in any context. This is particularly true with respect to

pharmaceutical products. Defendants' decision to mislabel the KMM Product to induce pharmacists to substitute the KMM Product for UltraSal-ER effectively overrides the medical judgment of physicians who prescribe UltraSal-ER to their patients and may deprive these patients from receiving the safe and effective treatment that they deserve.

~~13. The Court exercises its discretion and waives the bond requirement under Federal Rule of Civil Procedure 65.~~

Accordingly, for the reasons set forth above, is hereby ORDERED that:

1. Defendants and their agents, representatives, assigns, employees, owners, and members, and all persons acting in concert or privity with them, are hereby ENJOINED and RESTRAINED from:

- a. representing in any way, including by the KMM Product label, to any person or entity, that the KMM Product is a generic equivalent to UltraSal-ER, or has extended-release or virucidal properties; and
- b. selling, shipping, or distributing versions of the KMM Product labeled and marketed as an extended-release, virucidal solution.

2. Defendants, within forty-eight (48) hours of this Order, SHALL submit corrective advertising and publication, including to First DataBank, Inc. and other drug database companies, wholesalers, and pharmacies, advising that the KMM Product does not have extended-release or virucidal properties and is not a generic equivalent to UltraSal-ER.

3. Defendants and all persons acting in concert or privity with them, within forty-eight (48) hours of this Order, SHALL recall all versions of the KMM Product labeled and marketed as an extended-release, virucidal solution.